ARRAY BIOPHARMA INC Form 10-K August 15, 2008 Table of Contents

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	Washington, D.C. 20549
-	Form 10-K
ANNUAL REPORT PURSUA EXCHANGE ACT OF 1934	ANT TO SECTION 13 OR 15(d) OF THE SECURITIES
	For the fiscal year ended June 30, 2008
	OR
RANSITION REPORT PUI XCHANGE ACT OF 1934	RSUANT TO SECTION 13 OR 15(d) OF THE SECURITIE
	For the transition period from to
_	Commission File Number: 000-31979

(Exact Name of Registrant as Specified in Its Charter)

Delaware (State of Incorporation)

84-1460811 (I.R.S. Employer Identification No.)

3200 Walnut Street

Boulder, Colorado 80301

(Address of Principal Executive Offices)

(303) 381-6600

(Registrant s Telephone Number, Including Area Code)

Common Stock, Par Value \$.001 per Share

(Securities Registered Pursuant to Section 12(b) of the Act)

The NASDAQ Stock Market LLC (NASDAQ Global Market)

(Name of Exchange on Which Registered)

None

(Securities Registered Pursuant to Section 12(g) of the Act)

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act.

Yes o No x

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or 15(d) of the Exchange Act.

Yes o No x

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

Yes x No o

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

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

Large Accelerated Filer o Accelerated Filer x Non-Accelerated Filer o

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act).

Yes o No x

The aggregate market value of voting stock held by non-affiliates of the registrant as of December 31, 2007 (based upon the closing sale price of such shares as of the last trading day of the year, December 31, 2007, on the NASDAQ Global Market) was \$397,452,106. Shares of the Registrant s common stock held by each executive officer and director and by each entity that owns 5% or more of the Registrant s outstanding common stock have been excluded in that such persons or entities may be deemed to be affiliates. This determination of affiliate status is not necessarily a conclusive determination for other purposes.

Number of shares outstanding of the registrant s class of common stock as of August 7, 2008: 47,557,131.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant s definitive Proxy Statement to be filed with the Securities and Exchange Commission on Form 14A for the 2008 Annual Meeting of Stockholders are incorporated by reference in Part III of this Annual Report on 10-K to the extent stated therein.

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PART I

Array BioPharma Inc., the Array BioPharma Inc. logo and all other Array names are trademarks of Array BioPharma Inc. in the United States of America and in other selected countries. All other brand names or trademarks appearing in this report are the property of their respective holders. Unless the context requires otherwise, references in this report to Array, we, us, and our refer to Array BioPharma Inc.

FORWARD-LOOKING STATEMENTS

This Annual Report filed on Form 10-K and other documents we file with the Securities and Exchange Commission contain forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995 that involve significant risks and uncertainties. In addition, we may make forward-looking statements in our press releases or in other oral or written communications with the public. These forward-looking statements include, but are not limited to, statements concerning our projected timelines for the initiation and completion of preclinical and clinical trials; the potential for the results of ongoing preclinical or clinical trials to support regulatory approval or the marketing success of drug candidates; our plans with respect to the timing and scope of the expansion of our clinical and commercialization capabilities; other statements regarding our future product development and regulatory strategies, including with respect to specific indications; the ability of third-party contract manufacturing parties to support our drug development activities; any statements regarding our future financial performance, results of operations or sufficiency of capital resources to fund our operating requirements; and any other statements which are other than statements of historical fact.

Although we believe the assumptions upon which our forward-looking statements are based currently to be reasonable, our actual results could differ materially from those anticipated in these forward-looking statements as a result of many factors. These factors include, but are not limited to, our ability to continue to fund and successfully progress internal research and development efforts and to create effective, commercially viable drugs; our ability to effectively and timely conduct clinical trials in light of increasing costs and difficulties in locating appropriate trial sites and in enrolling patients who meet the criteria for certain clinical trials; our ability to achieve and maintain profitability; the extent to which the pharmaceutical and biotechnology industries are willing to in-license drug candidates for their product pipelines and to collaborate with and fund third parties on their drug discovery activities; our ability to out-license our proprietary candidates on favorable terms; risks associated with our dependence on our collaborators for the clinical development and commercialization of our out-licensed drug candidates; the ability of our collaborators and of Array to meet objectives tied to milestones and royalties; our ability to attract and retain experienced scientists, and management; and the risk factors set forth below under the caption Item 1A. Risk Factors. We are providing this information as of the date of this report. We undertake no duty to update any forward-looking statements to reflect the occurrence of events or circumstances after the date of such statements or of anticipated or unanticipated events that alter any assumptions underlying such statements.

ITEM 1 - BUSINESS

Our Business

We are a biopharmaceutical company focused on the discovery, development and commercialization of targeted small molecule drugs aimed at large market opportunities. Our proprietary drug development pipeline includes clinical candidates that are designed to treat patients afflicted with cancer, inflammatory diseases and pain. In addition, leading pharmaceutical and biotechnology companies collaborate with us to discover

and develop drug candidates across a broad range of therapeutic areas. We currently have six wholly-owned programs in our development pipeline:

- ARRY-797, a p38 inhibitor and pan-cytokine modulator for inflammation and for pain;
- ARRY-162, a MEK inhibitor for inflammation;
- ARRY-614, a p38/Tie 2 dual inhibitor for cancer and/or inflammation;
- ARRY-543, an ErbB family (EFGR / ErbB-2) inhibitor for cancer;
- ARRY-520, a KSP inhibitor for cancer; and
- ARRY-380, an ErbB-2 inhibitor for cancer.

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We also have a portfolio of drug discovery programs that we believe will generate one to three Investigational New Drug, or IND, applications each year. Our drug discovery efforts have also generated additional early-stage drug candidates that we may choose to out-license through research partnerships prior to filing an IND application.

Our Strategy

We are building a fully integrated, commercial-stage biopharmaceutical company that invents, develops and markets safe and effective small molecule drugs to treat patients afflicted with cancer, inflammatory diseases or pain. We intend to accomplish this through the following strategies:

- Inventing targeted small molecule drugs that are either first-in-class or second generation drugs that demonstrate a competitive advantage over drugs on the market or in clinical development;
- Partnering select drugs after establishing proof-of-concept for co-development and commercialization, while retaining the right to commercialize and/or co-promote in the U.S.;
- Partnering select early-stage programs for continued research and co-development in exchange for research funding, plus significant milestone payments and royalties;
- Expanding our clinical development organization to provide timely, robust proof of concept, and, in the longer term, to conduct later-stage development and seek marketing approval for important new drugs across multiple therapeutic areas; and
- Building commercial capabilities to position our drugs to maximize their overall value. As our first drug nears approval, we plan to build a U.S.-based, therapeutically-focused sales force to commercialize or co-promote our drugs.

Business History

We have built our proprietary pipeline of drug development and discovery programs on an investment of approximately \$240 million from our inception through June 30, 2008. Over the past three years, research and development expenses for proprietary drug discovery have significantly increased year over year to support, in particular, our clinical development efforts and were \$90.3 million for fiscal 2008, as compared to \$57.5 million for fiscal 2007 and \$33.4 million for fiscal 2006.

Additionally, we have received a total of \$322 million in research funding and in up-front and milestone payments from our collaboration partners through June 30, 2008. Under our existing collaboration agreements, we have the potential to earn \$1.4 billion in additional milestone payments if all the discovery and revenue objectives detailed in these agreements are achieved, as well as to earn royalties on any resulting product sales from 18 drug development programs.

Our three largest existing collaborators include:

- AstraZeneca, PLC, which licensed three of our MEK inhibitors for cancer, including AZD6244 (ARRY-886), which is currently in multiple Phase 2 clinical trials;
- Genentech, Inc., which entered into a worldwide strategic collaboration agreement with us to develop two of our cancer programs which has been expanded to include two additional cancer programs all four of which are in preclinical development; and
- Celgene Corporation, which entered into a worldwide strategic collaboration agreement with us focused on the discovery, development and commercialization of novel therapeutics in cancer and inflammation.

Through collaborations, we have also invented drug candidates that are currently in clinical development, including InterMune, Inc. s hepatitis C virus NS3/4 protease inhibitor, ITMN-191, and Eli Lilly and Company s (formerly ICOS Corporation) CHK-1 inhibitor, IC83. Our out-license and collaboration agreements with these and our other partners typically provide for up-front payments, research funding, success-based milestone payments and/or royalties on product sales.

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The following chart shows our six most advanced wholly-owned compounds, their stage in the drug development process and our expected future development plans.

Drug Candidates		Current Development Status Expected Developmen	
Inflammation & Pain			
ARRY-797	P38	Phase 2 dental pain trial and Phase 1b 28-day rheumatoid arthritis, or RA, trial	Initiate Phase 2 ankylosing spondylitis trial during the second half of calendar 2008
ARRY-162	MEK	Phase 2 worldwide, 12-week RA trial	Receive top-line results during the second half of calendar 2009
ARRY-614	P38/Tie2	Phase 1 trial with healthy volunteers	Initiate first-in-patient Phase 1b trial in cancer and/or inflammation during the first half of calendar 2009
<u>Cancer</u>			
ARRY-543	ErbB-2/EGFR	Phase 1 expansion and Phase 1b/2 trials in metastatic breast cancer	Initiate combination studies with Xeloda® (capecitabine) and Taxotere® (docetaxel) in the second half of calendar 2008
ARRY-520	KSP	Phase 1 expansion trial and Phase 2 acute myelogenous leukemia, or AML, trials	Initiate Phase 2 multiple myeloma trial in the first half of calendar 2009
		•	
ARRY-380	ErbB-2	Phase 1 trial with cancer patients	Initiate Phase 1b combination trial during the first half of 2009
ARRY-614	P38/Tie2	Phase 1 trial with healthy volunteers	Initiate first-in-patient Phase 1b trial in cancer and/or inflammation during the first half of calendar 2009

Proprietary Development Programs

ARRY-797 - Pan-cytokine / p38 Program

p38 is a critical mediator of pain and inflammation, which acts by modulating the production of the pro-inflammatory cytokines TNF, IL-6 and IL-1 as well as the pain mediator PGE2. ARRY-797 is a novel, selective, potent inhibitor of p38 with unique physical properties. It is highly selective with nanomolar potency, high water solubility and low potential to cross the blood brain barrier. In a Phase 1 clinical trial in healthy volunteers, ARRY-797 demonstrated dose-dependent marked suppression of all three of these cytokines, as measured in *ex vivo* LPS-stimulated whole blood samples. We believe that inhibition of p38 will modulate cytokine production in various inflammatory disorders and, as such, ARRY-797 will be evaluated for a variety of painful, inflammatory indications.

Our clinical development activities for ARRY-797 consisted of the following during fiscal 2008:

• Conducted a Phase 2 trial in acute inflammatory pain using a dental pain model. ARRY-797 achieved its primary and secondary endpoints for analgesic effect, was well tolerated, and prevented the rise in C-reactive protein that follows oral surgery.

• Initiated a second Phase 2 acute inflammatory pain trial in 250 patients, in which we compared three doses of ARRY-797 (200, 400 and 600 mg) with both placebo and with an active comparator, Celebrex® (celecoxib) (400 mg).

During fiscal 2009, we plan to initiate the following studies:

- A 28-day Phase 1 study in 30 rheumatoid arthritis, or RA, patients on stable doses of methotrexate.
- A 12-week Phase 2 study in ankylosing spondylitis.

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ARRY-162 - MEK for Inflammation Program

MEK has been demonstrated to modulate the biosynthesis of certain pro-inflammatory cytokines, in particular, TNF, IL-1 and IL-6. We believe that the inhibition of MEK will have applications in inflammatory diseases characterized by high levels of these cytokines, such as arthritis, psoriasis and inflammatory bowel disease. ARRY-162 is a first in class, orally-active, selective MEK inhibitor that is active, either alone, or in combination with other agents, in *in vivo* RA models. In Phase 1 clinical trials, ARRY-162 exhibited significant cytokine inhibition and has been well tolerated. We believe ARRY-162 is the only MEK inhibitor currently in development for RA.

Our clinical development activities for ARRY-162 consisted of the following during fiscal 2008:

- Reported Phase 1 clinical trial results in healthy volunteers in June 2008. In that trial, ARRY-162 showed no serious adverse events through 14 days of continuous dosing and significantly inhibited production of the inflammatory cytokines TNF, IL-1 and IL-6, as measured in *ex-vivo*, TPA-stimulated whole blood samples.
- Reported results from a Phase 1b trial of ARRY-162 in combination with methotrexate in stable RA patients. In this study, ARRY-162 showed linear increases in exposure with increasing dose and no drug / drug interactions between ARRY-162 and methotrexate were observed. In addition, ARRY-162 suppressed the production of inflammatory cytokines, relative to methotrexate alone, suggesting that this combination treatment may be more beneficial for patients with RA.
- Completed long-term toxicology studies.
- Initiated a worldwide Phase 2 trial with ARRY-162 added to methotrexate in 200 patients with RA.

We expect to receive top-line results on the Phase 2 RA trial during the second half of calendar 2009.

ARRY 614 - p38/Tie2 for Inflammation and Cancer Program

As discussed above, p38 regulates the production of numerous cytokines, such as TNF, IL-1 and IL-6, the increased production of which can cause inflammation and aberrant tissue proliferation. Tie2 plays an important role in angiogenesis, the growth, differentiation and maintenance of new blood vessels. ARRY-614, an orally active compound that inhibits both p38 and Tie2, has been shown to block angiogenesis, to inhibit inflammation and to antagonize tumor growth, while showing a low side effect profile after prolonged dosing in preclinical models. We believe this compound will have broad therapeutic benefits in various cancers and inflammatory diseases.

During fiscal 2008, we initiated a single and multiple dose escalation study with ARRY-614 in healthy volunteers for safety, tolerability, exposure and inhibition of mechanism-related biomarkers.

During fiscal 2009, we plan to initiate first-in-patient trials in either cancer or inflammatory disease.

ARRY-543 - Pan-ErbB - EGFR / ErbB-2 Program

ErbB-2 and EGFR are receptor kinase targets that are over-expressed in a number of malignancies, including breast, lung, pancreas, colon and head and neck cancers. ARRY-543 is a novel, orally-active dual inhibitor of ErbB-2 and EGFR. It behaves as a reversible ATP-competitive inhibitor with nanomolar potency both *in vitro* and in cell-based proliferation assays.

In preclinical models, ARRY-543 demonstrated significant dose-related tumor growth inhibition when administered orally. It has demonstrated superior activity versus Tykerb® (lapatinib) in most EGFR and ErbB-2 *in vivo* models, equivalent activity to Iressa® (gefitinib)/ Tarceva® (erlotinib) in EGFR models, and enhanced efficacy in certain preclinical models where dual inhibition is relevant when compared to Herceptin® (trastuzumab), Tarceva and Tykerb.

Our clinical development activities for ARRY-543 consisted of the following during fiscal 2008:

• Presented results from a Phase 1 trial of ARRY-543 at the 2007 AACR-NCI-EORTC International Conference on Molecular Targets and Cancer Therapeutics and at the San Antonio Breast Cancer Symposium. ARRY-543 produced prolonged stable disease in patients who have previously failed prior

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treatments with solid tumors. ARRY-543 was well-tolerated up to 400 mg twice daily, or BID, dosing. Systemic concentrations of ARRY-543 increased with escalating doses at all dose levels tested, providing continuous exposure over a 24-hour period. In completed cohorts, sixty percent of patients receiving doses of 200 mg BID and higher had prolonged stable disease. Based on these results, the BID regimen has been chosen for Phase 2 studies.

• Initiated a Phase 1b expansion cohort at the maximum tolerated dose for ARRY-543, with half of the patients with ErbB-2 positive metastatic breast cancer, who had been previously treated with Herceptin, and half of the patients with other ErbB-family expressing cancers.

During fiscal 2009, we plan to initiate two Phase 1b studies of ARRY-543 in combination with Xeloda® (capecitabine) or Taxotere® (docetaxel).

ARRY-520 - KSP Program

ARRY-520 inhibits kinesin spindle protein, or KSP, which plays an essential role in mitotic spindle formation. Like taxanes and vinca alkaloids, KSP inhibitors inhibit tumor growth by preventing mitotic spindle formation and cell division. However, unlike taxanes and vinca alkaloids, KSP inhibitors do not demonstrate certain side effects such as peripheral neuropathy and alopecia.

ARRY-520 has demonstrated efficacy in multiple preclinical cancer models. ARRY-520 caused marked tumor regression in preclinical models of human cancer at tolerated doses, and produced complete responses in two solid tumor models (colon and ovarian) and in leukemia models.

Our clinical development activities for ARRY-520 consisted of the following during fiscal 2008:

- Completed a Phase 1 dose escalation trial in advanced cancer patients.
- Initiated a Phase 1 expansion trial to evaluate the safety, tolerability and preliminary efficacy at maximum tolerated dose.
- Initiated a Phase 2 trial in acute myelogenous leukemia, or AML.

During fiscal 2009, we plan to begin a Phase 2 trial in multiple myeloma.

ARRY-380 - ErbB-2 Program

ErbB-2, also known as HER2, is a receptor kinase target that has been found to be over-expressed in breast cancer and other cancers. Our orally active ErbB-2 inhibitor, ARRY-380, has shown efficacy and a mild side effect profile in preclinical models of human cancer. Recently, Herceptin, the intravenously-dosed protein inhibitor that modulates ErbB-2, has been approved as an adjuvant to surgery in early stage breast cancer patients; it had already been approved for ErbB2+ metastatic breast cancer. This new indication has significantly expanded the number of breast cancer patients eligible for an ErbB-2 inhibitor.

During fiscal 2008, we filed an IND application for ARRY-380 with the U.S. Food and Drug Administration, or the FDA, and initiated a Phase 1 clinical trial in advanced cancer patients. During fiscal 2009, we plan to complete the Phase 1 trial and initiate Phase 1b combination trials.

Partnered Discovery and Development Programs

We have collaborations with leading pharmaceutical and biotechnology companies under which we have out-licensed certain of our proprietary drug programs for further research, development and commercialization. We also have research partnerships with leading pharmaceutical and biotechnology companies, for which we design, create and optimize drug candidates, and conduct preclinical testing across a broad range of therapeutic areas, on targets selected by our partners. In certain of these partnerships, we also perform process research and development, clinical development and manufacture clinical supplies.

Our discovery and development collaborations provide funding for research and development activities we conduct and, in a number of our current agreements, up-front fees, milestone payments and/or royalties based upon the success of the program. Our largest and most advanced collaborations include our agreements with AstraZeneca, Celgene, Genentech, InterMune, Eli Lilly, and VentiRx Pharmaceuticals, Inc.

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Information about collaborators that comprise 10 percent or more of our total revenue and about revenue we receive within and outside the U.S. can be found in Note 2 of the accompanying Financial Statements included elsewhere in this Annual Report.

Below are summaries of our most advanced ongoing partnered discovery and development programs.

AstraZeneca - AZD6244 / MEK Program

We initiated an anti-cancer research program targeting MEK in July 2001, and quickly identified AZD6244, an orally active clinical candidate. AZD6244 and other compounds have shown tumor suppressive or regressive activity in multiple preclinical models of human cancer, including melanoma, pancreatic, colon, lung, and breast cancers. Potential advantages of MEK inhibitors over current therapies include potential improved efficacy and reduced side effects.

In December 2003, we entered into an out-licensing and collaboration agreement with AstraZeneca to develop our MEK program solely in the field of oncology. Under the agreement, AstraZeneca acquired exclusive worldwide rights to our clinical development candidate, AZD6244, together with two other compounds we developed during the collaboration for oncology indications. We retain the rights to all non-oncology therapeutic indications for MEK compounds not selected by AstraZeneca for development. In April 2009, we or AstraZeneca may independently undertake research, development and commercialization of small molecule inhibitors of MEK for any therapeutic indication; however both of us will continue to work exclusively with each other for the development and commercialization of AZD6244 and the other two compounds selected by AstraZeneca in oncology. To date, we have earned \$21.5 million in up-front and milestone payments. The agreement also provides for research funding, which is now complete, and potential additional development milestone payments of approximately \$75 million and royalties on product sales. AstraZeneca is responsible for further clinical development and commercialization for AZD6244, and for clinical development and commercialization for the other two compounds it licensed.

