

ARRAY BIOPHARMA INC  
Form 10-K  
August 12, 2011

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**U.S. SECURITIES AND EXCHANGE COMMISSION**  
**Washington, D.C. 20549**

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**Form 10-K**

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

For the fiscal year ended June 30, 2011

OR

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

For the transition period from \_\_\_\_\_ to \_\_\_\_\_

**Commission File Number: 001-16633**

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**Array BioPharma Inc.**

(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  No

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  No

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

Yes  No

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files).

Yes  No

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

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

Large accelerated filer <input type="radio"/>	Accelerated filer <input checked="" type="radio"/>	Non-accelerated filer <input type="radio"/> (do not check if a smaller reporting company)	Smaller reporting company <input type="radio"/>
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Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act).

Yes  No

The aggregate market value of voting stock held by non-affiliates of the registrant as of December 31, 2010 (based upon the closing sale price of such shares as of the last trading day of the second fiscal quarter ended December 31, 2010, on the NASDAQ Global Market) was \$76,171,933. 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 5, 2011: 57,020,003.

**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 2011 Annual Meeting of Stockholders are incorporated by reference in Part III of this Annual Report on Form 10-K to the extent stated therein.

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**PART I**

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Array BioPharma Inc., the Array BioPharma Inc. logo and the marks "ARRAY BIOPHARMA THE DISCOVERY RESEARCH COMPANY," "TURNING GENOMICS INTO BREAKTHROUGH DRUGS," "OPTIMER," and "ARRAY DISCOVERY PLATFORM" are trademarks of Array BioPharma Inc. 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 the future drug development plans and projected timelines for the initiation and completion of preclinical and clinical trials by Array or our collaborators; the potential for the results of ongoing preclinical or clinical trials conducted by Array or our collaborators 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; 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; our ability to achieve and maintain profitability; 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 to treat patients afflicted with cancer and inflammatory diseases. Our proprietary drug development pipeline includes clinical candidates that are designed to regulate

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therapeutically important target pathways. In addition, leading pharmaceutical and biotechnology companies partner with us to discover and develop drugs across a broad range of therapeutic areas.

The five most advanced wholly-owned programs that we are developing internally are:

Program	Indication	Clinical Status
1. ARRY-520	Kinesin spindle protein, or KSP, inhibitor for multiple myeloma	Phase 2
2. ARRY-614	p38/Tie-2 dual inhibitor for myelodysplastic syndrome, or MDS	Phase 1
3. ARRY-380	HER2 inhibitor for breast cancer	Phase 1
4. ARRY-797	p38 inhibitor for pain	Phase 2
5. ARRY-502	CRTh2 antagonist for allergic inflammation	Phase 1

In addition to these development programs, our most advanced partnered drugs in clinical development are:

Drug Candidates	Indication	Partner	Clinical Status
1. Selumetinib and AZD8330	MEK inhibitors for cancer	AstraZeneca, PLC	Phase 2
2. MEK162 and MEK300	MEK inhibitors for cancer	Novartis International Pharmaceutical Ltd.	Phase 2
3. Danoprevir	Hepatitis C virus (HCV) protease inhibitor	InterMune (now being developed by Roche Holding AG)	Phase 2
4. ARRY-543	HER2/EGFR inhibitor for solid tumors	ASLAN Pharmaceuticals Pte Ltd.	Phase 2
5. LY2603618	ChK-1 inhibitor for cancer	Eli Lilly and Company	Phase 2
6. AMG 151	Glucokinase activator for Type 2 diabetes	Amgen Inc.	Phase 1b
7. GDC-0068	AKT inhibitor for cancer	Genentech Inc.	Phase 1b
8. VTX-2337	Toll-like receptor for cancer	VentiRx Pharmaceuticals, Inc.	Phase 1b
9. VTX-1463	Toll-like receptor for allergy	VentiRx	Phase 1b

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Pharmaceuticals, Inc.

10. ARRY-382                      cFMS inhibitor for cancer                      Celgene Corporation                      Phase 1

11. ARRY-575 and  
GDC-0425                      ChK-1 inhibitor for cancer                      Genentech Inc.                      Phase 1

*Any information we report about the development plans or the progress or results of clinical trials or other development activities of our partners is based on information that is publicly disclosed.*

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Our significant and / or recent collaborators under our partnered programs include:

*Amgen* We entered into a worldwide strategic collaboration with Amgen in December 2009 to develop and commercialize our glucokinase activator, AMG 151, and to discover potential back-up compounds for AMG 151.

*ASLAN Pharmaceuticals* We entered into a collaboration and license agreement with ASLAN Pharmaceuticals in July 2011 to develop Array's HER2 / EGFR inhibitor, ARRY-543, which is currently entering Phase 2 development for solid tumors.

*AstraZeneca* In December 2003, we entered into a collaboration and license agreement with AstraZeneca under which AstraZeneca received a license to three of our MEK inhibitors for cancer, including selumetinib, which is currently in multiple Phase 2 clinical trials.

*Celgene* We entered into a worldwide strategic collaboration agreement with Celgene in September 2007 focused on the discovery, development and commercialization of novel therapeutics in cancer and inflammation. The most advanced drug is ARRY-382, a cFMS inhibitor for cancer, which is currently in a Phase 1 clinical trial.

*Genentech* We entered into a worldwide strategic collaboration agreement with Genentech in January 2003, which was expanded in 2005, 2008, and 2009, and is focused on the discovery, development and commercialization of novel therapeutics. The most advanced drug is GDC-0068, an AKT inhibitor for cancer currently in a Phase 1b trial. The other programs under this collaboration are in preclinical development. In August 2011, we entered into an oncology partnership with Genentech for the development of each company's small-molecule Checkpoint kinase 1 (ChK-1) program. The programs include Genentech's compound GDC-0425 (RG7602), currently in Phase 1, and Array's compound, ARRY-575, which is being prepared for an investigational new drug application to initiate a Phase 1 trial in cancer patients.

*Novartis* We entered into a worldwide strategic collaboration with Novartis in April 2010 to develop and commercialize our MEK inhibitor, MEK162, and other MEK inhibitors identified in the agreement.

*InterMune (program acquired by Roche)* We entered into a collaboration with InterMune in 2002, which resulted in the joint discovery of danoprevir, a novel small molecule inhibitor of the Hepatitis C Virus NS3/4A protease. Roche Holding AG acquired danoprevir from InterMune in 2010. Danoprevir is currently in Phase 2b clinical trials.

Under our partnered drug discovery programs, we are generally entitled to receive payments upon achievement of clinical development and commercialization milestones and royalties based on sales of any resulting drugs. Under our existing partnered program agreements, we have the potential to earn over \$3.5 billion in additional milestone payments if we or our collaborators achieve the drug discovery, development and commercialization objectives detailed in those agreements. We also have the potential to earn royalties on any resulting product sales or share in the proceeds from development or commercialization arrangements resulting from 12 drug research and development programs.

Additionally, we have a portfolio of proprietary and partnered drug discovery programs generated by our internal discovery efforts. Our internal drug discovery programs include inhibitors that target Trk receptors for the treatment of pain and G-protein-coupled receptor 119, or GPR-119 for the treatment of diabetes. We may choose to out-license select promising candidates through research partnerships.



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**Business History**

We have built our clinical and discovery pipeline programs through spending \$464.1 million from our inception in 1998 through June 30, 2011. In fiscal 2011, we spent \$63.5 million in research and development expenses for proprietary drug discovery, compared to \$72.5 million and \$89.6 million for fiscal years 2010 and 2009, respectively. Over the past 20 months through the date of filing this Annual Report, we signed strategic collaborations with Amgen, Genentech and Novartis. Together these collaborations resulted in \$133 million in initial payments, and entitle Array to receive up to over \$2.2 billion in potential milestone payments if all clinical and commercialization milestones under the agreements are achieved, double digit royalties and/or commercial co-detailing rights. We have received a total of \$523.3 million in research funding and in up-front and milestone payments from our collaboration partners since inception through June 30, 2011.

**Our Strategy**

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

Invent targeted small molecule drugs that are either first-in-class or second generation drugs that demonstrate a competitive advantage over drugs currently on the market or in clinical development;

Partner our drugs for co-development and commercialization, selectively retaining U.S. commercial and/or co-promotion rights for drugs that can be distributed through a therapeutically specialized sales force;

Partner select early-stage programs for continued research and development to receive research funding plus significant milestone payments and royalties; and

Build a commercial capability 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.

Our out-license and collaboration agreements with our partners typically provide for up-front payments, research funding, success-based milestone payments, co-detailing rights and/or royalties on product sales. These agreements may also be structured to share in the proceeds received from a collaborator resulting from the further development or commercialization of resulting drugs.