Under our collaboration with AstraZeneca, we conducted Phase 1 clinical testing in 2004. The trial evaluated tolerability and pharmacokinetics of AZD6244 following oral administration to patients with advanced cancer. In addition, the trial examined patients for indications of biological activity as well as pharmacodynamic and tumor biomarkers. Phase 1 testing showed that AZD6244 inhibited the MEK pathway in tumor tissue at the dose that was later selected for the Phase 2 studies and provided prolonged disease stabilization in a number of cancer patients that had previously received numerous other cancer therapies.

In June 2006, AstraZeneca initiated a Phase 2 study for AZD6244 in malignant melanoma, resulting in a \$3 million milestone payment to us. The trial was a randomized Phase 2 study that compared AZD6244 to Temodar® (temozolomide) in the treatment of stage III / IV melanoma patients. AstraZeneca enrolled approximately 180 patients at 40 centers worldwide. AstraZeneca also initiated additional Phase 2 studies for AZD6244 in colorectal, pancreatic and non-small cell lung cancer during 2006.

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- AstraZeneca presented Phase 1 clinical trial results at the 2008 American Society of Clinical Oncology, or ASCO, annual meeting of a new AZD6244 capsule formulation that replaces the mix/drink formulation used in all prior trials to date. The new capsule s maximum tolerated dose was 25 percent lower yet provided, on average, higher exposure than historical values for the mix/drink formulation. The study also reported a complete response in one of the patients.
- AstraZeneca also presented Phase 2 clinical trial results of AZD6244 at ASCO:
- o In Phase 2 trial results comparing AZD6244 to Alimta® (pemetrexed) in 84 non small cell lung cancer, or NSCLC, patients, neither of these drugs demonstrated superior efficacy.
- o Phase 2 results showed no difference between the two treatment arms in the overall population comparing AZD6244 to Temodar® (temozolomide) in patients with advanced melanoma. The safety and tolerability profile for AZD6244 was found to be consistent with that reported from the Phase 1 trial.
- o Phase 2 results comparing AZD6244 to Xeloda® (capecitabine) in patients with metastatic colorectal cancer showed that AZD6244 was generally well tolerated, with neither of these drugs demonstrating superior efficacy.
- AZD6244 is also being investigated in a number of studies conducted by the National Cancer Institute in collaboration with AstraZeneca.

AstraZeneca also announced two additional Phase 2 trials of AZD6244 at ASCO. Preclinical data suggests that the potential benefit of AZD6244 may be maximized in some tumors when delivered as combination therapy. The two planned trials will be exploring combinations in advanced melanoma and non-small cell lung cancer, or NSCLC patients. Patient enrollment is expected to begin during the first quarter of calendar 2009.

InterMune - ITMN-191 / Hepatitis C Virus NS3/4 Protease Program

From 2002 to 2007, scientists from Array and InterMune have collaborated on the discovery of novel small molecule inhibitors of the Hepatitis C Virus, or HCV, NS3/4 protease. During the collaboration, the companies jointly discovered ITMN-191, which InterMune is now developing in partnership with Roche. Under the terms of collaboration agreement, InterMune funded certain drug discovery efforts, preclinical testing, process development and manufacturing in conformity with current Good Manufacturing Practices, or cGMP. InterMune will make milestone payments to us based on the selection and progress of clinical drug candidates, as well as royalties on sales of any products derived from the collaboration. We received our first milestone payment from InterMune in June 2004. Research funding under this agreement ended June 30, 2007.

AstraZeneca presented Phase 1 clinical trial results at the 2008 American Society of Clinical **O6**cology,

During 2006, we produced and delivered cGMP clinical supplies of ITMN-191, and InterMune initiated a Phase 1 clinical trial. We received a \$500 thousand milestone payment in February 2007 after the first subject was dosed.

During 2008, InterMune reported the following progress on the program:

- InterMune advanced ITMN-191 in a Phase 1b multiple-ascending-dose clinical trial evaluating ITMN-191 as monotherapy in patients with chronic HCV.
- InterMune also reported top-line results from four dose cohorts of treatment-naive patients demonstrating rapid and significant reductions in HCV PNA

Eli Lilly IC83 / CHK-1 Program

We entered into a collaboration agreement with ICOS Corporation in 1999 to create small molecule CHK-1 inhibitors. Our scientists and ICOS scientists invented IC83, and we received a milestone payment after the first patient was dosed with this molecule in a Phase 1 clinical trial in early 2007. The agreement provided research funding, which has now ended, and we are entitled to receive additional milestone payments based on Eli Lilly s achievement of clinical milestones. Eli Lilly acquired ICOS in 2007.

VentiRx - VTX-2337 & VTX-1463 / Toll-Like Receptor (TLR-8) Program

In February 2007, we entered into a licensing and collaboration agreement with privately held biopharmaceutical company VentiRx, under which we granted VentiRx exclusive worldwide rights to certain molecules from our toll-like receptor, or TLR, program. The program contains a number of compounds targeting TLR s to activate innate immunity. VentiRx expects to develop its first two candidates in cancer and allergy. We received an equity stake in VentiRx as well

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as an up-front payment, potential milestone payments and royalties on product sales. We retain an option to acquire a 50 percent ownership position in each VentiRx clinical oncology products developed under this agreement.

During fiscal 2008, VentiRx reported the following progress on the program:

- VentiRx filed an IND application on VTX-2337 for the treatment of cancer, and patients are expected to be enrolled in the Phase I trial during the second half of calendar 2008.
- VentiRx advanced VTX-1463 into regulated safety assessment testing for treatment of allergy, with an IND expected to be filed in calendar 2009.

During fiscal 2009, we will continue to collaborate with VentiRx on back-up molecules.

Genentech Oncology Programs

We entered into a licensing and collaboration agreement with Genentech in December 2003 to develop small molecule drugs against multiple therapeutic targets in the field of oncology. We initiated this collaboration to advance two of our proprietary oncology programs into clinical development. These programs included small molecule leads we had developed along with additional, related intellectual property. Under the agreement, Genentech made an up-front payment, provides research funding and paid a milestone to us for nominating a clinical candidate and advancing it into regulated safety assessment testing. In addition, Genentech has agreed to make additional potential development milestone payments and pay us royalties on any resulting product sales. Genentech is responsible for clinical development and commercialization of the resulting products.

In 2005 and in 2008, we expanded our collaboration with Genentech to develop clinical candidates directed against an additional third and fourth cancer target, respectively. Under the agreement, we receive additional research funding, as well as potential research and development milestone payments and product royalties based on the success of each new program. Genentech has the sole responsibility for clinical development and commercialization of any resulting products. In July 2008, Genentech extended the agreement for an additional two years of funded research through January 2011 and reduced the number of full-time equivalent scientists working on the program. Genentech may terminate its agreement with us upon 120 days notice.

Celgene Oncology and Inflammation Programs

In September 2007, we entered into a worldwide strategic collaboration with Celgene focused on the discovery, development and commercialization of novel therapeutics in cancer and inflammation. Under the agreement, Celgene made an upfront payment of \$40 million to us and, in return, we granted Celgene an option to select a limited number of drugs developed under the collaboration that are directed to two of four mutually selected discovery targets. We are responsible for all discovery and clinical development through Phase 1 or Phase 2a. Until this time, Celgene will have the option to select drugs resulting from up to two of these four therapeutic programs and will receive exclusive worldwide rights to those drugs, except for limited co-promotional rights in the U.S. Additionally, we are entitled to receive, for each drug, potential milestone payments of approximately \$200 million, if certain discovery, development and regulatory milestones are achieved and an additional \$300 million if certain commercial milestones are achieved, as well as royalties on net sales. We will retain all rights to the other programs. The agreement may be terminated in whole or in part with respect to individual drug development programs by Celgene upon six

months written notice to us and by either party, following certain cure periods, in the event of a breach by the other party of its obligations under the agreement.

Market Opportunity

We believe there is a tremendous opportunity in creating drugs for debilitating and life-threatening diseases, especially in cancer, inflammation and pain. The medical community is seeking targeted therapies that treat both the underlying disease as well as control symptoms more effectively and/or more safely than drugs that are currently available. We believe future patient care will improve with the use of screening to select targeted therapies for more effective disease treatment. Also, clinical trials aimed at well-defined patient populations may show improved response rates and may thereby increase the chances for FDA approval. This approach may result in a greater number of marketed drugs each aimed at a smaller subset of patients.

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Our proprietary pipeline is primarily directed at drugs that treat cancer, inflammatory disease and pain. The worldwide market for targeted cancer drugs -- the cancer drug market s fastest growing segment -- is expected to grow from \$25 billion in 2007 to \$56 billion in 2012. The inflammatory disease market is highly diverse and includes RA, osteoarthritis, ankylosing spondylitis, asthma, chronic obstructive pulmonary disease, psoriasis, and inflammatory bowel diseases. According to EvaluatePharma®, the worldwide markets for injectable targeted RA therapies and for prescription non-steroidal anti-inflammatory drugs, or NSAIDs, and opioids are expected to grow from \$17 billion in 2007 to \$28 billion in 2012. Additionally, with the safety concerns over the class of pain medications known as COX-2 inhibitors (such as Vioxx® and Celebrex®), new markets should emerge for drugs with novel mechanisms to treat chronic pain associated with arthritis and other painful inflammatory disorders. In addition, there remains a large need to address patients with acute or subacute pain, such as post-operative pain.

In addition, the drug industry has an ongoing need to fill clinical development pipelines with new drugs to drive future revenue growth. Despite increased spending on internal research, the industry has been unable to meet this demand. As a result, it has become increasingly reliant on biotech companies to acquire new drugs. The scarcity of later-stage clinical assets available for in-licensing is driving these companies to enter into licensing deals at earlier stages, including the preclinical stage. However, once a drug has entered clinical development, companies generally require proof of concept data, which includes both efficacy and safety, before they will consider licensing a drug candidate. Accordingly, we believe there is an opportunity to license first-in-class drugs at several stages during the drug development process.

Inflammation Market

Inflammation is a natural biologic response to injury or infectious attack to the human body. Unregulated inflammation results in a broad range of conditions, most of which are classified by the tissue or organ where the inflammation occurs. These conditions include RA in the joints, psoriasis in the skin, asthma and chronic obstructive pulmonary disease in the lung, fibrotic disease in the liver and kidney, Crohn s disease and ulcerative colitis in the intestine, and atherosclerosis in the arteries. Currently, many of these patients are treated with injectable protein therapeutics, such as Enbrel®, Remicade®, Humira® and Kineret®, which bind to and/or modulate the activity of the inflammatory cytokines TNF or IL-1. These injectable protein therapeutics have significant cost, safety and patient compliance issues. Other therapies currently on the market, including NSAIDs and opioids, have side effect and efficacy issues.

Despite their drawbacks, the worldwide market for injectable targeted therapies for RA and prescription NSAIDs and opioids are expected to grow from \$17 billion in 2007 to \$28 billion in 2012. We believe there are significant opportunities to create orally active drugs to treat many of these often-chronic diseases and conditions. We are developing drugs that modulate important biological targets in key intracellular pathways that control inflammation, potentially providing the ability to treat multiple diseases and conditions with a single oral agent as follows:

- Rheumatoid Arthritis RA is a debilitating autoimmune disease that affects more than two million Americans, and as many as one percent of the global population. RA hinders the daily activities of its sufferers. The damage that occurs in RA is a result of the immune system attacking joint tissue, causing painful chronic inflammation, often resulting in irreversible destruction of cartilage, tendons and bones. Common RA symptoms include inflammation of the joints, swelling, fatigue, stiffness and pain. Additionally, since RA is a systemic disease, it can have effects in other tissues such as the lungs and eyes.
- Ankylosing Spondylitis Ankylosing spondylitis is a chronic inflammatory disease of joints that causes a significant reduction in quality of life, health status and working ability for those afflicted with the disease. With moderate diagnosis and treatment rates, it is substantially more prevalent than previously believed, with up to 1.5 million sufferers in the U.S. Diagnosis of ankylosing spondylitis is often delayed primarily due to the insensitivity of radiographs, coupled with limited availability of therapeutic options and low disease awareness. Treatment options include physical therapy and NSAIDs. Conventional disease-modifying anti-rheumatic drugs are ineffective for axial disease. Recent data showed that 70% of ankylosing spondylitis patients progress to having a fusion of the spine within 10 to 15 years. While ankylosing spondylitis has considerable impact at both the individual and community level, it has received little attention due to the difficulty in diagnosing it early and the commonly held assumption of a low probability for good clinical outcome. With the recent success of anti-TNF therapies in treating ankylosing spondylitis, this outcome assumption has been challenged, with data showing the ability and efficacy of

anti-TNF therapy, which we believe may expand the market for small molecule cytokine modulators in the treatment of ankylosing spondylitis.

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Pain Market

Over 59 million patients in the U.S. alone are treated for acute pain annually. The incidence of acute pain typically occurs in surgical or trauma/emergency settings. Surgical patients typically experience moderate to severe pain for a few days or a few weeks and primarily use analgesics, including opiods and/or NSAIDs, to manage it. Additionally, the World Health Organization estimates that 5 million people suffer moderate to severe pain associated with cancer worldwide. The market size in the U.S. for acute pain drugs is estimated to be \$2.3 billion in 2008 and \$2.9 billion in 2012 and is expected to grow at a compound annual growth rate of approximately 1% over the next 10 years.

Opioids have been shown to be efficacious in the management of pain. Opioids, however, cause nausea, vomiting, constipation, and respiratory and psychological side effects. Additionally, drug abuse is a major concern with the use of opioids. NSAIDs have demonstrated modest pain reduction, but they are less effective than opioids. Although NSAIDS have a more favorable safety profile than opioids, renal toxicity and gastrointestinal bleeding are associated with their use. Cardiovascular side effects are linked with Cox-2 inhibitors. This presents an opportunity for a drug with comparable or better efficacy than NSAIDS, including Cox-2 inhibitors, and opioids.

Cancer Market

Despite a wide range of available cancer therapies, patient responses remain limited and variable. As a result, oncologists are increasingly using combination therapies and drug dosing regimens tailored for individual tumor types and patients. Targeted therapies are believed to be more efficacious with fewer side effects than first generation cytotoxic chemotherapy drugs, as they are able to specifically target the underlying mechanisms of the disease by regulating discrete aspects of cellular function affecting cancer cells to a greater extent than normal cells. We believe certain cancers will eventually become chronic diseases, treated with a combination of targeted therapies. Our research strategy in the cancer market is to build a pipeline of complementary targeted therapies.

According to the American Cancer Society, Surveillance Research Study for 2008, there are an estimated 1.4 million new cases of cancer in 2008 and nearly 600 thousand cancer related deaths. The five-year relative survival rate for all cancers diagnosed between 1996 and 2003 was only 66 percent. Earlier diagnosis and the use of new and/or improved treatments have resulted in improved survival rates. The following table shows estimated new cases diagnosed and estimated deaths in the U.S. during 2007 by major cancer types of interest to us:

Type of Cancer	New Cases	Deaths
Lung	215,020	161,840
Prostate	186,320	28,660
Breast	184,450	40,930
Colorectal	108,070	49,960
Melanoma	62,480	8,420
Pancreas	37,680	34,290
Multiple Myeloma	19,920	10,690
Acute Myelogenous Leukemia	13,290	8,820
	827,230	343,610

The use of targeted therapies has the potential to change the focus of cancer treatment away from categorization and treatment modality by organ type and towards categorization and treatment modalities by level of gene expression in individual patients, or personalized medicine. It is believed that targeted therapies and personalized medicine will result in increased survival with improved quality of life. However, a potential implication of personalized medicine is smaller market opportunities.

Oncology, both in treating cancer itself and palliative therapy, has been a major therapeutic category for biotechnology companies since the inception of the industry. Recently, major pharmaceutical companies have increased their research and development and in-licensing investment in this market, particularly the targeted

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cancer therapy market. Targeted therapies currently on the market that have been successful include Avastin®, Gleevec®, Herceptin and Rituxan®.

Breast Cancer

Breast Cancer is the third most prevalent cancer type in the U.S., with 184 thousand new cases diagnosed per year. Approximately 25 percent of all breast cancer patients are HER2+. Herceptin is an intravenously-dosed monoclonal antibody currently on the market for the treatment of breast cancers that over-express HER2 and is approved for HER2+ adjuvant breast cancer and all lines of HER2+ metastatic breast cancer. We believe the broad use of Herceptin in HER2+ breast cancer suggests a high potential value for an orally active drug that regulates HER2 and can be conveniently dosed for extended periods of time.

Tykerb, a small molecule drug that modulates ErbB-2 and EGFR, was approved in March 2007 for the treatment of patients with metastatic HER2+ breast cancer patients whose tumors have failed to respond to Herceptin and chemotherapy in second and third-line treatment. Tykerb in combination with Xeloda is currently being used in five percent of all treated breast cancer patients, approximately 15 percent of the HER2+ subpopulation. Tykerb sales during 2007 were \$102 million, with 2008 worldwide sales projected to reach \$228 million.

Multiple Myeloma

Multiple myeloma is a hematological cancer in which malignant plasma cells are overproduced in the bone marrow. Normal plasma cells are white blood cells that produce antibodies that fight infection and disease. Multiple Myeloma plasma cells replace normal plasma cells and other white blood cells which are important to maintaining the immune system.

Multiple myeloma is the second most common hematologic malignancy in the U.S. It is a disease which primarily afflicts the elderly, with an average onset occurring between the ages of 65 to 70. The incidence of multiple myeloma in 2007 is estimated to be over 40 thousand in the seven major global markets. Approximately 11 thousand people die annually from multiple myeloma in the U.S. alone.

Acute Myeloid Leukemia

Acute myelogenous leukemia, or AML, is a fast-growing cancer of the blood and bone marrow. In acute myelogenous leukemia, the bone marrow makes many unformed cells called blasts. Blasts normally develop into white blood cells that fight infection. However, the blasts are abnormal in AML. They do not develop and cannot fight infections. The bone marrow may also make abnormal red blood cells and platelets. The number of abnormal cells (or leukemia cells) grows quickly. They crowd out the normal red blood cells, white blood cells and platelets the body needs.

AML is the most common type of leukemia. More than 13 thousand new cases occur in the U.S. each year, mostly in older adults. The average age of a person with AML is 65 years.

Research and Development for Proprietary Drug Discovery

Our primary research efforts are centered on the treatment of cancer, inflammatory disease and pain. Our research focuses on biologic functions, or pathways, that have been identified as important in the treatment of human disease based on human clinical, genetic or preclinical data. Within these pathways, we seek to create first-in-class drugs regulating important therapeutic targets to treat patients with serious or life-threatening conditions, primarily in cancer, inflammatory disease and other important disease areas. In addition, we seek to identify opportunities to improve upon existing therapies or drugs in clinical development by creating clinical candidates with superior, or best-in-class, drug characteristics, including efficacy, tolerability or dosing to provide safer, more effective drugs. During fiscal years 2008, 2007 and 2006, we spent \$90.3 million, \$57.5 million and \$33.4 million, respectively, on research and development for proprietary drug discovery, which consist of costs associated with our proprietary drug programs for, among other things, salaries and benefits for scientific personnel, consulting and outsourced services, laboratory supplies, allocated facilities costs and depreciation.

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Drug Discovery and Development Timeline

The drug development process is highly uncertain, subject to a number of risks that are beyond our control and takes many years to complete. The following table outlines each phase in the drug development process. Completion times are difficult to estimate and can vary greatly based on the drug and indication. Therefore, the duration times shown in the table below are estimates only.

Phase	Objective	Estimated Duration
Discovery	Lead identification and target validation	2 to 4 years
Preclinical	Initial toxicology for preliminary identification of risks for humans; gather early pharmacokinetic data	1 to 2 years
Phase 1	Evaluate safety in humans; study how the drug works, metabolizes and interacts with other drugs	1 to 2 years
Phase 2	Establish effectiveness of the drug and its optimal dosage; continue safety evaluation	2 to 4 years
Phase 3	Confirm efficacy, dosage regime and safety profile of the drug; submit New Drug Application	2 to 4 years
FDA Approval	Approval by the FDA to sell and market the drug under approved labeling	6 months to 2 years

Animal and other non-clinical studies are often conducted during each phase of human clinical studies. Proof of concept for a drug candidate generally occurs during Phase 2 after safety and efficacy data is established.

Our Research and Development Technologies and Expertise

We are continuing to improve our comprehensive research and development capabilities, consisting of three integrated areas of expertise:

- Discovery Research Biology, Chemistry and Translational Medicine
- Process Research, Development and Manufacturing
- Clinical Development

These capabilities are supported by an integrated information technology system. Over the next three years, we plan to continue building a significant clinical development competency capable of delivering robust proof of concept results and to scale process research, development

and manufacturing to meet clinical needs, while optimizing our current discovery capability at approximately its current size. In the longer term, we plan to build a Phase 3 clinical and regulatory product filing capability and therapeutic sales force to become a fully integrated commercial stage biopharmaceutical company.

Research

We have a broad drug discovery platform with all the necessary capabilities to efficiently invent new chemical compounds. We continue to add to our knowledge breadth, refine our processes, and hire key scientists that enhance our current capabilities. We have expanded our translational medicine team, which designs and runs mechanistic studies in cell biology and pharmacology to provide insight into clinical development strategy, product differentiation, and biomarker support for clinical development. Today, we are recognized as having one of the premier small molecule drug discovery capabilities in the biotech industry in its comprehensiveness, scale and expertise. To date, our average cost to invent a new chemical entity and file an IND application is less than \$15 million, compared to estimates of up to \$100

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million spent by major pharmaceutical companies. The discovery group has created high quality clinical assets. To date, every wholly-owned, and to our knowledge, every partnered, drug to reach the clinic has been shown to modulate its mechanistic target, as measured by an appropriate clinical biomarker.

Process Research, Development, Formulation and Manufacturing

We have built and continue to enhance our process research and development and cGMP manufacturing to accommodate the productivity of our research platform and support of the clinical development plans. We enhanced our process research, development and manufacturing capabilities to include formulations, physical form characterization and certain aspects of clinical supply manufacturing during fiscal 2008. In parallel, we are growing and improving our abilities to manage the work of contract manufacturing organizations which we retain to perform certain of these functions.

Clinical Development

Our current key capabilities within clinical development include clinical operations, safety monitoring, biostatistics, programming and data management, regulatory strategy and program management. As our pipeline grows, we expect to continue to invest in building our clinical development expertise and resources. This group leads the development and implementation of our clinical and regulatory strategies. Our near term focus is on bringing our drugs through proof of concept clinical trials. Our proof of concept strategy is to efficiently conduct studies to demonstrate the value of each program in a therapeutic area so that decisions to continue, modify or cease development of a program can be made early in the development process. We believe that our broad development pipeline and productive discovery platform provide an incentive to design trials for each program with high hurdles to demonstrate the potential of the drug or to fail early.

The clinical group works closely with the discovery and translational medicine groups to select disease indications in which our drugs are studied in clinical trials. The clinical group designs, directs and implements all clinical operations, including identifying and selecting clinical investigators, recruiting study subjects to participate in our clinical trials, biostatistics, data management, drug safety evaluation, and adverse event reporting. The clinical group also is responsible for assuring that our development programs are conducted in compliance with applicable regulatory requirements. The group also works closely with the cross functional project and clinical teams to facilitate the appropriate and efficient development of our diverse product pipeline.

Information Technology

We believe that our information technology capabilities provide a competitive advantage. We understand the importance of this capability to maintain competitiveness in our information-rich environment and to increasing our productivity by capturing, organizing and providing appropriate information to improve decision making. We accomplished our primary goal of creating a paperless research environment, which we believe has empowered our scientists to improve real time decision-making at the bench top. Our goal is to develop a complementary capability in preclinical, clinical development and regulatory affairs to provide a similar competitive advantage as our research information technology platform provides. We have begun deployment of a state-of-the-art company-wide information system that organizes and provides access to real-time information, and is customizable to individual needs.

Competitors

The pharmaceutical and biotechnology industries are characterized by rapid and continuous technological innovation. We compete with companies worldwide that are engaged in the research and discovery, licensing, development and commercialization of drug candidates, including large pharmaceutical companies with internal discovery and development functions, biotech companies with competing products in the therapeutic areas we are targeting and contract research organizations that perform many of the functions we perform under our collaborations. In addition, we face competition from other pharmaceutical and biotechnology companies seeking to out-license drugs targeting the same disease class or condition as our drug candidates based on, among other things, patent position, product efficacy, safety, reliability, availability, patient convenience, price and reimbursement potential. Therefore, we may be unable to enter into collaboration, partnering, or out-licensing agreements on terms that are acceptable to us, or at all. We also compete with other clinical trials for patients who are eligible to be enrolled in clinical trials we or our collaborators are conducting, which may limit the number patients who meet the criteria for enrollment and delay or prevent us or our collaborators from completing trials when anticipated. Because the timing of entry of a drug in the market presents important competitive advantages, the speed with which we are able to complete drug development and clinical trials, obtain regulatory approval and

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supply commercial quantities of drugs to the market will affect our competitive position. Some of our competitors have a broader range of capabilities and have greater access to financial, technical, scientific, regulatory, business development, recruiting and other resources than we do. Their access to greater resources may allow them to develop processes or products that are more effective, safer or less costly, or gain greater market acceptance, than products we develop or for which they obtain FDA approval more rapidly than we do. We anticipate that we will face increased competition in the future as new companies enter the market and advanced technologies become available.

Government Regulation

Biopharmaceutical companies are subject to substantial regulation by governmental agencies in the U.S. and other countries. Virtually all pharmaceutical products are subject to rigorous preclinical and clinical testing and other approval procedures by the FDA and by foreign regulatory agencies. Before a drug product is approved by the FDA for commercial marketing, three phases of human clinical trials are usually conducted to test the safety and effectiveness of the product. Phase 1 clinical trials most typically involve testing the drug on a small number of healthy volunteers to assess the safety profile of the drug at different dosage levels. Phase 2 clinical trials, which may also enroll a relatively small number of patient volunteers, are designed to further evaluate the drug s safety profile and to provide preliminary data as to the drug s effectiveness in humans. Phase 3 clinical trials consist of larger, well-controlled studies that may involve several hundred or thousand patient volunteers representing the drug s targeted population. During any of these phases, the clinical trial can be placed on clinical hold, or temporarily or permanently stopped for a variety of reasons, principally for safety concerns. In addition, the failure to comply with applicable regulatory requirements in the U.S. and in other countries in which we conduct development activities could result in a variety of fines and sanctions, such as warning letters, product recalls, product seizures, suspension of operations, fines and civil penalties or criminal prosecution.

The approval process is time-consuming and expensive, and there are no assurances that approval will be granted on a timely basis, or at all. Even if regulatory approvals are granted, a marketed product is subject to continual review under federal and state laws and regulations. Post-marketing requirements include reporting adverse events, recordkeeping, and compliance with cGMP and marketing requirements. Adverse events reported after marketing of a drug can result in additional restrictions being placed on the use of a drug and, possibly, in withdrawal of the drug from the market. The FDA may also require labeling changes to products at any time based on new safety information.

If drug candidates we develop are approved for commercial marketing by the FDA, they would be subject to the provisions of the Drug Price Competition and Patent Term Restoration Act of 1984 known as the Hatch-Waxman Act. The Hatch-Waxman Act provides companies with marketing exclusivity for new chemical entities and allows companies to apply to extend patent protection for up to five additional years. It also provides a means for approving generic versions of a drug product once the marketing exclusivity period has ended and all relevant patents have expired (or have been successfully challenged and defeated). The period of exclusive marketing may be shortened, however, by a successful patent challenge.

All facilities and manufacturing processes used in the production of Active Pharmaceutical Ingredients for clinical use in the U.S. must be operated in conformity with cGMP as established by the FDA. We have a cGMP manufacturing facility, which allows us to produce cGMP compliant compounds. In our facility, we have the capacity to produce Active Pharmaceutical Ingredients for Phase 1 and Phase 2 clinical testing. We have validated this capability for compliance with FDA regulations and began our first cGMP manufacturing campaign in 2002. Our cGMP facility is subject to periodic regulatory inspections to ensure compliance with cGMP requirements. We could also be required to comply with specific requirements or specifications of our collaborators, which may be more stringent than regulatory requirements. If we fail to comply with applicable regulations, the FDA could require us to cease ongoing research or disqualify the data submitted to regulatory authorities. A finding that we had materially violated cGMP requirements could result in additional regulatory sanctions and, in severe cases, could result in a mandated closing of our cGMP facility, which would materially and adversely affect our business, financial condition and results of operations.

In the course of our business, we handle, store and dispose of chemicals and biological samples. We are subject to various federal, state and local laws and regulations relating to the use, manufacture, storage, handling and disposal of hazardous materials and waste products. These environmental laws generally impose liability

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regardless of the negligence or fault of a party and may expose us to liability for the conduct of, or conditions caused by, others.

Most health care providers, including research institutions from whom we or our collaborators obtain patient information, are subject to privacy rules under the Health Insurance Portability and Accountability Act of 1996, or HIPAA, the Directive 95/46-EC of the European Parliament on the protection of individuals with regard to the processing of personal data as well as individual European Union member states implementing additional legislation, and similar legislation in other countries. Although our clinical development efforts are not directly regulated by these privacy regulations, we could face substantial criminal penalties if we knowingly receive individually identifiable health information from a health care provider that has not satisfied HIPAA s or the European Union Data Protection Directive s disclosure standards. In addition, certain privacy laws and genetic testing laws may apply directly to our operations and/or those of our collaborators and may impose restrictions on the use and dissemination of individuals health information.

Our clinical development activities involve the production and use of intermediate and bulk active pharmaceutical ingredients, or API. We typically contract with third party manufacturers to produce API for us. Some of these manufacturers are located outside the U.S. and may obtain ingredients from suppliers in other foreign countries before shipping the bulk API to Array in the U.S. Cross-border shipments of pharmaceutical ingredients and products are subject to regulation in the United States by the FDA and in foreign countries, including, in the EU, under directives adopted by the EU member countries. These regulations generally impose notice requirements on us or our third party manufacturers and require confirmation that we are registered with the FDA and have an IND application, an approved New Drug Application or Biologics License Application.

We are subject to other regulations, including regulations under the Occupational Safety and Health Act, regulations promulgated by the U.S. Department of Agriculture, and regulations under other federal, state and local laws.

Intellectual Property

Our success depends in part on our ability to protect our potential drug candidates, other intellectual property rights and our proprietary software technologies. To establish and protect our proprietary technologies and products, we rely on a combination of patent, copyright, trademark and trade secret laws, as well as confidentiality provisions in our contracts with collaborators.

We attempt to protect our trade secrets by entering into confidentiality agreements with our employees, third parties and consultants. Our employees also sign agreements requiring that they assign to us their interests in inventions, original expressions and any corresponding patents and copyrights arising from their work for us. However, it is possible that these agreements may be breached, invalidated or rendered unenforceable, and if so, we may not have an adequate remedy available. Despite the measures we have taken to protect our intellectual property, parties to our agreements may breach the confidentiality provisions or infringe or misappropriate our patents, copyrights, trademarks, trade secrets and other proprietary rights. In addition, third parties may independently discover or invent competing technologies or reverse-engineer our trade secrets or other technology.

Our patent strategy is designed to protect inventions, technology and improvements to inventions that are commercially important to our business. We currently have 16 issued U.S. patents and numerous patent applications on file with the U.S. Patent and Trademark Office and around the world. The source code for our proprietary software programs is protected both as a trade secret and as a copyrighted work.

U.S. patents issued from applications filed on or after June 8, 1995, have a term of 20 years from the application filing date or earlier claimed priority. All of our patent applications were filed after June 8, 1995. Patents in most other countries have a term of 20 years from the date of filing of the patent application. Because the time from filing patent applications to issuance of patents is often several years, this process may result in a period of patent protection significantly shorter than 20 years, which may adversely affect our ability to exclude competitors from our markets. Our success will depend in part upon our ability to develop proprietary products and technologies and to obtain patent coverage for these products and technologies. We intend to continue to file patent

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applications covering newly developed products and technologies. We may not, however, commercialize the technology underlying any or all of our existing or future patent applications.

Patents provide some degree of protection for our proprietary technology. However, the pursuit and assertion of patent rights, particularly in areas like pharmaceuticals and biotechnology, involve complex legal and factual determinations and, therefore, are characterized by some uncertainty. In addition, the laws governing patentability and the scope of patent coverage continue to evolve, particularly in biotechnology. As a result, patents may not be issued from any of our patent applications or from applications licensed to us. The scope of any of our patents, if issued, may not be sufficiently broad to offer meaningful protection. In addition, our patents or patents licensed to us, if they are issued, may be successfully challenged, invalidated, circumvented or rendered unenforceable so that our patent rights might not create an effective competitive barrier. Moreover, the laws of some foreign countries may not protect our proprietary rights to the same extent as do the laws of the U.S. Any patents issued to us or our strategic partners may not provide a legal basis for establishing an exclusive market for our products or provide us with any competitive advantages. Moreover, the patents held by others may adversely affect our ability to do business or to continue to use our technologies freely. In view of these factors, our intellectual property positions bear some degree of uncertainty.

Employees

As of June 30, 2008, we had 386 full-time employees, including 292 scientists, of whom 131 have PhD s or MD s. None of our employees are covered by collective bargaining agreements, and we consider our employee relations to be good.

Our Corporate Information

Our principal executive offices are located at 3200 Walnut Street, Boulder, Colorado 80301 and our phone number is (303) 381-6600. We were founded in 1998 and became a public company in November 2000. Our stock is listed on the NASDAQ Global Market under the symbol ARRY.

Available Information

Electronic copies of our Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q and Current Reports on Form 8-K and other documents we file with or furnish to the SEC are available free of charge (i) on the Investor Relations section of our website at http://www.arraybiopharma.com or (ii) by sending a written request to Investor Relations at our corporate headquarters. Information on our website is not incorporated by reference into this report.

ITEM 1A. RISK FACTORS

In addition to the other factors discussed elsewhere in this report and in other reports we file with the SEC, the following factors could cause our actual results or events to differ materially from those contained in any forward-looking statements made by us or on our behalf. In addition, other risks and uncertainties not presently known to us or that we currently deem immaterial may impair our business operations. If any of the following risks or such other risks occur, it could adversely affect our business, operating results and financial condition, as well as cause the value of our common stock to decline.

Risks Related to Our Business

We Have a History of Losses and May Not Achieve or Sustain Profitability.

We are at an early stage of executing our business plan, and we have a limited history of developing and out-licensing our proprietary drug candidates and offering our drug discovery capabilities. We have incurred significant operating and net losses and negative cash flows from operations since our inception. As of June 30, 2008, we had an accumulated deficit of \$285.4 million. We had net losses of \$96.3 million, \$55.4 million and \$39.6 million for the fiscal years ended June 30, 2008, 2007 and 2006, respectively. We expect to incur additional losses and negative cash flows in the future, and these losses may continue or increase due in part to anticipated increases in expenses for research and development for proprietary drug discovery, particularly clinical development, expansion of our clinical and scientific capabilities, development of commercial capabilities and

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acquisitions of complementary technologies. At the same time, we expect that revenue from the sale of our research tools and services will continue to decline as a percentage of total revenue as we devote more resources to drug discovery and our proprietary drug programs. As a result, we may not be able to achieve or maintain profitability. Moreover, if we do achieve profitability, the level of any profitability cannot be predicted and may vary significantly.

We May Not Receive Royalty or Milestone Revenue Under Our Collaboration Agreements for Several Years, or at All.

Much of our current revenue is non-recurring in nature and unpredictable as to timing and amount. While several of our out-license and collaboration agreements provide for royalties on product sales, none of our drug candidates have been approved for commercial sale, our drug candidates are at early stages of development and drug development entails a high risk of failure. Consequently, we do not expect to receive any royalty revenue for several years, if at all. For the same reasons, we may never realize much of the milestone revenue provided for in our out-license and collaboration agreements. Similarly, drugs we select to commercialize ourselves or partner for later-stage co-development and commercialization may not generate revenue for several years, or at all.

Our Drug Candidates Are at Early Stages of Development, and We May Not Successfully Develop a Drug Candidate That Becomes a Commercially Viable Drug.

The drug discovery and development process is highly uncertain, and we have not developed, and may never develop, a drug candidate that ultimately leads to a commercially viable drug. All of our most advanced drug candidates are in the early stages of development, in either Phase 1 or Phase 2, and we do not have any drugs approved for commercial sale. Before a drug product is approved by the FDA for commercial marketing, it is tested for safety and effectiveness in clinical trials that can take up to six years or longer. Promising results in preclinical development or clinical trials may not be predictive of results obtained in later clinical trials. A number of pharmaceutical companies have experienced significant setbacks in advanced clinical trials, even after obtaining promising results in earlier preclinical and clinical trials. At any time, the FDA may place a clinical trial on clinical hold, or temporarily or permanently stop the trial, for a variety of reasons, principally for safety concerns. We or our collaborators may experience numerous unforeseen events during, or as a result of, the clinical development process that could delay or prevent our drug candidates from being approved, including:

- Failure to achieve clinical trial results that indicate a candidate is effective in treating a specified condition or illness in humans;
- Presence of harmful side effects;
- Determination by the FDA that the submitted data do not satisfy the criteria for approval;
- Lack of commercial viability of the drug;
- Failure to acquire, on reasonable terms, intellectual property rights necessary for commercialization; and
- Existence of therapeutics that are more effective.

We or Our Collaborators May Choose Not to Commercialize a Drug Candidate at Any Time During Development, Which Would Reduce or Eliminate Our Potential Return on Investment for That Drug.

At any time, we or our collaborators may decide to discontinue the development of a drug candidate or not to commercialize a candidate. If we terminate a preclinical program in which we have invested significant resources, we will have expended resources on a program that will not provide any or a full return on our investment and we will have missed the opportunity to have allocated those resources to potentially more productive uses. Even if one of our drug candidates receives regulatory approval for marketing, physicians or consumers may not find that its effectiveness, ease of use, side effect profile, cost or other factors make it effective in treating disease or more beneficial than or preferable to other drugs on the market. Additionally, third party payors, such as government health plans and health insurance plans or maintenance organizations, may choose not to include our drugs on their formulary lists for reimbursement. As a result, our drugs may not be used or may be used only for restricted applications.

We May Not Be Successful In Entering Into Additional Out-License Agreements on Favorable Terms.

We are committing significant resources to create our own proprietary drug candidates and to build a commercial-stage biopharmaceutical company. In fiscal 2008, we increased our investment in proprietary research to \$90.3 million in research and development for proprietary drug discovery expenses, compared to \$57.5 million and \$33.4 million for fiscal years 2007 and 2006, respectively. Our proprietary drug discovery programs are in their

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early stage of development and are unproven. To date, we have entered into five out-licensing agreements for the development and commercialization of our drug candidates. Although we have expended, and continue to expend, resources on internal research and development for proprietary drug discovery for our proprietary programs, we may not be successful in entering into additional out-licensing agreements with favorable terms, including up-front, milestone, royalty and/or license payments and the retention of certain valuable commercialization or co-promote rights, as a result of factors, many of which are outside of our control, and which include:

- Our ability to create valuable proprietary drug candidates targeting large market opportunities;
- Research and spending priorities of potential licensing partners;
- Willingness of and the resources available to pharmaceutical and biotechnology companies to in-license drug candidates to fill their clinical pipelines; or
- Our ability or inability to agree with a potential partner on the value of proprietary drug candidates we are seeking to out-license, or on the related terms.

Our Capital Requirements Could Significantly Increase If We Choose to Develop More of Our Proprietary Programs Internally.

We believe that the maximum value for certain proprietary drug candidates is best achieved by retaining the rights to develop and commercialize the candidate and not seeking a partner or by waiting until later in the development process to seek a partner to co-develop and commercialize or co-promote a product. It is difficult to predict which of our proprietary programs are likely to yield higher returns if we elect to develop them further before seeking a partner or to not seek a partner at all as a result of many factors, including the competitive position of the product, our capital resources, the perceived value among potential partners of the product and other factors outside of our control. Therefore, we may undertake and fund, solely at our expense, further development, clinical trials, manufacturing and marketing activities for a greater number of proprietary candidates than we planned. In addition, we may choose not to out-license certain of our proprietary programs if we are unable to do so on terms that are favorable to us. As a result, our requirements for capital could increase significantly. We may be unable to raise additional required capital on favorable terms, or at all, however, or we may be required to substantially reduce our development efforts, which would delay, limit or prevent our ability to commercialize and realize revenue from our drug candidates.

We May Not Out-License Our Proprietary Programs at the Most Appropriate Time to Maximize the Total Value or Return of These Programs to Us.