We also have a large number of research and development programs and are partnering certain of these programs with collaborators to provide funding, development, manufacturing and commercial resources. These partnering activities are central to our strategy over the next several years and may include co-development or co-commercialization and may be worldwide or limited to certain geographic areas. We plan to advance our most promising development assets internally at least through clinical proof-of-concept before partnering them, which we believe will maximize their value. We are also identifying certain programs to partner earlier during discovery or preclinical development with the goal of optimizing the potential return for Array on these programs.

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We have collaborations with leading pharmaceutical and biotechnology companies under which we have out-licensed certain proprietary drug programs for further research, development and commercialization. Our largest or most advanced collaborations include our agreements with Amgen, ASLAN Pharmaceuticals, AstraZeneca, Celgene, Genentech, Roche and Novartis. Under some of these collaborations, such as with Novartis for MEK162, we continue development work that is funded all or in part by our collaborators. Under some of our other partnered programs, our involvement in the development or research phase has ended but we retain the right to receive clinical and commercialization milestones and/or royalties on sales of any products covered by the collaboration. 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, perform clinical development and manufacture clinical supplies.

Information about our collaborators that comprise 10% or more of our total revenue and information about revenue we receive within and outside the U.S. can be found in *Note 2 Segments, Geographical Information and Significant Collaborators* to the accompanying audited financial statements included elsewhere in this Annual Report.

***Development Programs***

Below is a description of the five most advanced programs that we are developing, their stage in the drug development process and our expected future development plans. Each of these programs is wholly-owned by Array.

<b>Drug Candidates</b>		<b>Current Development Status</b>	<b>Future Development Plan</b>
ARRAY-520	KSP	Phase 2 single-agent and Phase 1b combination trials in patients with multiple myeloma.	Complete the Phase 2 and 1b trials.
ARRAY-614	p38/Tie2	Phase 1 expansion trial at the maximal administered dose in myelodysplastic syndromes patients and Phase 1 trial with new formulation in healthy volunteers.	Initiate Phase 1 dose escalation in myelodysplastic syndromes patients with the new formulation.
ARRAY-380	HER2	Phase 1 expansion trial in patients with metastatic breast cancer at the maximum tolerated dose in cancer patients.	Seek partner for further development.
ARRAY-797	p38	Phase 2 randomized, double-blind study in osteoarthritis patients.	Complete the Phase 2 trial and plan Phase 2 acute pain trial.
ARRAY-502	CRTh2	Phase 1 multiple ascending dose trial in healthy volunteers.	Initiate 28-day Phase 2a trial in patients with asthma

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**1. ARRY-520 KSP Program for Cancer**

ARRY-520 inhibits kinesin spindle protein, or KSP, which plays an essential role in mitotic spindle formation. KSP inhibitors induce proliferating cells to die by disrupting mitotic spindle formation during cell division. Unlike other mitosis inhibitors, such as taxanes and vinca alkaloids, KSP inhibitors are not expected to cause certain side effects such as peripheral neuropathy and alopecia.

In preclinical models of acute myeloid leukemia (AML) and multiple myeloma (MM), including MM models that do not respond to Velcade® (bortezomib), treatment with ARRY-520 resulted in significant tumor regression. ARRY-520 also showed synergy in combination with Velcade in several preclinical MM models. This activity was accompanied by a significant increase in apoptosis. ARRY-520 also showed synergy when combined with Revlimid® (lenalidomide) in preclinical MM models.

When administered alone, ARRY-520 has shown promising preliminary clinical activity in patients with relapsed and refractory MM who were previously treated with both an immunomodulatory agent, or IMiD, (such as Revlimid, Thalomid® (thalidomide) or pomalidomide) and a proteasome inhibitor (such as Velcade or carfilzomib). Array presented interim results of a Phase 1 trial of ARRY-520 in patients with MM at the 2010 Annual Meeting of the American Society of Hematology. Among the 30 evaluable patients enrolled in the Phase 1 trial across all dose levels, two partial responses and two minimal responses were reported and eight patients experienced stable disease or better for more than six months. Array plans to report updated Phase 1 and initial Phase 2 data from this study by the end of 2011.

*Development Status:* Our clinical development activities for ARRY-520 consisted of the following during fiscal 2011:

Completed a Phase 1 trial in patients with solid tumors

Completed a Phase 1 trial in patients with AML

Completed enrollment in a Phase 1 trial in patients with relapsed and refractory MM

Initiated a Phase 2 expansion cohort of ARRY-520 in combination with dexamethasone in refractory MM

Initiated a Phase 1b study of ARRY-520 in combination with Velcade and dexamethasone in relapsed and refractory MM

Continued enrollment in a Phase 2 single agent trial of ARRY-520 in MM

During fiscal 2012, we plan to:

Complete the ongoing Phase 2 single-agent study, including completing the expansion cohort of ARRY-520 in combination with dexamethasone in Revlimid and Velcade in patients with dual-refractory MM

Initiate a Phase 1b combination study with Revlimid in patients with relapsed and refractory MM

Collaborate with M.D. Anderson and Onyx Therapeutics, Inc. on an investigator-sponsored Phase 1b combination study with carfilzomib in patients with refractory MM

**2. ARRY 614 p38 /Tie-2 for Myelodysplastic Syndrome Program**

ARRY-614, an orally active compound that inhibits both p38 and Tie-2, has been found to block cytokine/chemokine signaling production and attenuate apoptosis. ARRY-614 demonstrates inhibition of inflammation and cytokine-dependent tumor growth in preclinical models.

Myelodysplastic syndromes (MDS) are late onset diseases that are characterized by over-production of myelosuppressive cytokines which leads to aberrant apoptosis in hematological progenitor cells. p38

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MAP kinase (p38) is implicated in dysregulation of apoptosis and myelosuppressive cytokine signaling and production. Tie-2 may affect this process by promoting cytokine production and altering stromal cell senescence. It is hypothesized that disrupting cytokine-driven apoptosis in the normal progenitors and stromal cells may improve hematopoiesis in lower risk MDS patients.

In a Phase 1 clinical trial in healthy volunteers, ARRY-614 demonstrated dose-dependent suppression of IL-1 $\beta$ , PGE2, IL-6 and TNF $\alpha$ , as measured in ex vivo LPS-stimulated whole blood samples. Based on these data, as well as work done on Tie-2 in other experiments, the plasma exposure observed in the volunteers was predicted to result in significant inhibition of p38 and Tie-2 activity in human tissue and plasma.

*Development Status:* During fiscal 2011, we completed a Phase 1 trial in patients with MDS to determine safety, maximum tolerated dose and pharmacokinetics, and to obtain preliminary efficacy data, of ARRY-614 in this patient population. We also initiated and completed a clinical study in healthy subjects to evaluate a new formulation. Over the next fiscal year, we plan to initiate a second dose-escalation Phase 1 trial in patients with MDS using the improved formulation.

**3. ARRY-380 HER2 Program for Cancer**

ARRY-380 is an orally active, reversible and selective HER2 inhibitor. HER2, also known as ErbB2, is a receptor tyrosine kinase that is over-expressed in breast cancer and other cancers such as gastric and ovarian cancer. In multiple preclinical tumor models, ARRY-380 was well tolerated and demonstrated significant dose-related tumor growth inhibition that was superior to Herceptin® (trastuzumab) and Tykerb® (lapatinib). Additionally, in these models, ARRY-380 was well tolerated and additive for tumor growth inhibition when dosed in combination with the standard of care therapeutics Herceptin or Taxotere® (docetaxel).

In December 2010, Array presented positive interim results of ARRY-380 in a Phase 1 trial in patients with advanced cancer at the San Antonio Breast Cancer Symposium. Interim results were presented on 19 patients with HER2-positive cancer evaluable for response who were treated with ARRY-380 at doses greater than or equal to 200 mg (twice daily). All of the HER2-positive metastatic breast cancer patients had been previously treated with Herceptin and 81% were previously treated with Tykerb. Thirty two percent of the 19 patients had clinical benefit as measured by a partial response or stable disease for six months or longer. Fifteen of the 19 patients had measurable disease as defined by the Response Evaluation Criteria in Solid Tumors (RECIST); of these patients, seven had regressions in target lesions. Of the four patients with no measurable disease, three had regressions of non-target chest wall lesions. ARRY-380 demonstrated an acceptable safety profile; the predominant treatment-related adverse events have been Grade 1. Because ARRY-380 is selective for HER2 and does not inhibit EGFR, there was, as expected, a low incidence and severity of diarrhea, rash and fatigue. Additionally, there were no Grade 4 treatment related adverse events or treatment related cardiac events reported. The maximum tolerated dose of ARRY-380 established in this Phase 1 trial is 600 mg (twice daily). An expansion cohort in patients with HER2-positive metastatic breast cancer is ongoing to confirm safety and investigate pharmacodynamic markers.