A critical aspect of our business strategy is to out-license drug candidates for late-stage development, co-development and/or commercialization to obtain the highest possible value while also evaluating earlier out-licensing opportunities to maximize our risk-adjusted return on our investment in proprietary research. Because the costs and risk of failure of bringing a drug to market are high, the value of out-licensing a drug candidate generally increases as it successfully progresses through clinical trials. We may choose or be forced to out-license a drug candidate or program on terms that require us to relinquish commercial or market rights or at a point in the research and development process that does not provide as great a value or return than what might have been obtained if we had further developed the candidate or program internally. Likewise, we may decline, or be unable to obtain favorable, early out-licensing opportunities in programs that do not result in a commercially viable drug, which could leave the resulting program with little or no value even though significant resources were invested in its development. Our inability to successfully out-license our programs on favorable terms could materially adversely affect our results of operations and cash flows.

If We Fail to Adequately Conduct Clinical Trials, Our Potential Return Could Be Reduced or Eliminated.

Before any of our drug candidates can be sold commercially, we or our collaborators must conduct clinical trials that demonstrate that drug is safe and effective for use in humans for the indications sought. The results of these clinical trials are used as the basis to obtain regulatory approval from government authorities such as the FDA. Conducting clinical trials is a complex, time-consuming and expensive process that requires an appropriate number of trial sites and patients to support the product label claims being sought. The length of time, number of trial sites and number of patients required for clinical trials vary substantially according to their type, complexity, novelty and the drug candidate s intended use, and therefore, we may spend as much as several years completing certain trials. Further, the time within which we can complete our clinical trials depends in large part on the ability to enroll eligible patients that meet the enrollment criteria and who are in proximity to the trial sites. We and our collaborators also face competition with other clinical trials for eligible patients. As a consequence, there may be limited availability of eligible patients, which can result in increased development costs, delays in

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regulatory approvals and associated delays in drug candidates reaching the market. Patients may also suffer adverse medical events or side effects in the course of our clinical trials that may delay or prohibit regulatory approval of our drug candidates. Even if we or our collaborators successfully conduct clinical trials, we or our collaborators may not obtain favorable clinical trial results and may not be able to obtain regulatory approval on this basis.

In addition, to execute our clinical development plans, we need to accelerate the growth of our clinical development organization and increase dependence on third-party clinical trial service providers. We anticipate that we will be required to contract with clinical sites and enroll patients in a number of new geographic locations where our experience conducting clinical trials is more limited, including some countries in Eastern Europe and South American, and in India. We are conducting and plan to conduct further clinical trial activities in territories outside the U.S. through third-party clinical trial service providers.

If we or our collaborators fail to adequately manage the increasing number, size and complexity of clinical trials, the clinical trials and corresponding regulatory approvals may be delayed or we or our collaborators may fail to gain approval for our drug candidates altogether. If we or our collaborators are unable to market and sell our drug candidates or are unable to obtain approvals in the timeframe needed to execute our product strategies, our business and results of operations would be materially adversely affected.

We Expect That Revenue From Our Funded Research Collaborations Will Decline In the Future As We Focus More Resources on Our Proprietary Research Programs.

We expect that revenue from our funded research collaborations to discover drug candidates against targets our collaborators select will decline. Historically, revenue from these collaborations has partially funded development of a drug discovery platform for identifying and developing early stage drug candidates. We believe the value of the drug candidates we have created for many of our collaborators under these collaboration agreements has exceeded the economic reward provided to us under the agreements. We intend to continue to implement our partnering strategy, a key component of which, in addition to potentially obtaining higher milestone and royalty rates, is to out-license later stage candidates and retain commercialization or promotional rights in parts of the world. As we implement this strategy, we expect to make significant investments in our own drug discovery and development efforts to discover additional candidates for out-licensing and to develop candidates to proof-of-concept and that our collaboration revenue will decline as our historical collaborations end.

We Have Limited Clinical Development and Commercialization Experience.

One of our business strategies is to develop select drug candidates through later stage clinical trials before out-licensing them to a pharmaceutical or biotechnology partner for further clinical development and commercialization and to commercialize select drug candidates ourselves. We have not yet conducted a Phase 3 or later stage clinical trial ourselves, nor have we commercialized a drug. We have limited experience conducting clinical trials and obtaining regulatory approvals, and we may not be successful in some or all of these activities. We have no experience as a company in the sales, marketing and distribution of pharmaceutical products and do not currently have a sales and marketing organization. We expect to expend significant amounts to recruit and retain high quality personnel with clinical development experience. Developing commercialization capabilities would be expensive and time-consuming, could delay any product launch, and we may never be able to develop this capacity. To the extent we are unable or determine not to develop these resources internally, we may be forced to rely on third-party clinical investigators, or clinical research or marketing organizations, which could subject us to costs and to delays that are outside our control. If we are unable to establish adequate capabilities independently or with others, we may be unable to generate product revenues for certain candidates.

Delays In the Commencement or Completion of Clinical Testing Could Result In Increased Costs to Us and Delay or Limit Our Ability to Generate Revenues.

Delays in the commencement or completion of clinical testing of our products could significantly affect our product development costs and our ability to generate revenue from these products. We do not know whether planned clinical trials will begin on time or be completed on schedule, if at all. The commencement and completion of clinical trials can be delayed for a number of reasons, including delays related to our ability to do the following:

• Obtain regulatory approval to commence a clinical trial;

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- Reach agreement on acceptable terms with prospective clinical research organizations, or CROs, and trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- Manufacture sufficient quantities of a product candidate for use in clinical trials;
- Obtain institutional review board, or IRB, approval to conduct a clinical trial at a prospective site;
- Recruit and enroll patients to participate in clinical trials, which can be impacted by many factors outside our control, including competition from other clinical trial programs for the same or similar indications; and
- Retain patients who have initiated a clinical trial but may be prone to withdraw due to side effects from the therapy, lack of efficacy or personal issues.

Clinical trials may also be delayed as a result of ambiguous or negative interim results. In addition, a clinical trial may be suspended or terminated by us, the FDA, the IRB overseeing the clinical trial at issue, any of our clinical trial sites with respect to that site, or other regulatory authorities due to a number of factors, including:

- Failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols;
- Inspection of the clinical trial operations or trial sites by the FDA or other regulatory authorities resulting in the imposition of a clinical hold;
- Unforeseen safety issues; and
- Lack of adequate funding to continue the clinical trial.

Additionally, changes in regulatory requirements and guidance may occur and we may need to amend clinical trial protocols to reflect these changes. Amendments may require us to resubmit our clinical trial protocols to IRBs for reexamination, which may impact the costs, timing or successful completion of a clinical trial. If we experience delays in completion of, or if we terminate, any of our clinical trials, the commercial prospects for our product candidates may be harmed and our ability to generate product revenues will be delayed and/or reduced. In addition, many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of a product candidate.

 $Drug\ Candidates\ That\ We\ Develop\ With\ Our\ Collaborators\ or\ on\ Our\ Own\ May\ Not\ Receive\ Regulatory\ Approval$

The development and commercialization of drug candidates for our collaborators and our own internal drug discovery efforts are subject to regulation. Pharmaceutical products require lengthy and costly testing in animals and humans and regulatory approval by governmental agencies prior to commercialization. It takes several years to complete testing, and failure can occur at any stage of testing. Results attained in preclinical testing and early clinical trials for any of our drug candidates may not be indicative of results that are obtained in later studies, and significant setbacks in advanced clinical trials may arise, even after promising results in earlier studies. Clinical trials may not demonstrate sufficient safety and efficacy to obtain the requisite regulatory approvals or result in marketable products. Furthermore, data obtained from preclinical and clinical studies are susceptible to varying interpretations that may delay, limit or prevent regulatory approval. In addition, the administration of any drug candidate we develop may produce undesirable side effects or safety issues that could result in the interruption, delay or suspension of

clinical trials, or the failure to obtain FDA or other regulatory approval for any or all targeted indications. Based on results at any stage of testing, we or our collaborators may decide to repeat or redesign a trial or discontinue development of a drug candidate.

Approval of a drug candidate as safe and effective for use in humans is never certain, and regulatory agencies may delay or deny approval of drug candidates for commercialization. These agencies may also delay or deny approval based on additional government regulation or administrative action, on changes in regulatory policy during the period of clinical trials in humans and regulatory review or on the availability of alternative treatments. Similar delays and denials may be encountered in foreign countries. None of our collaborators have obtained regulatory approval to manufacture and sell drug candidates owned by us or identified or developed under an agreement with us. If we or our collaborators cannot obtain this approval, we will not realize milestone or royalty payments based on commercialization goals for these drug candidates.

In light of widely publicized events concerning the safety of certain drug products, such as Vioxx, regulatory authorities, members of Congress, the Government Accountability Office, or the GAO, medical professionals, and the general public have raised concerns about potential drug safety issues. These events have resulted in the withdrawal of drug products, revisions to drug labeling that further limit use of the drug products, and establishment

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of risk management plans that may, for instance, restrict distribution of drug products. Although drug safety concerns have occurred over time, the increased attention to this issue may result in a more cautious approach by the FDA. As a result, data from clinical trials may receive greater scrutiny with respect to safety. Safety concerns may result in the FDA or other regulatory authorities terminating clinical trials before completion or requiring longer or additional clinical trials that may result in substantial additional expense and a delay or failure in obtaining approval or approval for a more limited indication than originally sought.

Even If Our Drug Candidates Obtain Regulatory Approval, We and Our Collaborators Will Be Subject to Ongoing Government Regulation.

Even if regulatory authorities approve any of our drug candidates, the manufacture, labeling, storage, recordkeeping, distribution, marketing and sale of these drugs will be subject to strict and ongoing regulation. Compliance with this regulation consumes substantial financial and management resources and may expose us and our collaborators to the potential for other adverse circumstances. For example, approval for a drug may be conditioned on costly post-marketing follow-up studies. Based on these studies, if a regulatory authority does not believe that the drug demonstrates a clinical benefit to patients, it could limit the indications for which a drug may be sold or revoke the drug s marketing approval. In addition, identification of certain side effects after a drug is on the market may result in the subsequent withdrawal of approval, reformulation of a drug, additional preclinical and clinical trials and changes in labeling or distribution. Any of these events could delay or prevent us from generating revenue from the commercialization of these drugs and cause us to incur significant additional costs.

Given the number of recent high profile safety events with certain drug products, the FDA may require, as a condition of approval, costly risk management programs with components including safety surveillance, restricted distribution and use, patient education, enhanced labeling, special packaging or labeling, expedited reporting of certain adverse events, pre-approval of promotional materials, and restrictions on direct-to-consumer advertising. Furthermore, heightened Congressional scrutiny on the adequacy of the FDA s drug approval process and the agency s efforts to assure the safety of marketed drugs has resulted in the proposal of new legislation addressing drug safety issues. If enacted, any new legislation could result in delays or increased costs for manufacturers and drug sponsors during the period of product development, clinical trials, and regulatory review and approval, as well as increased costs to assure compliance with any new post-approval regulatory requirements.

In addition, the marketing of these drugs by us or our collaborators will be regulated by federal and state laws pertaining to health care fraud and abuse, such as the federal anti-kickback law prohibiting bribes, kickbacks or other remuneration for the order, purchase or recommendation of items or services reimbursed by federal health care programs. Many states have similar laws applicable to items or services reimbursed by commercial insurers. Violations of fraud and abuse laws can result in fines and/or imprisonment.

If Our Drug Candidates Do Not Gain Market Acceptance, We May Be Unable to Generate Significant Revenue.

Even if our drug candidates are approved for sale, they may not be successful in the marketplace. Market acceptance of any of our drug candidates will depend on a number of factors including:

- Demonstration of clinical effectiveness and safety;
- Potential advantages of our drug candidates over alternative treatments;
- Ability to offer our drug candidates for sale at competitive prices;

- Availability of adequate third-party reimbursement; and
- Effectiveness of marketing and distribution methods for the products.

If our drug candidates do not gain market acceptance among physicians, patients and others in the medical community, our ability to generate meaningful revenues from our drug candidates would be limited.

If We Need But Are Unable to Obtain Additional Funding to Support Our Operations, We Could Be Unable to Successfully Execute Our Operating Plan or Be Forced to Reduce Our Operations.

We have historically funded our operations through revenue from our collaborations, the issuance of equity securities and debt financing. We used \$45.7 million in our operating activities in fiscal 2008, while we used \$44.5 million and \$24.3 million in our operating activities in fiscal 2007 and 2006, respectively. In addition, a portion of our cash flow is dedicated to the payment of principal and interest, and possibly to fund increased compensating and restricted cash balances with the lender, on our existing senior secured credit facility, which provides for a \$10

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million term loan and a \$5 million equipment line, and may be dedicated to the payment of principal and interest on our credit facility with Deerfield Private Design Fund, L.P. and Deerfield Private Design International Fund, L.P. (who we refer to collectively as Deerfield), which provides for an \$80 million term loan that at our option may be repaid with our common stock. Our debt obligations could therefore render us more vulnerable to competitive pressures and economic downturns and imposes some restrictions on our operations. Although we anticipate that we will use more cash in our operating activities in future periods, we believe that our existing cash, cash equivalents and marketable securities, amounts available on the Deerfield Credit Facility and anticipated cash flow from existing out-license and collaboration agreements will be sufficient to support our current operating plan for at least the next 12 months. However, our current operating plan and assumptions could change as a result of many factors, and we could require additional funding sooner than anticipated.

If we are unable to meet our capital requirements from cash generated by our future operating activities and are unable to obtain additional funds when needed, we may be required to curtail operations significantly or to obtain funds through other arrangements on unattractive terms, which could prevent us from successfully executing our operating plan. If we raise additional capital through the sale of equity or convertible debt securities, the issuance of those securities would result in dilution to our stockholders.

Our Collaborators Have Substantial Control and Discretion Over the Timing and the Continued Development and Marketing of Drug Candidates We Create for Them.

Our collaborators have significant discretion in determining the efforts and amount of resources that they dedicate to our collaborations. Our collaborators may determine not to proceed with clinical development or commercialization of a particular drug candidate for a number of reasons that are beyond our control, even under circumstances where we might have continued such a program. In addition, our ability to generate milestone payments and royalties from our collaborators depends on our collaborators abilities to establish the safety and efficacy of our drug candidates, obtain regulatory approvals and achieve market acceptance of products developed from our drug candidates. We also depend on our collaborators to manufacture clinical scale quantities of some of our drug candidates and would depend on them in the future for commercial scale manufacture, distribution and direct sales. Our collaborators may not be successful in manufacturing our drug candidates on a commercial scale or in successfully commercializing them.

We face additional risks in connection with our collaborations, including the following:

- Collaborators may develop and commercialize, either alone or with others, products and services that are similar to or competitive with the products that are the subject of the collaboration with us;
- Collaborators may under fund or not commit sufficient resources to the testing, marketing, distribution or other development of our drug candidates;
- Collaborators may not properly maintain or defend our intellectual property rights or they may utilize our proprietary information in such a way as to invite litigation that could jeopardize or potentially invalidate our intellectual property or proprietary information or expose us to potential liability;
- Collaborators may encounter conflicts of interest, changes in business strategy or other business issues which could adversely affect their willingness or ability to fulfill their obligations to us (for example, pharmaceutical and biotechnology companies historically have re-evaluated their priorities following mergers and consolidations, which have been common in recent years in these industries); and
- Disputes may arise between us and our collaborators delaying or terminating the research, development or commercialization of our drug candidates, resulting in significant litigation or arbitration that could be time-consuming and expensive, or causing collaborators to act in

their own self-interest and not in the interest of our stockholders.

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Revenue From Collaborations Depends on the Extent to Which the Pharmaceutical and Biotechnology Industries Collaborate With Other Companies for One or More Aspects of Their Drug Discovery Process.

Our capabilities include aspects of the drug discovery process that pharmaceutical and biotechnology companies have traditionally performed internally. The willingness of these companies to expand or continue drug discovery collaborations to enhance their research and development process is based on several factors that are beyond our control, any of which could cause our revenue to decline. These include their ability to hire and retain qualified scientists, the resources available for entering into drug discovery collaborations and the spending priorities among various types of research activities. In addition, our ability to convince these companies to use our drug discovery capabilities, rather than develop them internally, depends on many factors, including our ability to:

- Develop and implement drug discovery technologies that will result in the identification of higher-quality drug candidates;
- Attract and retain experienced, high caliber scientists;
- Achieve timely, high-quality results at an acceptable cost; and
- Design, create and manufacture our chemical compounds in quantities, at purity levels and at costs that are acceptable to our collaborators.

The importance of these factors varies depending on the company and type of discovery program, and we may be unable to meet any or all of them in the future. Even if we are able to address these factors, these companies may still decide to perform these activities internally or retain other companies that provide drug research and development expertise similar to ours.

Our Research and Development Capabilities May Not Produce Viable Drug Candidates.

We have entered into several research and development collaborations under which we provide drug discovery and development services to identify drug candidates for our collaborators. We also seek to identify and develop drug candidates for our proprietary programs. It is uncertain whether we will be able to provide drug discovery more efficiently or create high quality drug candidates that are suitable for our or our collaborators purposes, which may result in delayed or lost revenue, loss of collaborators or failure to expand our existing relationships. Our ability to create viable drug candidates for ourselves and our collaborators depends on many factors, including the implementation of appropriate technologies, the development of effective new research tools, the complexity of the chemistry and biology, the lack of predictability in the scientific process and the performance and decision-making capabilities of our scientists. Our information-driven technology platform, which we believe allows our scientists to make better decisions, may not enable our scientists to make correct decisions or develop viable drug candidates.

If Our Drug Discovery and Development Programs Do Not Progress As Anticipated, Our Revenue and Stock Price Could Be Negatively Impacted.

We estimate the timing of a variety of preclinical, clinical, regulatory and other milestones for planning purposes, including when a drug candidate is expected to enter clinical trials, when a clinical trial will be completed or when an application for regulatory approval will be filed. Some of our estimates are included in this report. We base our estimates on facts that are currently known to us and on a variety of assumptions, many of which are beyond our control. Delays may be caused by regulatory or patent issues, interim or final results of on-going clinical trials, scheduling conflicts with participating clinics and the availability of patients who meet the criteria for, and the rate of patient enrollment in, clinical trials. If we or our collaborators do not achieve milestones when anticipated, we may not achieve our planned revenue, and our stock price could decline. In addition, any delays in obtaining approvals to market and sell drugs may result in the loss of competitive advantages in

being on the market sooner than, or in advance of, competing products, which may reduce the value of these products and the potential revenue we receive from the eventual sale of these products, either directly or under agreements with our partners.

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We May Not Realize Anticipated Benefits From Future Acquisitions, Investments and Strategic Partnerships.

As part of our business strategy, we may acquire, invest in or form strategic partnerships with businesses with complementary products, services and/or technologies. Acquisitions, investments and strategic partnerships involve numerous risks, including, but not limited to:

- Difficulties and increased costs in connection with integration of the personnel, operations, technologies and products of acquired companies;
- Diversion of management s attention from other operational matters;
- Potential loss of key employees;
- Potential loss of key collaborators;
- Lack of synergy, or the inability to realize expected synergies, resulting from the acquisition or partnership; and
- Impairment of acquired intangible assets as a result of technological advancements or worse-than-expected clinical results or performance of the acquired company or the partnered assets.

Acquisitions, investments and strategic partnerships are inherently risky and involve significant investments in time and resources to effectively manage these risks and integrate an acquired business or create a successful drug with a strategic partner. Even with investments in time and resources, an acquisition or strategic partnership may not produce the revenues, earnings or business synergies we anticipate. An acquisition or strategic partnership that fails to meet our expectations could materially and adversely affect our business, financial condition and results of operations.

Because We Rely on a Small Number of Collaborators for a Significant Portion of Our Revenue, If One or More of Our Major Collaborators Terminates or Reduces the Scope of Their Agreement With Us, Our Revenue May Significantly Decrease.

A relatively small number of collaborators account for a significant portion of our revenue as outlined further in the section below entitled Management s Discussion and Analysis of Financial Condition and Results of Operations. We expect that revenue from a limited number of collaborators will continue to account for a large portion of our revenue in future quarters. In general, our collaborators may terminate their contracts with us upon 90 to 120 days notice for any reason. In addition, some of our major collaborators can determine the amount of products delivered and research or development performed under these agreements. As a result, if any one of our major collaborators cancels, declines to renew or reduces the scope of its contract with us, our revenue may significantly decrease.

We May Not Be Able to Recruit and Retain the Experienced Scientists and Management We Need to Compete In the Drug Research and Development Industry.