Recently, a sub-population of approximately one-third of HER2+ patients who express high level of truncated HER2 has been identified. This sub-population has been reported to have shorter progression free survival and overall survival from Herceptin-based therapy as compared to patients with low expression of truncated HER2. ARRY-380 targets the intracellular kinase portion of HER2 and retains activity against the truncated HER2, making this population of patients a potentially attractive option for further drug development of ARRY-380.

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*Development Status:* During fiscal 2011, we completed the dose escalation Phase 1 trial to evaluate the safety, maximum tolerated dose and pharmacokinetics of ARRAY-380 in patients with advanced cancer. The drug was shown to have good pharmacokinetics, an acceptable safety profile, and anti-tumor activity in patients who had previously received Herceptin and Tykerb. ARRAY-380 is currently in an expansion portion of the Phase 1 trial to confirm safety and the recommended dose for future trials. We are seeking a partner to further advance the program.

**4. ARRAY-797 p38 Program for Pain**

p38 MAPK is an important mediator of pain and inflammation which modulates the production of the pro-inflammatory cytokines TNF, IL-6 and IL-1 as well as the pain mediator PGE2. ARRAY-797 is an orally active inhibitor of p38 with unique physical properties: it is highly selective, highly water soluble and has low potential to cross the blood brain barrier. In a Phase 1 clinical trial in healthy volunteers, ARRAY-797 demonstrated dose-dependent marked suppression of all three of these cytokines, as measured in ex vivo LPS-stimulated whole blood samples.

To date, in Phase 1 and 2 studies, 417 individuals have received up to twelve weeks of ARRAY-797 and the drug has been well tolerated. Among these individuals, pain data are available for 309 patients from four studies. In 2008, Array announced top-line results demonstrating that ARRAY-797 achieved its primary endpoints for analgesic efficacy in two Phase 2 acute dental pain studies. ARRAY-797 was well tolerated with no serious adverse events. In 2009, post hoc analyses of two studies with a small number of patients: a 28-day rheumatoid arthritis study and a 12-week ankylosing spondylitis study indicated durable pain relief with ARRAY-797. Array believes ARRAY-797 has an opportunity to address a significant unmet medical need in both acute and chronic pain.

ARRAY-797 is currently being evaluated in a 28-day Phase 2 trial of patients with pain associated with osteoarthritis of the knee who are using concomitant nonsteroidal anti-inflammatory drugs. Array anticipates reporting top-line results of this trial during the first quarter of calendar 2012.

**5. ARRAY-502 CRTh2 Program for Asthma**

ARRAY-502, an oral CRTh2 antagonist, has the potential to be an effective treatment for patients with asthma, particularly those with severe conditions, and may have advantages over competitor molecules. In various preclinical models of allergic inflammation, ARRAY-502 has demonstrated a high level of anti-inflammatory activity. In initial Phase I clinical trials ARRAY-502 has been well tolerated and demonstrated pharmacodynamic activity.

Inappropriate inflammatory responses to environmental allergens underlie allergic reactions such as allergic asthma, allergic rhinitis and atopic dermatitis, which collectively affect up to 20% of the United States population. Despite the range of treatments used to treat allergic asthma, there remains a significant need for patients with severe asthma as well as for more convenient and safer therapies for those with mild to moderate asthma. Although severe asthma affects only approximately 10% of the asthmatic population, the condition results in approximately 60% of total healthcare costs associated with asthma. Currently, few treatment options exist for patients with severe asthma.

In severe allergic asthma, there is emerging evidence suggesting that a greater presence of the mediator prostaglandin D2, or PGD2, and an upregulation of CRTh2, a protein receptor for PGD2 that is expressed on inflammatory cells, may play a particularly important role in greater symptoms of asthma such as coughing and difficulty breathing and lower lung function. Indeed, activation of CRTh2 has been shown to result in chemotaxis and activation of inflammatory cells and stimulate the production of cytokines that are thought to drive asthma pathophysiology.

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Based on the role of CRTh2 in mediating the actions of PGD2, selective antagonism of CRTh2 presents an attractive therapeutic approach to the treatment of severe allergic conditions. There are selective antagonists of CRTh2 in various stages of clinical development with compounds currently being evaluated in early Phase 2 studies in allergic rhinitis, asthma and eosinophilic esophagitis.

*Development Status:* Array initiated a 14-day Phase 1, randomized, double-blind, multiple ascending dose trial with ARRY-502 in healthy volunteers for the evaluation of safety, pharmacokinetics and pharmacodynamics. Array expects to complete enrollment and announce top-line results by year-end. The results to date from the Phase 1 single ascending dose study indicate that ARRY-502 has been well-tolerated at the doses evaluated, has shown excellent exposure and demonstrated good activity in pharmacodynamic assessments. Array expects to initiate a 28-day Phase 2a trial in persistent asthma over the next fiscal year.

**Partnered Development Programs**

Below are summaries of our most advanced, ongoing partnered development programs. Any information we report about the development plans or the progress or results of clinical trials or other development activities of our partners is based on information that has been reported to us or is otherwise publicly disclosed by our collaboration partners.

***1. AstraZeneca Selumetinib and AZD8330 MEK Program***

In December 2003, we entered into an out-licensing and collaboration agreement with AstraZeneca to develop our MEK program. Under the agreement, AstraZeneca acquired exclusive worldwide rights to our clinical development candidate, selumetinib (previously known as ARRY-142886), together with two other compounds for oncology indications, including AZD8330, which we invented during the collaboration. We retained the rights to all therapeutic indications for MEK compounds not selected by AstraZeneca for development, subject to the parties' agreement to work exclusively together. In April 2009, the exclusivity of the parties' relationship ended and both companies are now free to independently research, develop and commercialize small molecule MEK inhibitors in the field of oncology. To date, we have earned \$21.5 million in up-front and milestone payments. The agreement also provided for research funding, which is now complete, and provides potential additional development milestone payments of approximately \$75 million and royalties on product sales.

Under this collaboration, we were responsible for Phase 1 clinical testing, which we completed in 2004, and AstraZeneca is responsible for all future development and commercialization of the compounds under the collaboration.

*Development Status.* The Phase 1 trial Array conducted in 2004 evaluated tolerability and pharmacokinetics of selumetinib 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. Selumetinib inhibited the MEK pathway in tumor tissue at the dose that was later selected for Phase 2 studies and provided prolonged disease stabilization in a number of cancer patients who had previously received numerous other cancer therapies.

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

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In 2008, AstraZeneca presented Phase 1 clinical trial results at the annual meeting of the American Society of Clinical Oncology, or ASCO, of a new selumetinib capsule formulation that replaces the mix/drink formulation used in all prior trials to that time. AstraZeneca reported that the new capsule's maximum tolerated dose was 25% lower yet provided, on average, higher exposure than historical values for the mix/drink formulation. AstraZeneca also reported a complete response in one of the patients. AstraZeneca also presented at ASCO the following Phase 2 clinical trial results of selumetinib using the prior formulation:

Selumetinib compared to Alimta® (pemetrexed) in 84 non-small cell lung cancer, or NSCLC, patients: neither of these drugs demonstrated superior efficacy.

Selumetinib compared to Temodar in patients with advanced melanoma: there was no difference between the two treatment arms in the overall population comparing the safety and tolerability profile for selumetinib and these results were consistent with the results reported from the Phase 1 trial.

Selumetinib compared to Xeloda® (capecitabine) in patients with metastatic colorectal cancer: results showed that selumetinib was generally well tolerated, with neither of these drugs demonstrating superior efficacy.

AstraZeneca also reported that, in patients suffering from melanomas with RAF mutations in clinical trials, selumetinib provided partial responses in two out of 14 patients using the Phase 2 mix/drink formulation and a complete response in one out of eight patients using the Phase 1 new capsule formulation.

AstraZeneca presented at the 2009 American Association for Cancer Research annual meeting results on a Phase 2 trial of selumetinib that showed a 12% overall response rate among patients with biliary cancer.