We have 386 employees as of June 30, 2008, and our future success depends upon our ability to attract, retain and motivate highly skilled scientists and management. Our ability to achieve our business strategies, including progressing drug candidates through later stage development or commercialization, attracting new collaborators and retaining, renewing and expanding existing collaborations, depends on our ability to hire and retain high caliber scientists and other qualified experts, particularly in clinical development and commercialization. We compete with

pharmaceutical and biotechnology companies, contract research companies and academic and research institutions to recruit personnel and face significant competition for qualified personnel, particularly clinical development personnel. We may incur greater costs than anticipated, or may not be successful, in attracting new scientists or management or in retaining or motivating our existing personnel.

Our future success also depends on the personal efforts and abilities of the principal members of our senior management and scientific staff to provide strategic direction, manage our operations and maintain a cohesive and stable environment. In particular, we rely on the services of Robert E. Conway, our Chief Executive Officer; Dr. Kevin Koch, our President and Chief Scientific Officer; Dr. David L. Snitman, our Chief Operating Officer and Vice President, Business Development; Dr. John Yates, our Chief Medical Officer, R. Michael Carruthers, our Chief Financial Officer; and John R. Moore, our Vice President and General Counsel. We have employment agreements with all of the above personnel that are terminable upon 30 days prior notice.

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Our cGMP and Pharmacology Facilities and Practices May Fail to Comply with Government Regulations.

All facilities and manufacturing processes used in the production of drug products, including Active Pharmaceutical Ingredients for clinical use in the U.S. must be operated in conformity with current Good Manufacturing Practices, or cGMP, as established by the FDA. Similar requirements exist for manufacture of drug products for clinical use in other countries. These requirements include, among other things, quality control, quality assurance and the maintenance of records and documentation. If we fail to comply with these requirements, we may not be able to continue the production of our products, and we could be subject to fines and penalties, suspension of production, suspension or delay in product approval, product seizure or recall, or withdrawal of product approval. We operate a clinical-scale manufacturing facility that we believe conforms to cGMP requirements. This facility and our cGMP practices are subject to periodic regulatory inspections to ensure compliance with cGMP requirements. In addition, we could be required to comply with specific requirements of our collaborators, which may exceed FDA or other applicable regulations. Failure on our part to comply with applicable regulations and specific requirements of our collaborators could result in the termination of ongoing research, disqualification of data for submission to regulatory authorities, delays or denials of new product approvals, warning letters, fines, consent decrees restricting or suspending manufacturing operations, injunctions, civil penalties, recall or seizure of products, and criminal prosecution. Material violations of cGMP requirements could result in regulatory sanctions and, in severe cases, could result in a mandated closing of our cGMP facility.

In connection with our application for commercial approvals and, if any drug candidate is approved by the FDA or other regulatory agencies for commercial sale, a significant scale-up in manufacturing may require additional validation studies. If we are unable to successfully increase the manufacturing capacity for a drug candidate, the regulatory approval or commercial launch of that drug candidate may be delayed, or there may be a shortage of supply, which could limit our ability to commercialize the drug.

In addition, our pharmacology facility may be subject to the U.S. Department of Agriculture, or USDA, regulations for certain animal species. Failure on our part to comply with applicable regulations and specific requirements of our collaborators could result in the termination of ongoing pharmacology research. Material violations of USDA requirements could result in additional regulatory sanctions and, in severe cases, could result in a mandated closing of our pharmacology facility for certain species.

Our Development, Testing and Manufacture of Drug Candidates May Expose Us to Product Liability and Other Lawsuits.

We develop, test and manufacture drug candidates that are generally intended for use in humans. Our drug discovery and development activities, including clinical trials we or our collaborators conduct, that result in the future manufacture and sale of drugs by us or our collaborators expose us to the risk of liability for personal injury or death to persons using these drug candidates. We may be required to pay substantial damages or incur legal costs in connection with defending any of these product liability claims, or we may not receive revenue from expected royalty or milestone payments if the commercialization of a drug is limited or ceases as a result of such claims. We have product liability insurance that contains customary exclusions and provides coverage up to \$10.0 million per occurrence and in the aggregate, which we believe is customary in our industry for our current operations. However, our product liability insurance does not cover every type of product liability claim that we may face or loss we may incur, and may not adequately compensate us for the entire amount of covered claims or losses or for the harm to our business reputation. We may be unable to acquire or maintain additional or maintain our current insurance policies at acceptable costs or at all.

If Our Use of Chemical and Hazardous Materials Violates Applicable Laws or Regulations or Causes Personal Injury We May Be Liable for Damages.

Our drug discovery activities, including the analysis and synthesis of chemical compounds, involve the controlled use of chemicals, including flammable, combustible, toxic and radioactive materials that are potentially hazardous. Our use, storage, handling and disposal of these materials is subject to federal, state and local laws and regulations, including the Resource Conservation and Recovery Act, the Occupational Safety and Health Act and local fire codes, and regulations promulgated by the Department of Transportation, the Drug Enforcement Agency, the Department of Energy, the Colorado Department of Public Health and Environment, and the Colorado Department of Human Services, Alcohol

and Drug Abuse Division. We may incur significant costs to comply with these laws and regulations in the future. In addition, we cannot completely eliminate the risk of accidental contamination or injury from these materials, which could result in material unanticipated expenses, such as substantial fines or penalties, remediation costs or damages, or the loss of a permit or other authorization

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to operate or engage in our business. Those expenses could exceed our net worth and limit our ability to raise additional capital.

Our Operations Could Be Interrupted By Damage to Our Specialized Laboratory Facilities.

Our operations are dependent upon the continued use of our highly specialized laboratories and equipment in Boulder and Longmont, Colorado. Catastrophic events, including fires or explosions, could damage our laboratories, equipment, scientific data, work in progress or inventories of chemical compounds and may materially interrupt our business. We employ safety precautions in our laboratory activities in order to reduce the likelihood of the occurrence of these catastrophic events; however, we cannot eliminate the chance that such an event will occur. The availability of laboratory space in these locations is limited, and rebuilding our facilities could be time consuming and result in substantial delays in fulfilling our agreements with our collaborators. We maintain business interruption insurance in the amount of \$18.0 million to cover continuing expenses and lost revenue caused by such occurrences. However, this insurance does not compensate us for the loss of opportunity and potential harm to customer relations that our inability to meet our collaborators needs in a timely manner could create.

Due to Our Reliance on Contract Research Organizations and Other Third Parties to Conduct Our Clinical Trials, We Are Unable to Directly Control the Timing, Conduct and Expense of Our Clinical Trials.

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

Controls We or Our Third Party Service Providers Have in Place to Ensure Compliance With Laws May Not Be Effective to Ensure Compliance With All Applicable Laws and Regulations.

The discovery and development of our products, together with our general operations, are subject to extensive regulation in the United States by state and federal agencies and, as we begin to conduct clinical trials and other activities outside the United States, in foreign countries. Due to escalating costs and difficulties associated with conducting certain types of clinical trials in the United States, we expect that we will be required to conduct certain clinical trials in foreign locations where we have little experience, including countries in eastern Europe, South America and India. We expect that we typically will conduct these trials through third party clinical trial service providers. In addition, we purchase from third party suppliers and manufacturers that are located outside the United States, principally countries in Europe, intermediate and bulk active pharmaceutical ingredients, or API, that are used in our development efforts. As a result, we and our contractors are subject to regulations in the United States and in the foreign countries in which the API is sourced and manufactured relating to the cross-border shipment of pharmaceutical ingredients. Although we have developed and instituted controls based on what we believe to be current best practices, we, our employees, our consultants or our contractors may not be in compliance with all potentially applicable U.S. federal and state regulations and/or laws or all potentially applicable foreign regulations and/or laws. Further, we have a limited ability to monitor and control the activities of third party service providers, suppliers and manufacturers to ensure compliance by such parties with all applicable regulations and/or laws. We may be subject to direct liabilities or be required to indemnify such parties against certain liabilities arising out of any failure by them to comply with such regulations and/or laws. If we or our employees, consultants or contractors fail to comply with any of these regulations and/or laws a range of actions could result, including, but not limited to, the termination of clinical trials, the failure to approve a product candidate, restrictions on our products or manufacturing processes, including withdrawal of our products from the market, significant fines, exclusion from government healthcare programs or other sanctions or litigation.

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Risks Related To Our Industry

The Concentration of the Pharmaceutical and Biotechnology Industry and Any Further Consolidation Could Reduce the Number of Our Potential Collaborators.

There are a limited number of pharmaceutical and biotechnology companies, and these companies represent a significant portion of the market for our capabilities. The number of our potential collaborators could decline even further through consolidation among these companies. If the number of our potential collaborators declines even further, they may be able to negotiate greater rights to the intellectual property they license from us, price discounts or other terms that are unfavorable to us.

Capital Market Conditions May Reduce Our Biotechnology Collaborators Ability to Fund Research.

Traditionally, many unprofitable biotechnology companies have funded their research and development expenditures through raising capital in the equity markets. Declines and uncertainties in these markets have severely restricted raising new capital at times in the past and have affected these companies—ability to continue to expand or fund existing research and development efforts. If our current or future biotechnology collaborators are unable to raise sufficient capital to fund research and development expenditures, we may not be able to expand or maintain current revenue.

Health Care Reform and Cost Control Initiatives By Third-Party Payors Could Reduce the Prices That Can Be Charged for Drugs, Which Could Limit the Commercial Success of Our Drug Candidates.

In the U.S., there have been and we expect there will continue to be a number of legislative and regulatory proposals to change the healthcare system in ways that could significantly affect our business. Federal and state lawmakers regularly propose and, at times, enact legislation that would result in significant changes to the healthcare system, some of which are intended to contain or reduce the costs of medical products and services. For instance, the Medicare Prescription Drug Improvement and Modernization Act of 2003, among other things, added a new Part D prescription drug benefit for Medicare beneficiaries otherwise without prescription drug coverage. Furthermore, future legislation may limit the prices that can be charged for drugs we develop and may limit our commercial opportunity and reduce any associated revenue and profits. For example, federal laws require drug manufacturers to pay specified rebates for medicines reimbursed by Medicaid and to provide discounts for out-patient medicines purchased by certain public health service entities and disproportionate share hospitals and for purchases by some federal governmental departments such as the Department of Veterans Affairs and the Department of Defense. In some countries other than the U.S., reimbursement, pricing and profitability of prescription pharmaceuticals and biopharmaceuticals are subject to government control. We are unable to predict what additional legislation or regulation, if any, relating to the healthcare industry or third-party coverage and reimbursement may be enacted in the future or what effect such legislation or regulation would have on our business.

Also, we expect managed care plans will continue to put pressure on the pricing of pharmaceutical and biopharmaceutical products. Cost control initiatives could decrease the price that we, or any potential collaborators, receive for any of our future products, which could adversely affect our profitability. These initiatives may also have the effect of reducing the resources that pharmaceutical and biotechnology companies can devote to in-licensing drug candidates and the research and development of new drugs, which could reduce our resulting revenue. Any cost containment measures or other reforms that are adopted could have a negative impact on our ability to commercialize successfully our products or could limit or eliminate our spending on development of new drugs and affect our profitability.

We or Our Collaborators May Not Obtain Favorable Reimbursement Rates for Our Drug Candidates.

The commercial success of our drug candidates will depend on the availability and adequacy of coverage and reimbursement from third-party payors, including government and private insurance plans. Third-party payors are increasingly challenging the prices charged for pharmaceuticals and other medical products. Our products may be considered less cost-effective than existing products, and, as such, coverage and reimbursement to the patient may not be available or be sufficient to allow the sale of our products on a competitive basis.

In addition, the market for our drug candidates will depend significantly on access to third-party payors drug formularies, or lists of medications for which third-party payors provide coverage and reimbursement. Industry competition to be included in such formularies can result in downward pricing pressures on pharmaceutical companies. As such, we cannot provide assurances that our products will be placed on third-party payors

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formularies. To the extent that our products are listed on third-party payors formularies, we or our collaborators may not be able to negotiate favorable reimbursement rates for our products. If we or our collaborators fail to obtain an adequate level of reimbursement for our products by third-party payors, sales of the drugs would be adversely affected or there may be no commercially viable market for the products.

The Drug Research and Development Industry Has a History of Patent and Other Intellectual Property Litigation, and We May Be Involved In Costly Intellectual Property Lawsuits.

The drug research and development industry has a history of patent and other intellectual property litigation, and we believe these lawsuits are likely to continue. Legal proceedings relating to intellectual property would be expensive, take significant time and divert management s attention from other business concerns. Because we produce drug candidates for a broad range of therapeutic areas and provide many different capabilities in this industry, we face potential patent infringement suits by companies that control patents for similar drug candidates or capabilities or other suits alleging infringement of their intellectual property rights. There could be issued patents of which we are not aware that our products infringe or patents that we believe we do not infringe that we are ultimately found to infringe. Moreover, patent applications are in many cases maintained in secrecy for eighteen months after filing or even until patents are issued. The publication of discoveries in the scientific or patent literature frequently occurs substantially later than the date on which the underlying discoveries were made and patent applications were filed. Because patent applications can take many years to issue, there may be currently pending applications of which we are unaware that may later result in issued patents that we infringe with our products. In addition, technology created under our research and development collaborations may infringe the intellectual property rights of third parties, in which case we may not receive milestone or royalty revenue from those collaborations.

If we do not prevail in an infringement lawsuit brought against us, we might have to pay substantial damages, including triple damages, and we could be required to stop the infringing activity or obtain a license to use the patented technology or redesign our products so as not to infringe the patent. We may not be able to enter into licensing arrangements at a reasonable cost or effectively redesign our products. Any inability to secure licenses or alternative technology could delay the introduction of our products or prevent us from manufacturing or selling products.

The Intellectual Property Rights We Rely on to Protect Our Proprietary Drug Candidates and the Technology Underlying Our Tools and Techniques May Be Inadequate to Prevent Third Parties From Using Our Technology or Developing Competing Capabilities or to Protect Our Interests In Our Proprietary Drug Candidates.

Our success depends in part on our ability to protect patents and maintain the secrecy of proprietary processes and other technologies we develop for the testing and synthesis of chemical compounds in the drug discovery process. We currently have 16 issued U.S. patents and numerous patent applications on file with the U.S. Patent and Trademark Office and around the world.

Any patents that we may own or license now or in the future may not afford meaningful protection for our drug candidates or our technology and tools. In order to protect or enforce our intellectual property rights, we may have to initiate legal proceedings against third parties. Our efforts to enforce and maintain our intellectual property rights may not be successful and may result in substantial costs and diversion of management time. In addition, other companies may challenge our patents and, as a result, these patents could be narrowed, invalidated or rendered unenforceable, or we may be forced to stop using the technology covered by these patents or to license the technology from third parties. In addition, current and future patent applications on which we depend may not result in the issuance of patents in the U.S. or foreign countries. Even if our rights are valid, enforceable and broad in scope, competitors may develop drug candidates or other products based on similar research or technology that is not covered by our patents.

Patent applications relating to or affecting our business may have been filed by a number of pharmaceutical and biopharmaceutical companies and academic institutions. A number of the technologies in these applications or patents may conflict with our technologies, patents or patent

applications, which could reduce the scope of patent protection we could otherwise obtain. We could also become involved in interference proceedings in connection with one or more of our patents or patent applications to determine priority of inventions. We cannot be certain that we are the first creator of inventions covered by pending patent applications, or that we were the first to file patent applications for any such inventions.

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Drug candidates we develop that are approved for commercial marketing by the FDA would be eligible for market exclusivity for varying time periods during which generic versions of a drug may not be marketed, and we could apply to extend patent protection for up to five additional years under the provisions of the Drug Price Competition and Patent Term Restoration Act of 1984, known as the Hatch-Waxman Act. The Hatch-Waxman Act provides a means for approving generic versions of a drug once the marketing exclusivity period has ended and all relevant patents have expired. The period of exclusive marketing, however, may be shortened if a patent is successfully challenged and defeated, which could reduce the amount of royalties we receive on the product.

Agreements We Have With Our Employees, Consultants and Collaborators May Not Afford Adequate Protection for Our Trade Secrets, Confidential Information and Other Proprietary Information.

In addition to patent protection, we also rely on copyright and trademark protection, trade secrets, know-how, continuing technological innovation and licensing opportunities. In an effort to maintain the confidentiality and ownership of our trade secrets and proprietary information, we require our employees, consultants and advisors to execute confidentiality and proprietary information agreements. However, these agreements may not provide us with adequate protection against improper use or disclosure of confidential information and there may not be adequate remedies in the event of unauthorized use or disclosure. Furthermore, we may from time to time hire scientific personnel formerly employed by other companies involved in one or more areas similar to the activities we conduct. In some situations, our confidentiality and proprietary information agreements may conflict with, or be subject to, the rights of third parties with whom our employees, consultants or advisors have prior employment or consulting relationships. Although we require our employees and consultants to maintain the confidentiality of all proprietary information of their previous employers, these individuals, or we, may be subject to allegations of trade secret misappropriation or other similar claims as a result of their prior affiliations. Finally, others may independently develop substantially equivalent proprietary information and techniques or otherwise gain access to our trade secrets. Our failure or inability to protect our proprietary information and techniques may inhibit or limit our ability to compete effectively, or exclude certain competitors from the market.

The Drug Research and Development Industry Is Highly Competitive, and We Compete With Some Companies That Offer a Broader Range of Capabilities and Have Better Access to Resources Than We Do.

The pharmaceutical and biotechnology industries are characterized by rapid and continuous technological innovation. We compete with many companies worldwide that are engaged in the research and discovery, licensing, development and commercialization of drug candidates. Some of our competitors have a broader range of capabilities and have greater access to financial, technical, scientific, regulatory, business development, recruiting and other resources than we do. Their access to greater resources may allow them to develop processes or products that are more effective, safer or less costly, or gain greater market acceptance, than products we develop or for which they obtain FDA approval more rapidly than we do. We anticipate that we will face increased competition in the future as new companies enter the market and advanced technologies become available.

We Face Potential Liability Related to the Privacy of Health Information We Obtain From Research Institutions.

Most health care providers, including research institutions from which we or our collaborators obtain patient information, are subject to privacy regulations promulgated under the Health Insurance Portability and Accountability Act of 1996, or HIPAA. Our clinical research efforts are not directly regulated by HIPAA. However, conduct by a person that may not be prosecuted directly under HIPAA s criminal provisions could potentially be prosecuted under aiding and abetting or conspiracy laws. Consequently, depending on the facts and circumstances, we could face substantial criminal penalties if we receive individually identifiable health information from a health care provider or research institution that has not satisfied HIPAA s disclosure standards. In addition, international data protection laws including the European Union Data Protection Directive and member state implementing legislation, may apply to some or all of the clinical data obtained outside of the U.S. Furthermore, certain privacy laws and genetic testing laws may apply directly to our operations and/or those of our collaborators and may impose restrictions on our use and dissemination of individuals health information. Moreover, patients about whom we or our collaborators obtain information, as well as the providers who share this information with us, may have contractual rights that limit our ability to use and disclose the information. Claims that we have violated individuals privacy rights or breached our contractual obligations, even if we are not found liable, could be expensive and time-consuming to defend and could result in adverse publicity that could harm our business.

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Risks Related To Our Stock

Our Officers and Directors Have Significant Control Over Us and Their Interests May Differ From Those of Our Stockholders.

As of June 30, 2008, our directors and officers beneficially owned or controlled approximately 11.4% of our common stock. Individually and in the aggregate, these stockholders significantly influence our management, affairs and all matters requiring stockholder approval. These stockholders may vote their shares in a way with which other stockholders do not agree. In particular, this concentration of ownership may have the effect of delaying, deferring or preventing an acquisition of us or entrenching management and may adversely affect the market price of our common stock.

Our Quarterly Operating Results Could Fluctuate Significantly, Which Could Cause Our Stock Price to Decline.

Our quarterly operating results have fluctuated in the past and are likely to fluctuate in the future. Entering into licensing or drug discovery collaborations typically involves significant technical evaluation and/or commitment of capital by our collaborators. Accordingly, negotiation can be lengthy and is subject to a number of significant risks, including collaborators budgetary constraints and internal acceptance reviews. In addition, a significant portion of our revenue is attributable to up-front payments and milestones that are non-recurring. Further, some of our collaborators can influence when we deliver products and perform services, and therefore receive revenue, under their contracts with us. Due to these factors, our operating results could fluctuate significantly from quarter to quarter. In addition, we may experience significant fluctuations in quarterly operating results due to factors such as general and industry-specific economic conditions that may affect the research and development expenditures of pharmaceutical and biotechnology companies.

Due to the possibility of fluctuations in our revenue and expenses, we believe that quarter-to-quarter comparisons of our operating results are not a good indication of our future performance. Our operating results in some quarters may not meet the expectations of stock market analysts and investors. If we do not meet analysts and/or investors expectations, our stock price could decline.

Because Our Stock Price May Be Volatile, Our Stock Price Could Experience Substantial Declines.

The market price of our common stock has historically experienced and may continue to experience volatility. The high and low closing bids for our common stock were \$4.66 and \$12.91, respectively, in fiscal 2008; \$14.40 and \$7.55, respectively, in fiscal 2007; and \$9.67 and \$5.99, respectively, in fiscal 2006. Our quarterly operating results, the success or failure of our internal drug discovery efforts, changes in general conditions in the economy or the financial markets and other developments affecting our collaborators, our competitors or us could cause the market price of our common stock to fluctuate substantially. This volatility coupled with market declines in our industry over the past several years have affected the market prices of securities issued by many companies, often for reasons unrelated to their operating performance, and may adversely affect the price of our common stock. In the past, securities class action litigation has often been instituted following periods of volatility in the market price of a company s securities. A securities class action suit against us could result in potential liabilities, substantial costs and the diversion of management s attention and resources, regardless of whether we win or lose.

Because We Do Not Intend to Pay Dividends, Stockholders Will Benefit From An Investment In Our Common Stock Only If It Appreciates In Value

We have never declared or paid any cash dividends on our common stock and are restricted in our ability to do so under our current credit agreement. We currently intend to retain our future earnings, if any, to finance the expansion of our business and do not expect to pay any cash dividends in the foreseeable future. As a result, the success of an investment in our common stock will depend entirely upon any future

appreciation. There is no guarantee that our common stock will appreciate in value or even maintain the price at which stockholders have purchased their shares.

The Ability of Our Stockholders to Control Our Policies and Effect a Change of Control of Our Company Is Limited, Which May Not Be In the Best Interests of Our Stockholders.

There are provisions in our certificate of incorporation and bylaws that may discourage a third party from making a proposal to acquire us, even if some of our stockholders might consider the proposal to be in their best interests. These include the following provisions in our certificate of incorporation:

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- Our certificate of incorporation provides for three classes of directors with the term of office of one class expiring each year, commonly referred to as a staggered board. By preventing stockholders from voting on the election of more than one class of directors at any annual meeting of stockholders, this provision may have the effect of keeping the current members of our Board of Directors in control for a longer period of time than stockholders may desire; and
- Our certificate of incorporation authorizes our Board of Directors to issue shares of preferred stock without stockholder approval and to establish the preferences and rights of any preferred stock issued, which would allow the board to issue one or more classes or series of preferred stock that could discourage or delay a tender offer or change in control.

In addition, our Board of Directors approved a Rights Agreement on August 2, 2001, which could prevent or deter a potential unsolicited takeover of us by causing substantial dilution of an acquirer of 15% or more of our outstanding common stock. We are also subject to the business combination provisions of Section 203 of the Delaware General Corporation Law, which, in general, imposes restrictions upon acquirers of 15% or more of our stock. As a result, it is difficult for a third party to acquire control of us without the approval of the Board of Directors and, therefore, mergers and acquisitions of us that our stockholders may consider in their best interests may not occur.

ITEM 1B. UNRESOLVED STAFF COMMENTS

None.

ITEM 2. PROPERTIES

We are headquartered in Boulder, Colorado, where we lease 150 thousand square feet of office and laboratory space under a lease that expires in July 2016. We lease 78 thousand square feet of laboratory space in Longmont, Colorado under a lease that expires in August 2016. We lease 20 thousand square feet of office space in Morrisville, North Carolina under a lease that expires in November 2013. We have options to extend each of the leases for up to two terms of five years each. In addition, we lease five thousand square feet of storage space in Boulder, Colorado under a lease that expires in March 2010.

ITEM 3. LEGAL PROCEEDINGS

We may be involved, from time to time, in various claims and legal proceedings arising in the ordinary course of our business. We are not currently a party to any such claims or proceedings that, if decided adversely to us, would either individually or in the aggregate have a material adverse effect on our business, financial condition or results of operations.

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

No matters were submitted to a vote of our security holders, through solicitation of proxies or otherwise, during the fourth quarter ended June 30, 2008.

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PART II

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

Common Stock Sales Prices

The following table sets forth, for the periods indicated, the range of the closing high and low sales prices for our common stock as reported by the NASDAQ Global Market.

Fiscal Year Ended June 30, 2008	High	Low
First Quarter	\$ 12.91	\$ 9.72
Second Quarter	\$ 12.25	\$ 7.96
Third Quarter	\$ 8.57	\$ 5.30
Fourth Quarter	\$ 7.16	\$ 4.66
Fiscal Year Ended June 30, 2007	High	Low
First Quarter	\$ 8.72	\$ 7.55
Second Quarter	\$ 13.57	\$ 8.30
Third Quarter	\$ 13.92	\$ 11.42
Time Quarter	Ψ 15.72	Ψ=

As of August 7, 2008, there were approximately 73 holders of record of our common stock. This does not include the number of persons whose stock is in nominee or street name accounts through brokers.

Dividends

We have never declared or paid any cash dividends on our common stock and we do not intend to pay any cash dividends in the foreseeable future. In addition, the terms of our loan agreements restrict our ability to pay cash dividends to our stockholders. We currently intend to retain all available funds and any future earnings for use in the operations of our business and to fund future growth.

Stock Performance Graph

This stock performance graph shall not be deemed filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended or the Exchange Act, or otherwise subject to the liabilities under that Section and shall not be deemed to be incorporated by reference into any filing of ours under the Securities Act of 1933, as amended, or the Exchange Act.

The following graph compares the cumulative total stockholder return for our common stock, the NASDAQ Global Markets Composite (U.S. companies) Index, the NASDAQ Pharmaceutical Index and the NASDAQ Biotechnology Index for the five year period ended June 30, 2008. The graph assumes that \$100 was invested on June 30, 2003 in the common stock of Array, the NASDAQ Composite Index, the NASDAQ Pharmaceutical Index and the NASDAQ Biotechnology Index. It also assumes that all dividends were reinvested.

The stock price performance on the following graph is not necessarily indicative of future stock price performance.

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COMPARISON OF FIVE YEAR CUMULATIVE TOTAL RETURNS

Among Array BioPharma Inc., the NASDAQ Composite Index,

the NASDAQ Pharmaceutical Index and the NASDAQ Biotechnology Index

	Array Bio		NASE Composit	•	NASD Pharmac Inde	eutical	NASI Biotech Ind	nology
6/30/2003	\$	100.00	\$	100.00	\$	100.00	\$	100.00
9/30/2003	\$	176.04	\$	109.81	\$	104.76	\$	104.99
12/31/2003	\$	181.79	\$	122.79	\$	105.12	\$	106.31
3/31/2004	\$	287.54	\$	124.75	\$	110.19	\$	113.28
6/30/2004	\$	253.99	\$	129.09	\$	109.95	\$	113.33
9/30/2004	\$	223.32	\$	121.22	\$	108.95	\$	108.94
12/31/2004	\$	304.15	\$	138.87	\$	117.86	\$	119.50
3/31/2005	\$	223.96	\$	126.45	\$	103.86	\$	105.48
6/30/2005	\$	201.28	\$	127.97	\$	102.44	\$	111.71
9/30/2005	\$	229.39	\$	134.33	\$	120.35	\$	132.42
12/31/2005	\$	223.96	\$	136.72	\$	118.83	\$	137.08
3/31/2006	\$	292.01	\$	148.01	\$	124.38	\$	142.20
6/30/2006	\$	274.76	\$	136.00	\$	113.55	\$	127.27
9/30/2006	\$	272.20	\$	142.29	\$	116.70	\$	132.72
12/31/2006	\$	412.78	\$	153.83	\$	120.86	\$	135.88
3/31/2007	\$	405.75	\$	153.87	\$	114.39	\$	131.94

6/30/2007	\$ 372.84	\$ 164.15	\$ 116.30	\$ 136.97
9/30/2007	\$ 358.79	\$ 171.17	\$ 122.68	\$ 145.26
12/31/2007	\$ 269.01	\$ 162.09	\$ 112.12	\$ 136.85
3/31/2008	\$ 223.96	\$ 141.25	\$ 107.98	\$ 132.05
6/30/2008	\$ 150.16	\$ 142.67	\$ 111.49	\$ 133.91

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ITEM 6. SELECTED FINANCIAL DATA

The following selected financial data is derived from our audited financial statements. These historical results do not necessarily indicate future results. When you read this data, it is important that you also read our financial statements and related notes, as well as the section entitled Management s Discussion and Analysis of Financial Condition and Results of Operations appearing elsewhere in this Annual Report on Form 10-K. Amounts are in thousands except per share data:

	Years Ended June 30,					
	2008	2007	2006	2005	2004	
Revenue						
Collaboration revenue	\$ 21,513	\$ 30,106	\$ 37,738	\$ 34,343	\$ 28,186	
License and milestone revenue	7,295	6,864	7,265	11,162	6,645	
Total revenue	28,808	36,970	45,003	45,505	34,831	
Operating expenses						
Cost of revenue	21,364	24,936	39,611	38,048	37,257	
Research and development for proprietary	,	,	,-	,-	,	
drug discovery	90,347	57,464	33,382	22,871	15,905	
General and administrative	15,591	13,644	13,683	9,372	8,016	
Total operating expenses	127,302	96,044	86,676	70,291	61,178	
Loss from operations	(98,494)	(59,074)	(41,673)	(24,786)	(26,347)	
Loss irom operations	(20,727)	(37,074)	(41,073)	(24,760)	(20,547)	
Other income (expense)						
Impairment of marketable securities	(1,872)	_	_	_	_	
Interest income	6,064	4,610	2,729	1,542	381	
Interest expense	(1,986)	(979)	(670)	-	-	
Total other income (expense)	2,206	3,631	2,059	1,542	381	
Net loss	\$ (96,288)	\$ (55,443)	\$ (39,614)	\$ (23,244)	\$ (25,966)	
Weighted average shares outstanding -						
basic and diluted	47,309	40,717	38,759	34,043	28,511	
Net loss per share - basic and diluted	\$ (2.04)	\$ (1.36)	\$ (1.02)	\$ (0.68)	\$ (0.91)	
			June 30,			
	2008	2007	2006	2005	2004	
Cash and cash equivalents, marketable						
securities and restricted cash	\$ 125,531	\$ 141,331	\$ 70,100	\$ 92,726	\$ 37,446	
Working capital	\$ 66,346	\$ 120,827	\$ 56,056	\$ 80,522	\$ 24,652	
Total assets	\$ 163,077	\$ 174,974	\$ 102,173	\$ 127,952	\$ 77,764	
Long-term debt, net of discount	\$ 35,355	\$ 15,000	\$ 14,150	\$ 10,000	\$ -	
Total stockholders equity	\$ 38,027	\$ 107,701	\$ 68,639	\$ 99,414	\$ 54,493	

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

The Management s Discussion and Analysis of Financial Condition and Results of Operations contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, including statements about our expectations related to the progress and success of our internal proprietary drug discovery activities, realizing new revenue streams and obtaining future out-licensing collaboration agreements that include up-front milestone and/or royalty payments, our ability to realize such up-front milestone and royalty payments under our existing or any future agreements, future research and development spending, our working capital

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requirements and our future headcount requirements. In some cases, forward-looking statements can be identified by the use of terminology such as may, will, expects, intends, plans, anticipates, estimates, potential, or continue, or the negative thereof or other comparable te These statements are based on current expectations and projections about our industry and assumptions made by management and are not guarantees of future performance. Although we believe that the expectations reflected in the forward-looking statements contained herein are reasonable, these expectations or any of the forward-looking statements could prove to be incorrect, and actual results could differ materially from those projected or assumed in the forward-looking statements. Our future financial condition, as well as any forward-looking statements are subject to significant risks and uncertainties, including but not limited to the factors set forth under the heading. Risk Factors in Item 1A of this Annual Report on Form 10-K. All forward looking statements and reasons why results may differ included in this Annual Report on Form 10-K are made as of the date hereof, and, unless required by law, we undertake no obligation to update any forward-looking statements or reasons why actual results may differ in this Annual Report on Form 10-K.

The following discussion of our financial condition and results of operations should be read in conjunction with the financial statements and notes to those statements included elsewhere in this report.

Overview

We are a biopharmaceutical company focused on the discovery, development and commercialization of targeted small molecule drugs aimed at large market opportunities. Our proprietary drug development pipeline includes clinical candidates that are designed to treat patients afflicted with cancer, inflammatory diseases and pain. In addition, leading pharmaceutical and biotechnology companies collaborate with us to discover and develop drug candidates across a broad range of therapeutic areas. Our six most advanced, wholly-owned programs in our development pipeline are as follows:

- ARRY-797, a p38 inhibitor and pan-cytokine modulator for inflammation and for pain;
- ARRY-162, a MEK inhibitor for inflammation;
- ARRY-614, a p38/Tie 2 dual inhibitor for cancer and/or inflammation;
- ARRY-543, an ErbB family (EFGR / ErbB-2) inhibitor for cancer;
- ARRY-520, a KSP inhibitor for cancer; and
- ARRY-380, an ErbB-2 inhibitor for cancer.

We also have a portfolio of discovery programs that we believe will generate one to three IND applications each year. Our discovery efforts have also generated additional early-stage drug candidates that we may choose to out-license through research partnerships prior to filing an IND application.

We have built our proprietary pipeline of research and development programs on an investment of approximately \$240 million from our inception through June 30, 2008. Over the past three years, research and development expenses have significantly increased year over year to support our clinical development efforts and were \$90.3 million for fiscal 2008, compared to \$57.5 million for fiscal 2007 and \$33.4 million for fiscal 2006.

Additionally, we have received a total of \$322 million in research funding and in up-front and milestone payments from our collaboration partners through June 30, 2008. Under our existing collaboration agreements, we have the potential to earn \$1.4 billion additional milestone payments if we achieve all the drug discovery objectives detailed in these agreements, as well as the potential to earn royalties on any resulting product sales from 18 drug development programs.

Our largest existing collaborators include:

- AstraZeneca, which licensed three of our MEK inhibitors for cancer, including AZD6244 (ARRY-886), which is currently in multiple Phase 2 clinical trials;
- Genentech, which entered into a worldwide strategic collaboration agreement with us to develop two of our cancer programs which has been expanded to include two additional cancer programs all four of which are in preclinical development; and
- Celgene, which entered into a worldwide strategic collaboration agreement with us focused on the discovery, development and commercialization of novel therapeutics in cancer and inflammation.

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We have incurred net losses since inception and expect to incur losses in the near future as we continue to invest in our proprietary drug discovery programs. As of June 30, 2008, we had an accumulated deficit of \$285.4 million.

Our fiscal year ends on June 30 each year. When we refer to a fiscal year, we are referring to the year in which the fiscal year ends. Therefore, fiscal 2008 refers to the fiscal year ended June 30, 2008.

Business Development and Collaborator Concentrations

We currently license or partner certain of our compounds and/or programs and enter into collaborations directly with pharmaceutical and biotechnology companies through opportunities identified by our business development group, senior management, scientists and customer referrals. In addition, we license our compounds and enter into collaborations in Japan through an agent.

The collaborators that contributed in excess of 10% of our revenue in each of the last three fiscal years is as follows:

		Years Ended June 30,					
	2008	2007	2006				
Genentech	54.1%	41.8%	34.8%				
Celgene	14.9%	0.0%	0.0%				
Ono	14.2%	13.0%	6.9%				
VentiRx	13.7%	4.0%	0.0%				
InterMune	1.0%	21.0%	24.0%				
AstraZeneca	0.0%	13.5%	15.8%				
	97.9%	93.3%	81.5%				

In general, certain of our collaborators may terminate their collaboration agreements with 90 to 120 days prior notice. Our agreement with Genentech can be terminated with 120 days notice. Celgene may terminate its agreement with us with six months notice. Our agreement with Ono ended in April 2008.

The following table details the countries from which we derive in excess of 10% of our revenue in each of the last three fiscal years based on the country in which collaborators are located or the ship-to destination for compounds:

	Years Ended June 30,				
	2008	2007	2006		
U.S.	84.7%	69.5%	68.8%		
Japan	14.3%	16.0%	14.0%		
Sweden	0.0%	13.6%	16.0%		

99.0% 99.1% 98.8%

All of our collaboration agreements are denominated in U.S. dollars.

Critical Accounting Policies and Estimates

Management s discussion and analysis of its financial condition and results of operations are based upon our accompanying Financial Statements which have been prepared in accordance with accounting principles generally accepted in the U.S. The preparation of these financial statements requires us to make estimates and assumptions that affect the reported amounts of assets, liabilities, revenue and expenses as well as the disclosure of contingent assets and liabilities. We regularly review our estimates and assumptions. These estimates and assumptions, which are based upon historical

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experience and on various other factors believed to be reasonable under the circumstances, form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Reported amounts and disclosures may have been different had management used different estimates and assumptions or if different conditions had occurred in the periods presented.

Below is a discussion of the policies and estimates that we believe involve a high degree of judgment and complexity.

Revenue Recognition

Most of our revenue is derived from designing, creating, optimizing, evaluating and developing drug candidates for our collaborators. Our agreements with our collaboration partners include fees based on contracted annual rates for full time equivalent employees working on a project, and may also include non-refundable license and up-front fees, non-refundable milestone payments that are triggered upon achievement of specific research or development goals, and future royalties on sales of products that result from the collaboration. A small portion of our revenue comes from fixed fee agreements or from sales of compounds on a per-compound basis. We report revenue for lead generation and lead optimization research, custom synthesis and process research, the development and sale of chemical compounds and the co-development of proprietary drug candidates we out-license, as collaboration revenue. License and milestone revenue is combined and reported separately from collaboration revenue.

Arrangements that include multiple elements are evaluated under Emerging Issues Task Force (EITF) Issue No. 00-21 *Revenue Arrangements with Multiple Deliverables* (EITF 00-21), to determine whether the element has value to the customer on a stand-alone basis and whether reliable evidence of fair value for the delivered elements exists. Deliverables in an arrangement that do not meet the separation criteria of EITF 00-21 are treated as a single unit of accounting, generally applying applicable revenue recognition guidance for the final deliverable to the combined unit of accounting as defined in Staff Accounting Bulletin No. 104 *Revenue Recognition* (SAB 104). SAB 104 in turn established four criteria, each of which must be met, in order to recognize revenue related to the performance of services or the shipment of products. Revenue is recognized when (a) persuasive evidence of an arrangement exists, (b) products are delivered or services are rendered, (c) the sales price is fixed or determinable and (d) collectability is reasonably assured.

We recognize revenue from non-refundable up-front payments and license fees on a straight-line basis over the term of performance under the agreement, which is generally the research term specified in the agreement. These advance payments are deferred and recorded as advance payments from collaborators upon receipt, pending recognition, and are classified as a short-term or long-term liability on our balance sheet. When the performance period is not specifically identifiable from the agreement, we estimate the performance period based upon provisions contained within the agreement, such as the duration of the research term, the specific number of full time equivalent scientists working a defined number of hours per year at a stated price under the agreement, the existence or likelihood of development commitments, and other significant commitments of ours.

Similarly to advance payments, for agreements that provide for milestone payments, a portion of each milestone payment is recognized as revenue when the specific milestone is achieved based on the applicable percentage of the estimated research term that has elapsed to the total estimated research term. Revenue recognition related to non-refundable license fees and up-front payments and to milestone payments could be accelerated in the event of early termination of programs.

Revenue from sales of compounds in our Lead Generation Library and Optimer building blocks is generally recognized as the compounds are shipped. We recognize revenue based on contracted annual rates for full time equivalent employees working on a project on a monthly basis as work is performed.

We determined that the performance period applicable to our agreement with Celgene Corporation is seven years ending September 2014; and we determined the performance period for our agreement with VentiRx to be one year. Each of these periods coincides with the research terms specified in each agreement. We periodically review the expected performance periods under each of our agreements that provide for non-refundable up-front payments and license fees. To date, there has not been a significant change in an estimate or assumption of the expected period of performance that has had a material effect on the timing or amount of revenue recognized.