In 2010, AstraZeneca presented at the ASCO annual meeting results of a Phase 1 clinical trial using the selumetinib capsule formulation in melanoma patients. This study evaluated two doses of selumetinib (50 mg twice daily and 75 mg twice daily) in combination with four different chemotherapies: DTIC® (dacarbazine) (1000 mg/m<sup>2</sup>), Taxotere (75 mg/m<sup>2</sup>), Tarceva® (erlotinib) (100 mg daily) or Torisel® (temsirolimus) (25 mg weekly). The study enrolled 25 melanoma patients, 18 of whom had evaluable tumors. Fourteen out of the 18 patients were treated with selumetinib plus DTIC, three with selumetinib plus Taxotere and one with selumetinib plus Torisel. Sixty-seven percent of these patients had previously failed at least one prior systemic treatment. Of the 18 patients, nine had BRAF mutations. Of those patients with BRAF mutations, five had a partial response, four had stable disease with a median time-to-progression of 31 weeks. The other nine patients had wild-type BRAF, five of whom had stable disease and four of whom had progressive disease with a median time-to-progression of eight weeks. The median time to progression difference between BRAF mutant and wild type BRAF was statistically significant (p=0.01, Wilcoxon rank-sum test). Selumetinib plus chemotherapy had a 56% response rate in patients with BRAF mutations, whereas no responses were observed in patients with wild-type BRAF. While the number of patients analyzed is small, the trend toward clinical benefit in patients with BRAF mutation is inferred. This is the first disclosed efficacy data with the new formulation of selumetinib, which provides twice the drug exposure at the preferred dose.

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During 2010, AstraZeneca completed enrollment in two Phase 2 trials with selumetinib, which are the first two randomized Phase 2 combination trials with a MEK inhibitor:

Selumetinib in combination with DTIC compared with DTIC alone in first-line melanoma patients with BRAF- mutation. The trial completed enrollment of 91 patients in March 2010 with the primary end-point of overall survival.

Selumetinib in combination with Taxotere compared with Taxotere alone in second-line non-small cell lung cancer patients with KRAS-mutation. The trial completed enrollment of approximately 80 patients in July 2010 with the primary end-point of overall survival.

Selumetinib is currently the subject of the following select additional Phase 2 trials:

Selumetinib or Temodar in patients with uveal melanoma. One hundred fifty nine patients are anticipated to enroll in this trial.

Selumetinib in combination with irinotecan in second-line patients with KRAS or BRAF mutation positive advanced or metastatic colorectal cancer. Fifty-seven patients are anticipated to enroll in this trial.

Selumetinib in combination with Tarceva in non-small cell lung cancer patients with KRAS or KRAS wild-type mutations. One hundred patients are anticipated to enroll in this trial.

Selumetinib in combination with Nexavar® (sorafenib) in patients with advanced hepatocellular cancer. One hundred patients are anticipated to enroll in this trial.

Selumetinib in combination with MK-2206 in patients with advanced colorectal cancer. Thirty eight patients are anticipated to enroll in this trial.

In addition to the selumetinib trials described above, AstraZeneca has an ongoing Phase 1 clinical trial with ASD8330 in patients with solid tumors. In March 2007, AstraZeneca reported that it had dosed its first cancer patient in a Phase 1 clinical trial with AZD8330, triggering a \$2 million milestone payment to us.

**2. *Novartis MEK162 and MEK300 MEK Inhibitor Program***

In April 2010, we granted Novartis under a License Agreement the exclusive worldwide right to develop and commercialize MEK162, which is currently in multiple Phase 1 and Phase 2 cancer trials. Also included in the agreement were ARRY-300 (also known as MEK300) and other specified MEK inhibitors. Under the agreement, we are responsible for completing the on-going Phase 1 clinical trial of MEK162 and may conduct further development of MEK162 in a specific cancer. Novartis is responsible for all other development activities. Novartis is also responsible for the commercialization of products under the agreement, subject to our option to co-detail approved drugs in the U.S.

In connection with signing the agreement, Novartis paid us \$45 million, comprising an upfront fee and an initial milestone payment. In April 2011, we received a \$10 million clinical research milestone from Novartis after Novartis had its first patient visit in a Phase 2 clinical trial. We are also eligible under the agreement to receive up to approximately \$412 million in aggregate milestone payments if all clinical, regulatory and commercial milestones specified in the agreement are achieved for MEK162 and additional commercial milestone payments for MEK300 and other MEK inhibitors Novartis elects to develop under the agreement. The agreement provides Array with double-digit royalties on worldwide sales of any approved drugs, with royalties on U.S. sales at a significantly higher level. We will pay a



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percentage of development costs up to a maximum amount with annual caps. We may opt out of paying such development costs with respect to one or more products; in which case the U.S. royalty rate would then be reduced for any such product based on a specified formula, subject to a minimum that equals the royalty rate on sales outside the U.S. and we would no longer have the right to develop or detail such product.

The agreement with Novartis will be in effect on a product-by-product and country-by-country basis until no further payments are due with respect to the applicable product in the applicable country, unless terminated earlier. Either party may terminate the agreement in the event of a material breach of a material obligation under the agreement by the other party that remains uncured after 90 days prior notice. Novartis may terminate portions of the agreement following a change in control of Array and may terminate the agreement in its entirety or on a product-by-product basis with 180 days prior notice. Array and Novartis have each further agreed to indemnify the other party for manufacturing or commercialization activities conducted by it under the agreement, negligence or willful misconduct or breach of covenants, warranties or representations made by it under the agreement.

Research suggests that the MEK pathway acts as an important axis in the proliferation of some common human tumors including melanoma, non-small cell lung, head, neck and pancreatic cancers. Increasing evidence suggests that MEK inhibition, either alone or in combination with other agents, may become an important therapeutic strategy in treating cancer. We believe MEK162 will be most effective in selected populations of cancer patients, such as those with tumors having BRAF<sup>V600E</sup> or KRAS mutations as well as in targeted combinations. MEK162 has been administered to more than 300 patients/volunteers in clinical trials for either safety assessment or the treatment of oncology or inflammatory disease. The drug has demonstrated an acceptable safety profile and has demonstrated significant pharmacodynamic responses in the completed trials.

*Development Status:* During fiscal 2011, we completed enrollment of Phase 1 dose expansion cohorts in patients with biliary tract cancer, and patients with KRAS mutant colorectal cancer and initiated a Phase 1 dose expansion cohort in patients with BRAF mutant colorectal cancer. In addition, Novartis initiated a Phase 2 open-label study to assess the safety and efficacy of MEK162 in patients with locally advanced and unresectable or metastatic malignant cutaneous melanoma harboring BRAF<sup>V600E</sup> or NRAS- mutations. The trial is designed to measure the objective response rate to treatment with MEK162 when administered orally to patients. The trial will also evaluate progression-free survival, safety and tolerability. In addition, Novartis initiated three Phase 1b combination trials over the past three months:

Safety, pharmacokinetics and pharmacodynamics of BEZ235 plus MEK162 in selected advanced solid tumor patients

Safety, pharmacokinetics and pharmacodynamics of BKM120 plus MEK162 in selected advanced solid tumor patients

MEK162 and RAF265 in adult patients with advanced solid tumors harboring RAS or BRAF<sup>V600E</sup> mutations

**3. *InterMune (being developed by Roche) Danoprevir Hepatitis C Virus NS3/4 Protease Program***

In 2002, we entered into a collaboration with InterMune for the discovery of novel small molecule inhibitors of the Hepatitis C Virus, or HCV, NS3/4A protease. Under the terms of Array's collaboration agreement with InterMune, InterMune funded certain drug discovery efforts, preclinical testing, process development and manufacturing in conformity with current Good Manufacturing Practices, or cGMP.

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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. To date, we have received \$1.8 million in milestone payments and have the potential to earn an additional \$9.0 million if all clinical and commercialization milestones are achieved under the agreement.

*Development Status:* From 2002 to 2007, scientists from Array and InterMune collaborated on discovery activities that resulted in the joint discovery of danoprevir, which was acquired by Roche in October 2010 for \$175 million. During 2008, InterMune advanced danoprevir in a Phase 1b multiple ascending dose clinical trial evaluating danoprevir in combination with standard of care therapies in treatment-naïve patients with chronic HCV genotype 1 infection. Results from the trial showed that danoprevir in combination with standard of care resulted in rapid and persistent reductions in HCV RNA in the patients. In addition, viral rebound was not observed in any patients receiving the treatment and danoprevir in combination with standard of care was safe and generally well-tolerated over 14 days.

During 2009, InterMune initiated a Phase 2b trial evaluating danoprevir in combination with standard of care therapies. In April 2010, InterMune announced top-line results from a planned interim analysis of the trial. Danoprevir was administered at either 300 mg three times daily, 600 mg twice daily or 900 mg twice daily for 12 weeks in combination with PEGASYS® (pegylated interferon alfa-2a) and COPEGUS® (ribavirin), compared with placebo for the same duration plus PEGASYS and COPEGUS. In November 2009, InterMune reported that due to a safety signal, dosing in the 900 mg group had been stopped. InterMune reported that results from the study indicate danoprevir plus PEGASYS and COPEGUS are capable of achieving complete early virologic response rates as high as 90% compared to 43% in the placebo group. In addition, InterMune completed a Phase 1b trial (INFORM-1) of danoprevir and a polymerase inhibitor, RG7128.

*Development Status:* Danoprevir is currently being tested in the following trials:

Phase 2b trial with boosted danoprevir, PEGASYS and COPEGUS in genotype 1 +4, which enrolled 421 patients

Phase 2b trial with boosted danoprevir in triple, quad and interferon-free combinations which expects to enroll 421 patients

**4. ASLAN Pharmaceuticals ARRY-543 HER2 /EGFR Program**

In July 2011, we entered into a collaboration agreement with ASLAN Pharmaceuticals Pte Ltd to develop Array's HER2 / EGFR inhibitor, ARRY-543, which is currently entering Phase 2 development for solid tumors. Under the agreement, ASLAN will fund and develop ARRY-543 through clinical proof of concept, initially targeting patients with gastric cancer through a development program conducted in Asia. Upon achievement of proof of concept, ASLAN will identify a global partner for Phase 3 development and commercialization. Array will share a significant portion of the proceeds of such partnering transaction.

The agreement with ASLAN will remain in effect for two years after conclusion of the initial development plan, unless ASLAN has entered into a license agreement with a third party for the further development and commercialization of the program, in which case the agreement shall remain in force and effect. Either party may terminate the agreement prior to expiration of the term following breach of the agreement by the other party. ASLAN is responsible for diligently advancing development ARRY-543 under an agreed upon development plan.

ARRY-543 is a novel, selective and oral HER2 / EGFR inhibitor, and has shown clinical activity in both HER2-positive and EGFR-positive tumors. Over 200 patients have received ARRY-543 either as monotherapy or in combination with chemotherapy.

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Gastric cancer is a major public-health problem in East Asia. Patients with locally advanced, metastatic or recurrent disease have a poor prognosis, with an overall median survival of approximately 11 months. EGFR and HER2 receptors are commonly overexpressed together in gastric cancer. Recent data from pivotal studies of Herceptin indicate that the activity of this drug is limited to the subset of patients whose disease has amplified copies of the HER2 gene. We believe ARRAY-543 has the potential to augment or supersede the activity of Herceptin in this population, and in the broader population of gastric cancers that co-express both EGFR and HER2 receptors.

In a Phase 1 trial, ARRAY-543 produced prolonged stable disease in patients with solid tumors who had previously failed prior treatments. Tablets of ARRAY-543 were well-tolerated up to 500 mg twice daily dosing. Systemic concentrations of ARRAY-543 increased with escalating doses at all dose levels tested. Sixty percent of patients receiving doses of 200 mg twice daily and higher had prolonged stable disease.

In a Phase 1 expansion cohort in patients with HER2-positive metastatic breast cancer or other ErbB-family cancer, ARRAY-543 was generally well tolerated and demonstrated evidence of tumor regression and prolonged stable disease in EGFR- and HER2-expressing cancers. Twenty-one metastatic breast cancer patients were evaluated: of the 12 with available biopsies, eight were confirmed HER2-positive. Of the confirmed patients with HER2-positive metastatic breast cancer in this study, 63% had stable disease. Clinical benefit (measured by tumor regression or stable disease) was demonstrated in five of the eight confirmed HER2 patients and patients with confirmed co-expression of HER2 and EGFR tended to have the best clinical benefit. In a cohort of patients with other cancers shown to over-express HER2 and EGFR, a patient with cholangiocarcinoma experienced a tumor marker response that was accompanied by a 25% regression of target lesions.

*Development Status:* During fiscal 2011, we achieved the maximum tolerated dose and completed enrollment in three Phase 1b studies of ARRAY-543 in combination with Xeloda, Taxotere and Gemzar® (gemcitabine) in patients with solid tumors. In July 2011, ASLAN began funding further development of ARRAY-543 through clinical proof of concept, initially targeting patients with gastric cancer through a development program conducted in Asia.

**5. Eli Lilly LY2603618 CHK-1 Inhibitor Program**

In 1999 and 2000, Array entered into collaboration agreements involving small molecule ChK-1 inhibitors with ICOS Corporation. IC83 resulted from the collaboration between Array and ICOS. Eli Lilly and Company acquired ICOS in 2007. Array received a \$250 thousand milestone payment after the first patient was dosed with IC83, now LY2603618, in a Phase 1 clinical trial in early 2007. The agreements provided research funding, which has now ended. Array is entitled to receive additional milestone payments totaling \$3.5 million based on Eli Lilly's achievement of clinical and regulatory milestones with LY2603618.

*Development Status:* LY2603618 is currently in multiple Phase 1b/2 clinical trials, including four that began during the first half of 2011, in cancers such as non-small cell lung and pancreatic.

**6. Amgen AMG 151 Glucokinase Activator for Type 2 Diabetes Program**

In December 2009, Array granted Amgen the exclusive worldwide rights to our small molecule glucokinase activator (GKA) program, including AMG 151. Under the Collaboration and License Agreement with Amgen, we were responsible for completing certain Phase 1 clinical trials of AMG 151, which we completed during fiscal 2011. Amgen is also funding an agreed upon number of full-time Array employees as part of the research collaboration intended to identify and advance second-generation GKAs. Amgen is responsible for the further development and commercialization of AMG 151 and any

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resulting second-generation compounds. The agreement also provides Array with an option to co-promote any approved GKAs with Amgen in the U.S. with certain limitations.

In partial consideration for the rights granted to Amgen under the agreement, Amgen paid an up-front fee of \$60 million. Array is also entitled to receive up to approximately \$666 million in aggregate milestone payments if all clinical and commercialization milestones specified in the agreement for AMG 151 and at least one backup compound are achieved. We will also receive royalties on sales of any approved drugs developed under the agreement.

The agreement with Amgen will remain in effect on a product-by-product and country-by-country basis until no further payments are due under the agreement unless terminated earlier. Either party may terminate the agreement in the event of a material breach of a material obligation under the agreement by the other party that remains uncured after 90 days prior notice. Amgen may terminate the agreement at any time upon notice of 60 or 90 days depending on the development activities going on at the time of such notice. The parties have also agreed to indemnify each other for certain liabilities arising under the agreement.

GKAs, such as AMG 151, represent a promising new class of drugs for the treatment of Type 2 diabetes. Glucokinase is the enzyme that senses glucose in the pancreas. Glucokinase also increases glucose utilization and decreases glucose production in the liver. GKAs regulate glucose levels via a dual mechanism of action - working in both the pancreas and the liver. The activation of glucokinase lowers glucose levels by enhancing the ability of the pancreas to sense glucose, which leads to increased insulin production. Simultaneously, GKAs increase the net uptake of blood glucose by the liver. In multiple well-established preclinical models of Type 2 diabetes, AMG 151 was highly efficacious in controlling both fasting and non-fasting blood glucose, with rapid onset of effect and maximal efficacy within five to eight once daily doses. When combined with existing standard-of-care drugs (metformin, Januvia® (sitagliptin) or Actos® (pioglitazone), AMG 151 provided additional glucose control, which reached maximal efficacy after five to seven days of once-daily dosing. AMG 151 did not increase body weight, plasma triglycerides or total cholesterol, whether used as monotherapy or in combination with other diabetes drugs.

*Development Status:* During fiscal 2011, Array completed two Phase 1 studies, a multiple ascending dose trial in patients with Type 2 diabetes to evaluate safety, exposure and glucose control over a 10-day period and a relative bioavailability study assessing the effect of food and formulation on exposure. Amgen is responsible for all future development.

**7. Genentech GDC-0068, GDC-0425 (RG7602), ARRY-575 and other 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 has so far paid us milestones for nominating a clinical candidate and advancing it into regulated safety assessment testing and Phase I. In addition, Genentech has agreed to make additional potential development milestone payments and pay us royalties on any resulting product sales. Genentech is solely responsible for clinical development and commercialization of the resulting products.

In 2005, 2008 and 2009, we expanded our collaboration with Genentech to develop clinical candidates directed against an additional third, fourth and fifth 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 paid Array a total of

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\$15.5 million in up-front and milestone payments, and we have the potential to earn an additional \$60 million for all programs if Genentech continues development and achieves the remaining clinical milestones set forth in the agreement.