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In February 2007, we entered into a collaboration and licensing agreement with VentiRx in which we received a non-refundable cash technology access fee and shares of preferred stock valued at \$1.5 million based on the price at which such preferred stock was sold to investors in a private offering. Both the technology access fee and the value of the preferred stock were recorded as advance payments from collaborators and deferred revenue, and were recognized as revenue on a straight-line basis over the estimated one-year research term. The preferred stock has been recorded in Other Long-term Assets in the accompanying Balance Sheets.

Cost of Revenue and Research and Development for Proprietary Drug Discovery

Cost of revenue represents research and development conducted for our collaborators and the cost of chemical compounds sold. These costs consist mainly of compensation, associated fringe benefits, share-based compensation and other collaboration-related costs, including supplies, small tools, facilities, depreciation, recruiting and relocation and other direct and indirect chemical handling and laboratory support costs. We allocate these costs between Cost of Revenue and Research and Development for Proprietary Drug Discovery based upon the respective time spent on each by our scientists on development conducted for our collaborators and for our internal proprietary programs, respectively.

Where our collaboration agreements provide for us to conduct development of drug candidates, and for which our partner has an option to obtain the right to conduct further development and to commercialize a product, we attribute a portion of our research and development costs to Cost of Revenue based on the percentage of total compounds under the agreement that may be selected by the partner. For example, we granted to Celgene an option to select up to two of four drugs developed under the collaboration. Accordingly, we report costs associated with the Celgene collaboration as follows: 50% to cost of revenue, with the remaining 50% to research and development for proprietary drug discovery. See the further discussion on this transaction in Note 6 to the accompanying Financial Statements.

Investments in Marketable Securities

Our investments in marketable securities include domestic public corporate debt securities, commercial paper issued by domestic public companies, obligations of U.S. federal government agencies and auction rate securities, or ARS. Marketable securities are classified as short-term or long-term based on the nature of these securities and the availability of these securities to meet current operating requirements. The specific identification method is used to determine the cost of securities disposed of, with realized gains and losses reflected in Interest Income or Interest Expense, as appropriate in the accompanying Financial Statements. Temporary impairments are recognized in Accumulated Other Comprehensive Loss in the accompanying Balance Sheets and other-than-temporary impairments are recognized in Impairments of Marketable Securities in the accompanying Statements of Operations and Comprehensive Loss. All of our investments in marketable securities are held in our name at a limited number of financial institutions.

Included within long-term marketable securities are our investments in ARS. During the fiscal year ended June 30, 2008 and subsequent thereto, auctions for all of our ARS, amounting to seven securities with a par value of \$32.9 million, were unsuccessful. We recorded an other-than-temporary impairment of \$1.9 million on two of our ARS, primarily as a result of the continuous decline and magnitude of the fair value discount from par value, which is due in part to the relative weakness in the performance of the underlying trust assets. Accordingly, the other-than-temporary impairment is recorded in Impairment of Marketable Securities in the accompanying Statements of Operations and Comprehensive Loss.

We believe that impairment in the other five ARS in the portfolio, amounting to \$1.9 million, is temporary, primarily because of stronger performance of the underlying trust assets, the relatively smaller discount of fair value from par value, and because these securities have not incurred significant continuous declines in fair value during recent periods. Accordingly, the temporary impairment is recorded in Accumulated Other Comprehensive Loss in the accompanying Balance Sheets as of June 30, 2008.

While we now earn a higher contractual interest rate on these ARS investments, the investments are not currently liquid. In the event we need to access these funds, we will not be able to do so until auctions of these investments are successful, the original issuers retire these securities or a secondary market develops for these securities. Therefore, they are classified as Marketable Securities Long Term in the accompanying Balance Sheets as of June 30, 2008.

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Preclinical Study and Clinical Trial Outsourcing Accruals

Substantial portions of our preclinical studies and all of our clinical trials have been performed by third-party medical centers or contract research organizations, which we refer to collectively as CROs. Some CROs bill monthly for services performed, while others bill based upon milestone achievement. We accrue expenses each month for agreements involving significant costs and that bill based on milestone achievement. For preclinical studies, accruals are based upon the estimated percentage of work completed and the contract milestones remaining. For costs for clinical study activities performed by CROs, accruals are estimated based upon the estimated work completed on each study and, for clinical trial expenses, accruals are based upon the number of patients enrolled and the expected duration of the study for which they will be enrolled. We monitor patient enrollment and related activities to the extent possible through internal reviews, correspondence with the CROs, clinical site visits, and review of contractual terms. Our estimates are highly dependant upon the timeliness and accuracy of the data provided by our CROs regarding the status of each program and total program spending. We periodically evaluate our estimates to determine if adjustments are necessary or appropriate based on information we receive concerning changing circumstances, conditions or events that may affect such estimates. No material adjustments to preclinical study and clinical trial expenses have been recognized to date.

Income Taxes

We estimate our actual current tax expense together with our temporary differences resulting from differing treatment of items for tax and accounting purposes. These temporary differences result in deferred tax assets and/or liabilities. We must then assess the likelihood that our deferred tax assets will be recovered from future taxable income and to the extent that we believe that it is more likely than not we will not recover these deferred assets, we must establish a valuation allowance against these tax assets. Significant management judgment is required in determining our provision for income taxes, our deferred tax assets and liabilities and any valuation allowance against our deferred tax assets. To the extent that we believe a valuation allowance is required, we must include and expense the tax effect of the allowance within the tax provision in our statement of operations.

Results of Operations

Revenue

Collaboration revenue consists of revenue for lead generation and lead optimization research, custom synthesis and process research, the development and sale of chemical compounds and the co-development of proprietary drug candidates we out-license. License and milestone revenue is combined and reported separately from Collaboration Revenue.

A summary of our revenue follows (amounts in thousands):

	Year	s Ended June 3	0,	Change 2008	vs. 2007	Change 2007 vs. 2006		
	2008	2007	2006	\$	%	\$	%	
Collaboration revenue	\$21,513	\$30,106	\$37,738	\$ (8,593)	(28.5%)	\$ (7,632)	(20.2%)	
License and milestone								
revenue	7,295	6,864	7,265	431	6.3%	(401)	(5.5%)	
Total revenue	\$28,808	\$36,970	\$45,003	\$ (8,162)	(22.1%)	\$ (8,033)	(17.8%)	

Fiscal 2008 as compared to Fiscal 2007 Collaboration revenue decreased by \$8.6 million due to the expiration of collaborations with InterMune and Takeda in June and March of 2007, respectively, as well as the expiration of our collaboration with Ono during the fourth quarter of fiscal 2008. Additionally, collaboration revenue from the sale of Optimer building blocks decreased by approximately \$300 thousand compared to fiscal 2007. Partially offsetting these decreases was increased revenue of approximately \$960 thousand from our collaborations with VentiRx and Genentech. Collaboration revenue is expected to further decline in fiscal 2009 as we continue to focus on our own discovery and development programs.

License and milestone revenue increased by approximately \$431 thousand due to increased revenue of \$5.4 million from our collaborations with Celgene and VentiRx. Largely offsetting this increase was the full recognition of two milestone payments totaling \$5.0 million from AstraZeneca during fiscal 2007 as discussed below.

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Fiscal 2007 as compared to Fiscal 2006 - Collaboration revenue declined by \$10.2 million due to the expiration of collaborations with AstraZeneca, Roche and Eli Lilly during fiscal 2006 as well as the research portions of collaborations with InterMune and Takeda that expired in fiscal 2007. Additionally, collaboration revenue from the sale of Optimer building blocks and Lead Generation Libraries decreased by \$1.0 million during these same periods. Partially offsetting these decreases was increased revenue of \$3.6 million from our collaborations with Genentech and Ono, as well as the initiation of a new research agreement with VentiRx.

License and milestone revenue declined by \$6.7 million during fiscal 2007 because previously received license and milestone payments from AstraZeneca and Genentech had been fully recognized as revenue as of June 30, 2006. This decrease was partially offset by the recognition of two milestone payments totaling \$5.0 million from AstraZeneca during fiscal 2007 for the advancement of AZD6244 into Phase 2 clinical trials and ARRY-704 into Phase 1 clinical trials. Additional license and milestone revenue of \$1.3 million was recognized in fiscal 2007 from VentiRx, InterMune and Eli Lilly.

Cost of Revenue

Cost of revenue represents research and development conducted for our collaborators and the cost of chemical compounds sold from our inventory. These costs consist mainly of compensation, associated fringe benefits and other collaboration-related costs, including supplies, small tools, facilities, depreciation, recruiting and relocation and other direct and indirect chemical handling and laboratory support costs. Fine chemicals consumed as well as any required inventory reserve adjustments are also recorded as cost of revenue.

A summary of our cost of revenue follows (amounts in thousands):

	Year	rs Ended June 30),	Change 2008	vs. 2007	Change 2007 vs. 2006		
	2008	2007	2006	\$	%	\$	%	
Cost of revenue as a	\$ 21,364	\$ 24,936	\$ 39,611	\$ (3,572)	(14.3%)	\$ (14,675)	(37.0%)	
percentage of total revenue	74.2%	67.4%	88.0%					

Fiscal 2008 as compared to Fiscal 2007 Cost of revenue for fiscal 2008 decreased 14.3% from fiscal 2007 as a result of a reduction in the number of scientists working on external collaborations that expired in the prior fiscal year. These scientific resources were shifted to our proprietary drug research and the Celgene collaboration upon expiration of these external collaborations. Half of the research-related costs of the Celgene program is charged to Cost of Revenue, as discussed further in Note 6 to the accompanying Financial Statements. We expect an additional decline in future periods as a result of the expiration of our collaboration with Ono during the fourth quarter of fiscal 2008.

During July and August 2006, we terminated our prior facilities leases and executed new lease agreements with a new landlord. As a result of this transaction, we reversed a \$1.6 million deferred rent liability balance and reduced our rent expense by the same amount. Because we allocate rent expense, the reduction in rent expense resulted in a decrease to cost of revenue of approximately \$600 thousand for fiscal 2008.

Fiscal 2007 as compared to Fiscal 2006 - Cost of revenue for fiscal 2007 decreased by 37.0% from fiscal 2006, primarily reflecting a decrease in collaboration related services as a greater percentage of our resources were focused on advancing our proprietary drug discovery programs. Cost of revenue as a percentage of total revenue decreased to 67.4% for the 2007 fiscal year compared with 88.0% for the prior fiscal year. These decreases were largely the result of increased average pricing received from collaborations for full-time equivalent scientists during fiscal 2007 resulting in fewer scientific resources used in generating the same approximate level of collaboration revenue. Additionally, share-based compensation expense charged to cost of revenue for 2007 fiscal year decreased by approximately \$960 thousand due to options that became fully vested in the prior fiscal year.

On June 22, 2006, we assigned options we owned to purchase our Boulder and Longmont, Colorado facilities to BioMed Realty L.P., which purchased those facilities in July and August 2006. We entered into new lease

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agreements for these facilities with BioMed over a ten-year lease term and began amortizing our leasehold improvement costs for these facilities over a ten-year life. Prior to completing these transactions, we had determined that we were reasonably assured during fiscal 2006 that we would be vacating our Boulder facility at the end of the initial lease term in March 2008 and therefore amortized the cost of leasehold improvements for that facility over an approximate two-year life. We determined the lease terms under our new facilities leases to be the fixed, non-cancelable ten-year term because we concluded that the exercise of optional extension periods available under the leases was not reasonably assured.

This conclusion was based on our experience with prior lease facilities and management s determination that it was unable to predict in the early years of a long-term lease whether it would remain in the facilities beyond the initial lease term as a result of changing business, economic or other conditions. The change in the amortization period from two to 10 years resulted in a decrease of approximately \$775 thousand in amortized leasehold improvement costs charged to cost of revenue for fiscal 2007 as compared to the prior fiscal year.

Research and Development Expenses for Proprietary Drug Discovery

Our research and development expenses for proprietary drug discovery include costs associated with our proprietary drug programs for scientific personnel, supplies, equipment, consultants, sponsored research, allocated facility costs, costs related to preclinical and clinical trials, and share-based compensation. We manage our proprietary programs based on scientific data and achievement of research plan goals. Our scientists record their time to specific projects when possible.

However, many activities simultaneously benefit multiple projects and cannot be readily attributed to a specific project. Accordingly, the accurate assignment of time and costs to a specific project is difficult and may not give a true indication of the actual costs of a particular project. As a result, we do not report costs on a program basis. The following table shows our research and development expenses by categories of costs for the periods presented (amounts in thousands):

	Years Ended June 30,				Change 2008 vs. 2007			Change 2007 vs. 2006		
	2	008	2007	2006		\$	%	\$	%	
Salaries, benefits and share-based										
compensation	\$	33,304	\$21,805	\$ 12,394	\$	11,499	52.7%	\$ 9,411	75.9%	
Outsourced services and										
consulting		34,570	19,953	7,921		14,617	73.3%	12,032	151.9%	
Laboratory supplies		10,521	6,878	5,538		3,643	53.0%	1,340	24.2%	
Facilities and depreciation		10,148	7,910	7,063		2,238	28.3%	847	12.0%	
Other		1,804	918	466		886	96.5%	452	97.0%	
Total research and development for proprietary drug discovery	\$	90,347	\$57,464	\$ 33,382	\$	32,883	57.2%	\$ 24,082	72.1%	

Fiscal 2008 as compared to Fiscal 2007 Research and development expenses increased 57.2% over the prior fiscal year as a result of the deployment of existing scientific personnel previously engaged in our external collaborations to advance our proprietary research. In addition, we expanded our clinical development group and moved into more advanced clinical trials and increased the amount of outsourced pharmacology to advance our proprietary development compounds. The most significant increases resulted in the advancement of the following programs:

- 1. ARRY-797, a p38 inhibitor and pan-cytokine modulator for inflammation and for pain;
- 2. ARRY-162, a MEK inhibitor for inflammation;
- 3. ARRY-614, a p38/Tie 2 dual inhibitor for cancer and/or inflammation;
- 4. ARRY-543, an ErbB family (EFGR / ErbB-2) inhibitor for cancer;
- 5. ARRY-520, a KSP inhibitor for cancer; and
- 6. ARRY-380, an ErbB-2 inhibitor for cancer.

During fiscal 2008, we expensed \$3.3 million of share-based compensation expense as compared to \$1.7 million for fiscal 2007. We expect that research and development for proprietary drug discovery spending will continue to

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increase in fiscal 2009 as we focus more resources on our proprietary drug discovery and development programs and advancing our programs through clinical development.

Fiscal 2007 as compared to Fiscal 2006 - Research and development for proprietary drug discovery expenses increased 72.1% over the prior fiscal year as a result of increases in the number of scientists devoted to proprietary programs, reflecting both increased headcount as well as a shift of existing scientific resources from collaborative projects to internal proprietary discovery. The most significant increase in costs came from outsourced pharmacology studies and clinical trial related expenses supporting the advancement of our ErbB-2/EGFR, MEK for inflammation, ErbB-2, P38/Tie2 and other programs. During fiscal 2007 we expensed \$1.7 million of share-based compensation expense to research and development for proprietary drug discovery expenses compared to \$1.3 million for the prior fiscal year.

These increases were partially offset by reductions in leasehold improvement amortization and rent expense allocated to research and development for proprietary drug discovery expenses as described in Cost of Revenue above. The change in estimated useful life of our leasehold improvements resulted in a reduction of amortization of leasehold improvement costs charged to research and development for proprietary drug discovery expenses for the 2007 fiscal year of approximately \$900 thousand. Additionally, the reversal of the prior year deferred rent balance resulted in a reduction to rent expense allocated to research and development for proprietary drug discovery expenses for the 2007 fiscal year of approximately \$850 thousand.

As discussed in the section above entitled Business Proprietary Development Programs, we have multiple programs in different phases of preclinical and clinical development. We anticipate that we will make determinations as to which research programs to pursue and how much funding to direct to each program on an ongoing basis in response to the scientific and clinical success of each drug candidate. The lengthy process of developing and testing a drug candidate, seeking regulatory approvals, and subsequent compliance with applicable regulations, require the expenditure of substantial resources that generally increase as the candidate moves through the development process.

Although we expect our research and development costs to increase as we progress our programs through later-stage development, the scope and magnitude of future research and development expenses are difficult to predict given the number of studies that will need to be conducted for any of our potential products, as well as our limited capital resources. The successful development and commercialization of drugs resulting from our proprietary programs is highly uncertain and subject to a number of risks that are beyond our control. The duration and cost of discovery, preclinical, non-clinical and clinical trials may vary significantly based on the type, complexity and novelty of a product and are difficult to predict. The FDA and comparable agencies in foreign countries impose substantial requirements on the introduction of therapeutic pharmaceutical products, typically requiring lengthy and detailed laboratory and clinical testing procedures, sampling activities and other costly and time-consuming procedures. Data obtained from preclinical, non-clinical and clinical activities at any step in the testing process may be adverse and lead to discontinuation or redirection of development activity or be susceptible to varying interpretations, which could delay, limit or prevent regulatory approval. Consequently, accurate and meaningful estimates of the ultimate costs to bring our drug candidates to market are not available. Given the uncertainties related to development, we are currently unable to reliably estimate when, if ever, our drug candidates will generate revenue and net cash inflows.

General and Administrative Expenses

General and administrative expenses consist mainly of compensation and associated fringe benefits not included in cost of revenue or research and development for proprietary drug discovery expenses and include other management, business development, accounting, information technology and administration costs, including patent prosecution, recruiting and relocation, consulting and professional services, travel and

meals, sales commissions, facilities, depreciation and other office expenses.

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A summary of our general and administrative expenses follows (amounts in thousands):

	Ye	ars Ended June 3	0,	Change 2008	vs. 2007	Change 2007 vs. 2006		
	2008	2007	2006	\$	%	\$	%	
General and administrative	\$ 15,591	\$ 13,644	\$ 13,683	\$ 1,947	14.3%	\$ (39)	(0.3%)	

Fiscal 2008 as compared to Fiscal 2007 - General and administrative expenses increased by approximately \$1.9 million during the 2008 fiscal year over the prior fiscal year primarily due to increased compensation and benefit expenses of \$1.0 million associated with the addition of general and administrative personnel. Audit, legal and other consulting expenses increased by approximately \$750 thousand as a result of increased legal and audit fees for general corporate matters and strategic consulting. Other general and administrative expenses associated with increased personnel, such as travel and office related costs make up the remaining increase of approximately \$190 thousand.

Fiscal 2007 as compared to Fiscal 2006 - General and administrative expenses decreased by approximately \$145 thousand during the 2007 fiscal year over the prior fiscal year primarily as a result of decreased share-based compensation expense of approximately \$790 thousand recognized upon the vesting of option shares in the prior fiscal year. As described in Cost of Revenue above, the change in estimated useful life of our leasehold improvements resulted in a reduction of amortization of leasehold improvement costs charged to general and administrative expenses for the 2007 fiscal year of approximately \$90 thousand and the reversal of the prior year deferred rent balance resulted in a reduction to rent expense allocated to general and administrative expenses for the 2007 fiscal year of approximately \$150 thousand. Partially offsetting all these decreases in general and administrative expenses were increases in patent and patent application costs of approximately \$830 thousand for the 2007 fiscal year associated with the advancement of our propriety drug development programs. The remaining increase in general and administrative expenses of \$55 thousand from the prior year was attributable to increases in compensation and benefit expenses.

Other Income (Expense)

A summary of our other income (expense) follows (amounts in thousands):

	Years Ended June 30,			C	Change 2008 vs. 2007			Change 2007 vs. 2006				
	20	08	20	07	2006		\$		%		\$	%
Impairment of marketable												
securities	\$	(1,872)	\$	-	\$ -	\$	(1,872)		0.0%	\$	-	0.0%
Interest income		6,064		4,610	2,729		1,454		31.5%		1,881	68.9%
Interest expense		(1,986)		(979)	(670)		(1,007)	1	02.9%		(309)	46.1%
Total other income	\$	2,206	\$	3,631	\$ 2,059	\$	(1,425)	(.)	39.2%)	\$	1,572	76.3%

Fiscal 2008 as compared to Fiscal 2007 Other income and expense, net in fiscal 2008 includes an other-than-temporary impairment of certain ARS. Interest income increased in fiscal 2008 compared to fiscal 2007 primarily due to higher effective interest rates and higher average cash, cash equivalent and investment balances. Interest expense increased in fiscal 2008 compared to fiscal 2007 due to increased borrowings and higher effective interest rates related to our long-term borrowings. We expect interest expense to increase as a result of our Credit Facility entered into in April 2008 with Deerfield.