In September 2010, we and Genentech extended the agreement for an additional two years of funded research through January 2013. Genentech may terminate the agreement upon 120 days' notice.

In June 2011, Genentech disclosed that one collaborative drug, GDC-0068, an AKT inhibitor, was advancing to a Phase 1b, open label, dose escalation study of the safety and pharmacology of GDC-0068 in combination with either Taxotere or fluoropyrimidine plus oxaliplatin in patients with advanced solid tumors.

In August 2011, Array and Genentech, a member of the Roche Group, entered into an oncology agreement with for the development of each company's small-molecule Checkpoint kinase 1 (ChK-1) program. The programs include Genentech's compound GDC-0425 (RG7602), currently in Phase 1, and Array's compound ARRY-575, which is being prepared for an investigational new drug application to initiate a Phase 1 trial in cancer patients. Under the terms of the agreement, Genentech is responsible for all clinical development and commercialization activities. Array will receive an upfront payment of \$28 million and is eligible to receive clinical and commercial milestone payments up to \$685 million and up to double-digit royalties on sales of any resulting drugs. The agreement will remain in effect until Genentech's obligations to make milestone or royalty payments have passed or expired. Either party may terminate the agreement prior to expiration of the term following breach of the agreement by the other party, and Genentech may terminate the agreement upon at least 60 days' prior notice to Array. If Genentech terminates the agreement for breach of the agreement by Array, the license Array granted to Genentech will become irrevocable and the royalty payable to Array will be reduced to a specified percentage. If the agreement is terminated by Genentech for convenience or by Array for breach of the agreement by Genentech, the licenses Array granted to Genentech will terminate, Genentech will continue to be required to pay milestone and royalty payments on any programs for which Genentech had initiated clinical development and Array's exclusivity obligations will continue so long as Genentech is developing or commercializing at least one product subject to the agreement. Array and Genentech have also agreed to indemnify the other party for breaches of representations or warranties made under the agreement and for certain of their respective activities under the agreement.

**8. *VentiRx VTX-2337 and VTX-1463 /Toll-Like Receptor (TLR) Program***

In February 2007, we entered into a licensing and collaboration agreement with the 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 TLRs to activate innate immunity. We received equity in VentiRx as well as an up-front payment and the right to receive potential milestone payments and royalties on product sales. To date, we have received \$1.1 million in milestone payments and have the potential to earn \$57.5 million if VentiRx achieves the remaining clinical and commercial milestones under the agreement. See *Note 5 Equity Investment* to the accompanying audited financial statements included elsewhere in this Annual Report on Form 10-K for a description of the equity interest we received in VentiRx as a result of this agreement.

VentiRx has reported that it completed Phase 1 clinical trials on its first two candidates, VTX-2337 in cancer and VTX-1463 in allergy. VentiRx reported results from both trials at recent scientific meetings. Phase 1 results on VTX-1463 were reported at The American Academy of Allergy & Immunology (AAAAI) 2011 Annual Meeting in March 2011. This clinical trial assessed safety and efficacy of VTX-1463 in a randomized, placebo-controlled study in 80 patients with confirmed allergy to grass pollen. The patients

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were divided into two dosing regimens or received placebo. Group A received ascending doses of 25, 50, 75 and 100 micrograms once weekly for four weeks. Group B received once weekly administrations of 62.5 micrograms for four weeks. Patients underwent grass pollen exposure on Day 24. Both treatment groups demonstrated statistically significant improvement in the primary endpoint: allergy symptoms based on the Total Nasal Symptom Score (TNSS), a sum of scores for nasal congestion, itching, sneezing and rhinorrhea, compared to placebo ( $p=0.012$  for group A;  $p=0.008$  for Group B). TNSS is the key regulatory endpoint for allergic rhinitis. According to the AAAAI, allergic rhinitis, also known as hay fever, affects 60 million people in the U.S. Treatment was generally well-tolerated.

Phase 1 results on VTX-2337 were reported at the 2011 American Society of Clinical Oncology Annual Meeting in June 2011. Overall, VTX-2337 was well-tolerated, with the most common drug-related adverse events being mild to moderate in severity and including injection-site reactions and transient flu-like symptoms. The maximum tolerated dose of VTX-2337 was established to be 3.9 mg/m<sup>2</sup>. In addition, pharmacodynamic effects as measured by a defined panel of biomarkers identified in preclinical studies provide evidence of the biological activity of VTX-2337 in stimulating an innate immune response in cancer patients. Twenty five percent of patients (N=8) treated with VTX-2337 experienced disease stabilization based on RECIST criteria at eight weeks. Patients with disease stabilization at eight weeks received additional doses of VTX-2337, ranging from 1 to 6 additional cycles (3 to 18 additional doses), until disease progression. One patient with metastatic melanoma demonstrated tumor regression after cessation of VTX-2337 remains disease free at 18 months post-treatment.

VentiRx has also reported that it plans to advance a broad clinical development program for VTX-2337, with four clinical studies targeted to begin in 2011. These trials will evaluate VTX-2337 in multiple oncology indications in combination with a variety of anticancer agents, including chemotherapy, monoclonal antibody therapy and radiation therapy.

**9. Celgene ARRY-382 and other 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 in part to provide research funding for activities conducted by Array. We are responsible for all discovery and clinical development through Phase 1 or Phase 2a. Celgene has an option to select a limited number of drugs developed under the collaboration that are directed to up to two of four mutually selected discovery targets and will receive exclusive worldwide rights to the drugs, except for limited co-promotional rights in the U.S. Celgene's option may be exercised with respect to drugs directed at any of the four targets at any time until the earlier of completion of Phase 1 or Phase 2a trials for the drug or September 2014. Additionally, we are entitled to receive, for each drug, potential milestone payments of \$200 million if certain discovery, development and regulatory milestones are achieved and an additional \$300 million if certain commercial milestones are achieved. We will also receive royalties on net sales of any drugs. We retain all rights to the other programs.

In June 2009, the parties amended the agreement to substitute a new discovery target in place of an existing target and Celgene paid Array an up-front fee of \$4.5 million in consideration for the amendment. In September 2009, Celgene notified us that it was waiving its rights to one of the programs leaving Celgene the option to select two of the remaining three targets. In April 2010, Celgene announced names of three of our collaborative research programs: cFMS (oncology), TYK2 (inflammation) and PDGFR (fibrosis). In November 2010, Array received a \$10 million milestone payment upon filing an IND application for ARRY-382, a cFMS inhibitor, which is currently in a Phase 1 clinical trial.

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Celgene may terminate the agreement in whole, or in part with respect to individual drug development programs for which Celgene has exercised its option, upon six months' written notice to us. In addition, either party may terminate the agreement, following certain cure periods, in the event of a breach by the other party of its obligations under the agreement. Celgene can also choose to terminate its participation in any drug development program for which they have not exercised an option at any time, provided that they must give us prior notice, generally less than 30 days. In this event, all rights to the program remain with Array and we would no longer be entitled to receive milestone payments for further development or regulatory milestones we achieve if we choose to continue development of the program.

**Market Opportunity**

Our proprietary pipeline is focused on targeted drugs that treat cancer and inflammatory diseases and related pain. We believe there is a substantial opportunity in creating drugs for these diseases that meet the demand from the medical community for 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 approval with regulatory agencies such as the U.S. Food and Drug Administration, or FDA. This approach may result in a greater number of marketed drugs each aimed at a smaller subset of patients.

The worldwide market for targeted cancer drugs – the cancer drug market's fastest growing segment – is forecast to grow from \$35.0 billion in 2010 to \$71.2 billion in 2016. There remains a large need to address patients with acute or subacute pain, such as postoperative pain and musculoskeletal pain, as well as pain from chronic conditions such as osteoarthritis pain and chronic lower back pain. The worldwide market for key classes of medications used to treat these types of acute, subacute and chronic pain conditions, nonsteroidal anti-inflammatory drugs, or NSAIDs, cyclooxygenase-2, or COX-2, inhibitors, opioids, dual-acting opioids and other non-narcotic analgesics are forecast to grow from \$18.6 billion in 2010 to \$22.1 billion in 2016. The inflammatory disease market is highly diverse and includes respiratory diseases such as asthma, allergic rhinitis, and chronic obstructive pulmonary disease, or COPD; dermatological conditions such as psoriasis and atopic dermatitis; gastrointestinal disorders such as Crohn's disease and ulcerative colitis; musculoskeletal disorders such as rheumatoid arthritis, systemic lupus erythematosus, or SLE, and gout; and spondyloarthropathies such as psoriatic arthritis and ankylosing spondylitis. The inflammatory disease market is forecast to grow from \$70.0 billion in 2010 to \$85.8 billion in 2016.

In addition, the pharmaceutical 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. Due to the scarcity of later-stage clinical assets available for in-licensing, these companies have been willing to enter into licensing deals at early 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 data, before they will consider licensing a drug candidate. Accordingly, we believe there is an opportunity to license drugs at several stages during the drug development process.

***Cancer Market***

Despite a wide range of available cancer therapies, patients' treatment 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 able to specifically target the

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underlying mechanisms of the disease by regulating discrete aspects of cellular function affecting cancer cells to a greater extent than normal cells. As such, they hold the promise of being more efficacious with fewer side effects than cytotoxic chemotherapy drugs. Further, biomarkers are increasingly playing a role in both patient prognosis and drug selection. 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 targeted therapies.

According to estimates contained in the American Cancer Society, *Cancer Facts and Figures 2011*, in the U.S. there will be an estimated 1.6 million new cases of cancer in 2011 and nearly 600 thousand cancer-related deaths. The five-year relative survival rate for all cancers diagnosed between 1999 and 2006 was 68%. This represents a 50% improvement from 1975 to 1977. Earlier diagnosis and the use of new and/or better treatments have driven this improvement.

The following table shows estimated new cases diagnosed and estimated deaths in the U.S. during 2011 by major cancer types of interest to Array:

Type of Cancer	Estimated 2011	
	New Cases	Deaths
Lung	221,130	156,940
Breast	232,620	39,970
Colorectal	141,210	49,380
Melanoma	70,230	8,790
Non-Hodgkin Lymphoma	66,360	19,320
Myelodysplastic Syndromes	45,000	unknown
Pancreas	44,030	37,660
Ovarian	21,990	15,460
Stomach	21,520	10,340
Myeloma	20,520	10,610
Acute Myeloid Leukemia	12,950	9,050
Gallbladder and Other Biliary	9,250	3,300
	906,810	360,820

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." Targeted therapies and personalized medicine hold the promise of increased survival with improved quality of life.

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 cancer therapy market. Some of the targeted therapies currently on the market that have been successful include Avastin®(bevacizumab), Gleevec®(imatinib mesylate), Herceptin and Rituxan®(rituximab).

***Multiple Myeloma (ARRY-520 KSP inhibitor)***

Multiple Myeloma, or MM, 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 to fight infection and disease. MM plasma cells replace normal plasma cells that are important to maintaining the immune system.



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MM is the third most common hematologic malignancy, and garners significant sales due to the cost of treatment regimens and relatively long life expectancies among patients. Despite advances in therapy over the last ten years, it remains an incurable, fatal disease in all patients and accounts for approximately 1% of deaths worldwide. It primarily afflicts the elderly with median age at diagnosis of 68 for men and 70 for women in the U.S. The annual incidence of newly diagnosed MM patients is approximately 45 thousand in the seven major global markets (U.S., France, Germany, Italy, Spain, the U.K. and Japan) with approximately 20 thousand in the U.S. Survival has increased in recent years to approximately five years for patients able to undergo stem cell transplant in combination with high-dose targeted drug therapy. There were approximately 65 thousand patients with MM in the U.S. in 2008.

Market growth of therapies that treat MM is expected to be strong, with sales across the seven major pharmaceutical markets forecasted to grow annually by 6.6% from \$3.2 billion in 2010 to \$5.8 billion in 2019. This growth will be driven by three factors:

1. Increased efficacy of current treatments, notably the leading targeted therapies (the proteasome inhibitor Velcade, and the IMiDs Revlimid and Thalomid, leading to longer life expectancy and allowing for more drug therapy to be administered over the disease course;
2. Increased use of existing and new drug combinations, particularly combinations with Velcade and Revlimid, leading to higher overall regimen costs; and
3. Introduction and uptake of new, higher cost therapies, particularly greater uptake of Revlimid and anticipated launch of premium priced next generation proteasome inhibitors and IMiDs such as carfilzomib and pomalidomide.

Despite progress in treating MM, current treatments do not cure the disease and are accompanied by high toxicity. Patients who have become refractory to both IMiD and proteasome inhibitor therapy have a particularly poor outcome, with a median overall survival of six to nine months. Therefore, opportunities remain for drug therapies with novel mechanisms of action and/or drugs that can treat refractory patients and can act synergistically with existing leading therapies.

ARRY-520, which targets the mitotic kinesin motor protein KSP, has a distinct mechanism of action from current standard of care drugs: it has been found active in preclinical disease models where standard of care drugs have not been effective. In clinical trials, ARRY-520 has shown signs of clinical activity in heavily pre-treated patients as a single agent; it is one of the very few non-IMiD or proteasome inhibitor drugs to show single agent activity in this patient population. ARRY-520 has also shown activity in patients who have been previously treated with Revlimid and Velcade which supports the potential for further development of ARRY-520 in patients refractory to other therapies. Based on this activity, we believe ARRY-520 has potential as a single agent for treating patients with MM who are refractory to both Revlimid and Velcade, and in combination with standard of care therapies in relapsed and refractory MM.

***Myelodysplastic Syndromes (ARRY-614 p38/Tie-2 inhibitor)***

Formerly known as "pre-leukemia", the myelodysplastic syndromes (MDS) are a spectrum of diseases in which the bone marrow does not make enough normal blood cells. Patients with MDS develop severe anemia, and platelet and neutrophil cytopenias, due to bone marrow failure. As MDS progresses, patients require frequent blood and platelet transfusions, and are prone to severe and fatal infections. Approximately 30% of MDS patients progress to Acute Myeloid Leukemia (AML) which accounted for approximately 9,000 deaths in 2010 in the U.S. MDS primarily afflicts the elderly, with 86% aged 60 years or above.

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According to an article published in the Journal of Clinical Oncology, June 2010, there were 45,000 new cases of Myelodysplastic Syndromes during 2003 in the U.S. This is four to five times greater than official estimates of MDS incidence based on the National Cancer Institute Surveillance, Epidemiology and End Results Program. The analysis also concluded that MDS patients have debilitating comorbidities, with significantly greater frequency than the overall population, such as cardiac complications (73%), dyspnea (49%), diabetes (40%) and severe infections (22%). Further, over a three-year period, 40% of MDS patients died compared with 15% for the overall population of the same age. These findings on the significance of comorbidities have been demonstrated in other studies. Notably, in a recent subpopulation study of "low" grade MDS patients at M.D. Anderson Cancer Center, infections were the most common cause of disease related death (38%), with hemorrhage (13%) also significant. These findings underscore the importance of addressing aspects of the disease such as neutrophil and platelet deficiencies and may support earlier therapeutic interventions.

MDS is forecast to grow rapidly by over 12% annually from 2010 to 2017; total sales of existing therapies are projected to increase from \$653 million in 2010 to \$1.5 billion in 2017 across the seven major pharmaceutical markets. This forecast does not include additional potential growth resulting from any novel, emerging therapies. Current therapies on the market include Vidaza® (azacitidine), Revlimid and Dacogen® (decitabine). Vidaza and Revlimid will have captured nearly 80% of the market by end of 2011, although a complete response following treatment with these agents is rare. We expect the recent approvals of these agents for MDS to also drive an increase in the overall drug-treated population, because access to these agents will encourage treatment and because there are no other therapeutic drug options currently available.

A number of other therapies which target the underlying biology of the disease are being investigated in MDS. These include p38, MAPK p38 and Tie-2. p38 is well-known for its role in the regulation of cytokine and chemokine signaling and production. There is a growing understanding of the role of p38 in the modulation of apoptosis and survival, particularly in the presence of DNA damage. Tie-2 signaling may promote stromal cell senescence and production of myelosuppressive cytokines leading to inappropriate apoptosis. We believe ARRY-614, a dual p38/Tie-2 inhibitor, may be effective in the treatment of MDS, particularly "low-to-intermediate" grade, by providing clinical benefit through hematological improvement (i.e. an increase in red blood cells, neutrophil cells and platelets), thereby reducing the need for red blood cell and platelet transfusions.

***Lung Cancer (MEK162 and selumetinib MEK inhibitors)***

Lung cancer is by far the leading cause of cancer-related mortality in the U.S. Lung cancer forms in the tissues of the lung, usually in the cells lining air passages. The two main types are non-small cell lung cancer, or NSCLC, which represents about 80% of lung cancer, and small cell lung cancer, which represents about 17%. In 2011, the estimated new cases and deaths from all lung cancer in the U.S. were 221,130 and 156,940, respectively. The overall five-year relative survival rate for the period of 2001 to 2007 for patients with lung cancer was 15.6%. The five-year relative survival rate varies markedly depending on the stage at diagnosis, from 52% to 24% to 4% for patients with local, regional and distant stage disease, respectively.