Fiscal 2007 as compared to Fiscal 2006 - Interest income increased in fiscal 2007 compared to fiscal 2006 primarily due to higher effective interest rates and higher average cash, cash equivalent and investment balances. Interest expense increased in fiscal 2007 compared to fiscal 2006 due to increased borrowings and higher effective interest rates related to our long-term borrowings.

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Liquidity and Capital Resources

We have historically funded our operations through revenue from our collaborations and the issuance of debt and of equity securities.

Our future capital requirements will depend on a number of factors, including the rate at which we invest in proprietary research, the growth of our clinical development capabilities, the growth or decline of our collaboration business and the amount of collaboration research funding we receive, the timing of milestone and royalty payments, if any, from our collaboration and out-licensed programs, our capital spending on new facilities and equipment, the number and size of Phase 2 and Phase 3 clinical trials we decide to run, expenses associated with unforeseen litigation, regulatory changes, competition and technological developments, general economic and market conditions and the extent to which we acquire or invest in other businesses, products and technologies.

In addition, our future capital requirements may be impacted if we do not receive potential milestone or royalty payments under our existing or future collaboration agreements. Our ability to realize these payments is subject to a number of risks, many of which are beyond our control and include the following: the drug development process is risky and highly uncertain, and we or our collaborators may not be successful in commercializing drug candidates we create; our collaborators have substantial control and discretion over the timing and continued development and marketing of drug candidates we create; the sale and manufacture of drug candidates we develop may not obtain regulatory approval; and, if regulatory approval is received, drugs we develop will remain subject to regulation or may not gain market acceptance, which could delay or prevent us from generating milestone, royalty revenue or product revenue from the commercialization of these drugs.

We believe that our existing cash, cash equivalents, marketable securities, credit facilities and anticipated cash flow from existing collaboration agreements will be sufficient to support our current operating plan for at least the next 12 months. This estimate of our future capital requirements is a forward-looking statement that is based on assumptions that may prove to be wrong and that involve substantial risks and uncertainties. Our actual future capital requirements could vary as a result of a number of factors, including:

- The progress of our research and development activities;
- Our ability to enter into agreements to out-license and co-develop our proprietary drug candidates, and the timing of those agreements in each candidate s development stage;
- The number and scope of our research and development programs;
- The progress of our preclinical and clinical development activities;
- The number and scope of phase 2 and phase 3 studies we may decide to run;
- The progress of the development efforts of our collaborators;
- The availability of resources for revenue generating collaborations as we devote more resources to our proprietary programs;

- Our ability to establish and maintain current and new collaboration agreements;
- The ability of our collaborators to fund research and development programs;
- The costs involved in enforcing patent claims and other intellectual property rights;
- The costs and timing of regulatory approvals; and
- The costs of establishing clinical development and distribution or commercialization capabilities.

Until we can generate sufficient levels of cash from our operations, which we do not expect to achieve in the foreseeable future, we expect to continue to utilize our existing cash, cash equivalents and marketable securities that were primarily generated from the proceeds of our credit facilities and equity offerings and from our collaborations. In addition, we may finance future cash needs through the sale of equity securities, strategic collaboration agreements and debt financing. We cannot assure that we will be successful in obtaining new or in retaining existing out-license or collaboration agreements, in securing agreements for the co-development of our proprietary drug candidates, or in receiving milestone and/or royalty payments under those agreements, that our existing cash, cash equivalents and marketable securities resources will be adequate or that additional financing will be available when needed or that, if available, this financing will be obtained on terms favorable to us or our stockholders. Insufficient funds may require us to delay, scale back or eliminate some or all of our research or development programs or to relinquish greater or all rights to product candidates at an earlier stage of

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development or on less favorable terms than we would otherwise choose, or may adversely affect our ability to operate as a going concern. If we raise additional funds by issuing equity securities, substantial dilution to existing stockholders may result.

The following discussion highlights our cash flow activities during the fiscal years ended June 30, 2008, 2007 and 2006.

Cash, Cash Equivalents and Marketable Securities

We consider short-term, highly liquid financial instruments that are readily convertible to cash and have maturities of 90 days or less from the date of purchase to be cash equivalents.

Marketable securities classified as short-term consist of various financial instruments such as commercial paper, U.S. government agency obligations and corporate notes and bonds with high credit quality with maturities of greater than 90 days when purchased. Marketable securities classified as long-term consist of our investments in ARS.

Following is a summary of our cash, cash equivalents and marketable securities (amounts in thousands):

	Years Ended June 30,			Change 200	8 vs. 2007	Change 2007 vs. 2006		
	2008	2007	2006	\$	%	\$	%	
Cash and cash equivalents	\$ 56,448	\$ 10,670	\$ 15,568	\$ 45,778	429.0%	\$ (4,898)	(31.5%)	
Marketable securities - short-term	39,243	130,661	54,532	(91,418)	(70.0%)	76,129	139.6%	
Marketable securities - long-term	29,840	-	-	29,840	0.0%	-	0.0%	
Total	\$ 125,531	\$141,331	\$ 70,100	\$ (15,800)	(11.2%)	\$ 71,231	101.6%	

Cash Flow Activities

Following is a summary of our cash flow activities (amounts in thousands):

	Years Ended June 30,			Change 2008	3 vs. 2007	Change 2007 vs. 2006		
	2008	2007	2006	\$	%	\$	%	
Cash flows provided by (used in):								
Operating activities	\$ (45,736)	\$ (44,523)	\$ (24,298)	\$ (2,213)	5.0%	\$ (20,225)	83.2%	
Investing activities	50,726	(50,663)	20,613	101,389	*	(71,276)	*	
Financing activities	40,788	90,288	6,824	(48,500)	(53.7%)	83,464	*	
Total	\$ 45,778	\$ (4,898)	\$ 3.139	\$ 50.676	*	\$ (8,037)	*	

^{*} Percentage calculation excluded as we have determined that it was not meaningful

Fiscal 2008 as compared to Fiscal 2007 Net cash used in operating activities for fiscal year 2008 was \$45.7 million, compared to \$44.5 million for fiscal 2007. During fiscal year 2008, our net loss of \$96.3 million was reduced by non-cash charges of \$6.1 million for depreciation and amortization expense, \$6.2 million for share-based compensation expense, a \$1.9 million other-than temporary impairment charge related to certain ARS and \$944 thousand of amortization of debt discount. Changes in operating assets and liabilities included an increase of \$32.6 million of deferred revenue primarily from Celgene, an increase of \$7.6 million in accrued outsourcing costs due to increased obligations for outsourced pharmacology and clinical trial expenses, a decrease of \$2.6 million related to amortization or deferred rent, a decrease in accounts payable of \$1.7 million resulting from lower capital expenditures during the last quarter of 2008 relative to 2007, an increase in prepaid expenses and other current assets of \$818 thousand resulting from increased equipment deposits, sales tax refunds and prepaid interest, an increase in accrued compensation and benefits of \$961 thousand associated with increased employment and \$544 thousand of changes in other current liabilities and accrued expenses.

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Net cash provided by (used in) investing activities was \$50.7 million and \$(50.7) million in fiscal 2008 and 2007, respectively. During fiscal 2008, we invested \$8.2 million in property and equipment, primarily in lab equipment and facilities for research and development and various computer equipment hardware and software associated with new employees. Purchases of marketable securities used \$71.6 million in cash, and proceeds from sales and maturities of marketable securities provided \$130.5 million.

Net cash provided by financing activities was \$40.8 million and \$90.3 million in fiscal 2008 and 2007, respectively. During fiscal 2008, we received proceeds of \$40 million in connection with our \$80 million convertible debt facility in June of 2008 and paid \$1.0 million of transaction fees. We also received proceeds of \$1.8 million from exercises of employee stock options and purchases of stock by employees under our ESPP.

Fiscal 2007 as compared to Fiscal 2006 - Net cash used in operating activities for fiscal year 2007 was \$44.5 million, compared to \$24.3 million for fiscal 2006. During fiscal year 2007, our net loss of \$55.4 million was reduced by non-cash charges of \$11.1 million, primarily associated with depreciation and amortization expense and, share-based compensation expense. For fiscal year 2007, our net operating assets and liabilities excluding cash decreased by \$270 thousand. Accounts payable and assured outstanding increased by \$3.9 million due to increased obligations for outsourced pharmacology and clinical trial expenses, fine chemicals, and facilities improvements. Accrued compensation and benefits increased by \$772 thousand, half of which was due to increased amounts reserved for fiscal year 2007 employee bonuses with the remainder due to increased vacation reserves as well as increased 401(k), deferred compensation and ESPP payroll withholdings attributable to our larger employee base. Deferred rent liabilities decreased by \$4 million due to the BioMed facilities transaction. Deferred revenues decreased by approximately \$2 million as we concluded collaboration programs with InterMune and Takeda. Other operating assets and liabilities increased by \$1 million making up the remainder of the change.

Net cash provided by (used in) investing activities was \$(50.7) million and \$20.6 million for fiscal year 2007 and 2006, respectively. During fiscal year 2007, we received net proceeds of \$32.3 million from BioMed related to the assignment of purchase options of our Boulder and Longmont, Colorado facilities. We invested \$7.1 million in property and equipment, primarily in lab equipment for drug metabolism, analytical research and development operations, process chemistry and biology, as well as in improvements to our facilities, and various computer hardware and software. Purchases of marketable securities used \$144.9 million of cash while proceeds from the sale and maturity of marketable securities provided \$69.2 million of cash.

Financing activities provided \$90.3 million of cash consisting of \$85.2 million in net proceeds from our public common stock offering, \$4.2 million of cash resulting from the exercise of stock options under our stock option plan and purchases of stock under our ESPP, and approximately \$850 thousand of proceeds received from the issuance of long-term debt used to finance purchases of capital equipment.

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Obligations and Commitments

The following table shows our contractual obligations and commitments as of June 30, 2008 (amounts in thousands):

	Than ear	1 t Ye	o 3 ars	4 to Yes	o 5 ars	Over :	5 Years	To	otal
Debt obligations (1)	\$ -	\$	15,000	\$	-	\$	40,000	\$	55,000
Interest on debt obligations (3) (4)	2,096		3,688		1,603		40,977		48,364
Operating lease commitments (2)	7,643		15,969		16,462		24,954		65,028
Purchase obligations (2)	13,908		8,003		1,314		-		23,225
Total	\$ 23,647	\$	42,660	\$	19,379	\$	105,931	\$	191,617

- (1) Reflected in the accompanying Balance Sheets
- (2) Not reflected in the accompanying Balance Sheets
- (3) Interest on the variable debt obligations was calculated at 3.25%, the interest rate in effect as of June 30, 2008.
- (4) Includes \$1.2 million of interest accrued for in the accompanying Balance Sheets. The remaining amounts are not reflected in the accompanying Balance Sheets.

We are obligated under non-cancelable operating leases for all of our facilities and under certain equipment leases. Original lease terms for our facilities in effect as of June 30, 2008 were five to ten years and generally require us to pay the real estate taxes, insurance and other operating costs. Equipment lease terms generally range from three to five years.

Total operating lease obligations under the Boulder Lease amount to \$52.0 million over the lease term, and account for \$42.5 million of operating lease obligations within the above table. Total operating lease obligations under the Longmont lease are \$24.2 million over the lease term, and account for \$20.0 million of operating lease obligations within the above table.

Purchase obligations totaling \$19.2 million were primarily for outsourced clinical and pharmacology services. Additional purchase obligations of \$4.0 million were primarily for software to support the advancement of clinical trials, facilities improvements and lab supplies.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Market risk represents the risk of loss that may impact our financial position, results of operations or cash flows due to adverse changes in financial and commodity market prices, the liquidity of our ARS, and interest rates. All of our collaboration agreements and nearly all purchase orders are denominated in U.S. dollars. As a result, historically and as of June 30, 2008, we have had little or no exposure to market risk from changes in foreign currency or exchange rates.

Our exposure to market risk for changes in interest rates relates primarily to our investments in marketable securities. The investment portfolio is comprised primarily of readily marketable, high-quality securities diversified and structured to minimize market risks while providing a reasonable return on invested funds. As of June 30, 2008, \$29.1 million of our investment portfolio is invested in ARS that are not marketable. We target our average portfolio maturity at one year or less. Nevertheless, the securities held in our investment portfolio are subject to changes in market value in response to changes in interest rates and liquidity. In addition, a significant change in market interest rates could have a material impact on interest income earned from our investment portfolio.

Given the current balance of \$125.5 million of investments classified as cash and cash equivalents, and short-term and long-term marketable securities available for sale, a theoretical 100 basis point change in interest rates and security prices would impact our net income (loss) positively or negatively by approximately \$1.3 million.

Our long-term marketable securities investment portfolio includes ARS. During the fiscal year ended June 30, 2008 and subsequent thereto, auctions for all of our ARS, amounting to seven securities with a par value of \$32.9 million, were unsuccessful. We recorded an other-than-temporary impairment of \$1.9 million on two of our ARS, primarily due the continuous decline and magnitude of the fair value discount from par value, which is due in

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part to the relative weakness in the performance of the underlying trust assets. We believe that impairment in the other five ARS in the portfolio, amounting to \$1.9 million, is temporary, primarily because of stronger performance of the underlying trust assets, the relatively smaller discount of fair value from par value, and because these securities have not incurred significant continuous declines in fair value during recent periods. If credit market liquidity conditions deteriorate further, we may be required to record additional temporary or other-than-temporary impairments of our ARS, which could adversely affect our financial condition, cash flow and reported earnings. In the event we need to access any of our ARS, we will not be able to do so until auctions of these investments are successful, the original issuers retire these securities or a secondary market develops for these securities.

We are also impacted by adverse changes in interest rates relating to variable-rate borrowings under our senior secured Credit Facility with Comerica Bank. We pay interest on advances under our loan agreement at one of three variable rates, which are adjusted periodically for changes in the underlying prevailing rate. Changes in prevailing interest rates will affect the fair value of our debt, and will impact future results of operations and cash flows. As of June 30, 2008, we had \$55.9 million of long-term debt outstanding, exclusive of the debt discount of \$20.5 million, of which \$15.0 million is under our variable rate term loan and equipment advance facilities. The variable rate is adjusted based on changes in the bank s prime lending rate. The interest rate on the remainder of our long-term debt is fixed. Assuming constant debt levels, a theoretical change of 100 basis points on our current interest rate of 3.25% as of June 30, 2008 would result in a change in our annual interest expense of approximately \$150 thousand.

Historically, and as of June 30, 2008, we have not used derivative instruments or engaged in hedging activities.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

The financial statements required by this item are located in Item 15 beginning on page F-1 of this Annual Report on Form 10-K and are incorporated herein by reference.

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

None.

ITEM 9A. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

As of the end of the period covered by this Annual Report on Form 10-K, under the supervision of our Chief Executive Officer and our Chief Financial Officer, we evaluated the effectiveness of our disclosure controls and procedures, as such term is defined in Rule 13a-15(e) and

Rule 15d-15(e) under the Securities Exchange Act of 1934. Based on this evaluation, our Chief Executive Officer and our Chief Financial Officer have concluded that our disclosure controls and procedures are effective to ensure that information we are required to disclose in reports that we file or submit under the Securities Exchange Act of 1934: (1) is recorded, processed, summarized and reported within the time periods specified in Securities and Exchange Commission rules and forms, and (2) is accumulated and communicated to our management, including our Chief Executive Officer and our Chief Financial Officer, as appropriate to allow timely decisions regarding required disclosure. Our disclosure controls and procedures include components of our internal control over financial reporting. Management s assessment of the effectiveness of our internal control over financial reporting set forth below is expressed at the level of reasonable assurance because a control system, no matter how well designed and operated, can provide only reasonable, but not absolute, assurance that the control system s objectives will be met.

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Evaluation of Internal Control over Financial Reporting
Pursuant to Section 404 of the Sarbanes-Oxley Act of 2002, we have included a report on management s assessment of the design and effectiveness of its internal control over financial reporting as part of this Annual Report on Form 10-K for the fiscal year ended June 30, 2008. Our independent registered public accounting firm also audited and reported on the effectiveness of internal control over financial reporting. Management s report and the independent registered public accounting firm s attestation report are included under the captions entitled Management s Report on Internal Control Over Financial Reporting and Report of Independent Registered Public Accounting Firm on Internal Control Over Financial Reporting in Item 15 of this Annual Report on Form 10-K and are incorporated herein by reference.
Based on their evaluation as of June 30, 2008, our principal executive officer and our principal financial officer have concluded that our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act) are effective.
Changes in Internal Control over Financial Reporting
There has been no change in our internal control over financial reporting during the fourth quarter of our fiscal year ended June 30, 2008 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.
ITEM 9B. OTHER INFORMATION
None.
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PART III

ITEM 10. DIRECTORS AND EXECUTIVE OFFICERS OF THE REGISTRANT

The information required by this item is incorporated by reference from the information under the captions Proposal 1-Election of Directors, Executive Officers and Section 16(a) Beneficial Ownership Reporting Compliance contained in the Proxy Statement of Array BioPharma Inc. relating to the annual meeting of stockholders to be held on October 30, 2008.

Code of Ethics

We have adopted a Code of Business Conduct that applies to all of our directors, officers and employees, including our principal executive officer, principal financial officer and principal accounting officer. The Code of Business Conduct is posted under the Investor Relations portion of our website at www.arraybiopharma.com.

We intend to satisfy the disclosure requirement of Form 8-K regarding amendments to or waivers from a provision of our Code of Business Conduct by posting such information on our website at www.arraybiopharma.com and, to the extent required by the NASDAQ Global Market, by filing a current report on Form 8-K with the SEC, disclosing such information.

ITEM 11. EXECUTIVE COMPENSATION

The information required by this item is incorporated by reference from the information under the caption Executive Compensation contained in the Proxy Statement of Array BioPharma Inc. relating to the annual meeting of stockholders to be held on October 30, 2008.

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

The information required by this item is incorporated by reference from the information under the captions Principal Stockholders and Proposal 2 Approval of Amendment to Employee Stock Purchase Plan contained in the Proxy Statement of Array BioPharma Inc. relating to the annual meeting of stockholders to be held on October 30, 2008.

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

The information required by this item is incorporated by reference from the information under the captions Certain Relationships and Transactions and Proposal 1 Election of Directors Meetings of the Board of Directors and Committees of the Board of Directors contained in the Proxy Statement of Array BioPharma Inc. relating to the annual meeting of stockholders to be held on October 30, 2008.

ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES

The information required by this item is incorporated by reference from the information under the caption Fees Billed by the Principal Accountant contained in the Proxy Statement of Array BioPharma Inc. relating to the annual meeting of stockholders to be held on October 30, 2008.

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PART IV

ITEM 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES

The following documents are filed as part of this Report on Form 10-K:

1. Financial Statements

Reference is made to the Index to the Financial Statements is set forth on page F-1 of this Annual Report on Form 10-K.

2. Financial Statement Schedules

All schedules have been omitted as the required information is either not required, not applicable, or otherwise included in the Financial Statements and notes thereto.

3. *Exhibits*

Reference is made to the Exhibit Index that is set forth after the Financial Statements referenced above in this Annual Report on Form 10-K.

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SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, as amended, the Registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized, in the City of Boulder, State of Colorado, on August 15, 2008.

ARRAY BIOPHARMA INC.

By: /s/ ROBERT E. CONWAY

Robert E. Conway Chief Executive Officer

SIGNATURE TITLE		DATE	
/s/ ROBERT E. CONWAY Robert E. Conway	Chief Executive Officer and Director (Principal Executive Officer)	August 15, 2008	
/s/ KYLE A. LEFKOFF Kyle A. Lefkoff	Chairman of the Board of Directors	August 15, 2008	
/s/ R. MICHAEL CARRUTHERS R. Michael Carruthers	Chief Financial Officer (Principal Financial And Accounting Officer)	August 15, 2008	
/s/ FRANCIS J. BULLOCK Francis J. Bullock, Ph.D.	Director	August 15, 2008	
/s/ MARVIN H. CARUTHERS Marvin H. Caruthers, Ph.D.	Director	August 15, 2008	
/s/ KEVIN KOCH Kevin Koch, Ph.D.	Director	August 15, 2008	
/s/ DAVID L. SNITMAN David L. Snitman, Ph.D.	Director	August 15, 2008	
/s/ GIL J. VAN LUNSEN Gil J. Van Lunsen	Director	August 15, 2008	
/s/ DOUGLAS E. WILLIAMS Douglas E. Williams, Ph.D.	Director	August 15, 2008	
/s/ JOHN L. ZABRISKIE			