Patients with resectable disease may be cured by surgery or surgery with adjuvant chemotherapy. Local control can be achieved with radiation therapy in a large number of patients with unresectable disease, but a cure is seen only in a small number of patients. Patients with locally advanced, unresectable disease may have long-term survival with radiation therapy combined with chemotherapy. Patients with advanced metastatic disease may achieve improved survival and palliation of symptoms with chemotherapy, however metastatic NSCLC remains a fatal disease.

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Market growth of NSCLC drug therapies is expected to be moderate, with sales across the seven major pharmaceutical markets forecasted to grow annually by 5.5% from \$4.0 billion in 2010 to \$6.5 billion in 2019. This growth will be driven largely by the increased uptake of Alimta and the anticipated introduction of several novel agents.

The need for more effective and less toxic therapies as alternatives to or in combination with chemotherapy has led to the investigation of targeted therapies. In NSCLC, major components of cell signaling pathways such as the Ras-Raf-MEK-MAPK pathway and components of the normal cell cycle are frequently altered, with KRAS mutations in 15% to 20% NSCLC. These provide the rationale for the evaluation of therapies that target these aberrant pathways including MEK inhibitors.

***Melanoma (MEK162 and selumetinib MEK inhibitors)***

The number of new malignant melanoma cases is increasing at a rate greater than any other human cancer. According to the American Cancer Society, the estimated new cases and deaths from melanoma in the U.S. in 2011 are 70,230 and 8,790, respectively. Melanoma is a malignant tumor of cells that make the pigment melanin and are derived from the neural crest. Although most melanomas arise in the skin, they may also arise from mucosal surfaces or at other sites to which neural crest cells migrate. Melanoma occurs predominantly in adults and more than 50% of the cases arise in apparently normal areas of the skin. Melanoma in women occurs more commonly on the extremities and in men on the trunk or head and neck, but it can arise from any site on the skin surface. Early signs in a nevus or mole that would suggest malignant change into melanoma include darker or variable discoloration, itching, an increase in size, or the development of satellite moles. Ulceration or bleeding are typically later signs.

The optimal treatment for melanoma varies with the stage of the disease. In patients with early disease, surgical excision is the treatment of choice with some of these patients receiving adjuvant therapy with interferon alfa (IFNa). Surgical excision of limited distant metastatic disease can occasionally produce durable benefit, but most patients with distant metastases require systemic therapy. Systemic therapies include chemotherapy and immunotherapy, used either alone or in combination.

Several novel targeted therapies are under study including several that target the Ras-Raf-MEK-MAPK pathway and specific molecular abnormalities such as BRAF mutation, with BRAF mutations in 40% to 45% of melanoma. The BRAF inhibitor, vemurafenib has shown promising late stage trial results in metastatic melanoma. As MEK inhibitors target the Ras-Raf-MEK-MAPK pathway which is activated with BRAF mutation, they may also have the potential for activity in BRAF mutant melanoma.

***Pancreatic Cancer (MEK162 MEK inhibitor)***

Pancreatic cancer is one of the most lethal forms of cancer. In 2011, there are an estimated 44,030 new cases and 37,660 disease related deaths in the U.S., making it the fourth highest cause of cancer-related death. The failure of numerous agents in this disease over the past decade has only augmented the already considerable unmet need.

Pancreatic cancer is a disease of the elderly, with approximately 67% of patients 65 years or older at diagnosis. However, given the disease's rapid progression and dismal prognosis, the 30% of pancreatic cancer patients between 45 and 64 years old has received considerable attention in the public consciousness. Most patients present with metastatic disease and have a median survival of only four to six months a timeframe that has remained largely unchanged over the last few decades. Underpinning this lack of progress is a poor understanding of the underlying mechanisms of the disease. While some risk factors such as smoking and diabetes have been associated with a heightened risk of the disease,

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the most readily identified factor, genetics, accounts for less than 10% of the cases. Further, no diagnostic or treatment response biomarkers have been validated for pancreatic cancer.

Treatment options for pancreatic cancer are limited and have remained largely the same over the past two decades. Surgery is the only potentially curative treatment in early stage patients, with 50-80% of resected patients relapsing following surgery. However, given the vast majority of patients present with late stage disease, palliative chemotherapy, with the leading standard of care, Gemzar, is the main treatment for most patients.

Market growth of pancreatic cancer drug therapies is expected to be modest, with sales across the seven major pharmaceutical markets forecasted to grow annually by 3.4% from \$612 million in 2010 to \$829 million in 2019. This growth, largely driven by the entry of the only significant new drug expected to be approved, Abraxane® (albumin-bound nanoparticle paclitaxel) and rapid uptake in the multi-agent cytotoxic regimen of FOLIRINOX, will be offset by Gemzar suffering continued price erosion from increased generic competition.

Several novel targeted therapies are under study, including several that target the Ras-Raf-MEK-MAPK pathway. KRAS gene mutations occur in 70-90% of pancreatic cancer patients, and thus, are thought to play a critical role in the progression and maintenance of the disease. As MEK inhibitors target the Ras-Raf-MEK-MAPK pathway, which is activated with KRAS mutation, they may also have the potential for activity in KRAS mutated pancreatic cancer.

***Colorectal Cancer (Selumetinib MEK inhibitor)***

Colon and rectal cancers, collectively referred to as colorectal cancer, is one of the most common forms of cancer. According to the American Cancer Society, in the U.S. alone in 2011, there are an estimated 141,210 new cases and 49,380 deaths, making this the second highest cause of cancer-related death in the U.S. From 2010 to 2019, the number of newly diagnosed cases of colon cancer is projected to increase by over 16% across the seven major pharmaceutical markets. Also during this period, there is projected to be a 19% growth in the number of all those living with a history of colon cancer. The risk of colorectal cancer increases exponentially with age. For this reason, the aging population in the U.S., Western Europe and Japan may result in an increase in the incidence of colorectal cancer.

Treatment of colorectal cancer is closely linked to disease stage. Treatment modalities include surgery, radiotherapy and chemotherapy. Surgical resection of the primary tumor and regional lymph nodes is the only curative treatment and may cure up to 50% of patients. Pharmaceutical therapies play an important adjunctive and palliative role in most cases of stage III and IV colorectal cancer by helping reduce the incidence of recurrence, prolonging survival and improving quality of life. Three biological agents have been approved for metastatic colorectal cancer Avastin, Erbitux® (cetuximab) and Vectibix®(panitumumab). Use of these biologics is confined to the metastatic setting, although they are being tested in the adjuvant setting.

Market growth of colorectal cancer drug therapies is expected to be nearly flat, with sales across the seven major pharmaceutical markets forecasted to grow annually by less than 1% from \$6.3 billion in 2010 to \$6.7 billion in 2019. Despite the anticipated introduction of several novel therapies, the entry of generic/bio-similar competition for key agents such as Avastin and Erbitux is expected to result in considerable price erosion of these agents.

The roles of epidermal growth factor receptor, or EGFR, and vascular endothelial growth factor receptor, or VEGF, are well established and the focus of many current pharmaceutical therapies in development for the treatment of colorectal cancer. Treatment of colorectal cancer is becoming more individualized,

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however, following recent data showing that patients with mutated KRAS genes do not respond to anti-EGFR therapy. Consequently, pharmaceutical and biotechnology companies have begun to develop therapies that are based on the testing of the presence of biomarkers, such as KRAS and, to a lesser extent, BRAF mutations, to estimate the efficacy of drugs. Testing for biomarkers is a new paradigm in the treatment of colorectal cancer and we expect biomarkers for drug efficacy to play an ever-increasing role in colorectal cancer treatment. KRAS and BRAF mutations are thought to play a critical role in colorectal cancer progression and maintenance, with approximately 40% of colorectal cancer patients exhibiting KRAS mutations, due to activation of the Ras-Raf-MEK-MAPK pathway. We believe that a therapeutic approach to block this pathway with a MEK inhibitor may provide an effective therapy in patients with colorectal cancers that have these mutations.

***Breast Cancer (ARRY-380 HER2 inhibitor)***

Breast cancer is the second most common cancer type in the U.S. with estimates of 232,620 new cases and 39,970 deaths in 2011. Approximately 24% of all breast cancer patients are HER2 positive. Herceptin is an intravenously-dosed monoclonal antibody currently on the market for the treatment of breast cancers that over express HER2 and is approved as adjuvant therapy for HER2 positive breast cancer and all lines of HER2 positive metastatic breast cancer.

Market growth of breast cancer drug therapies is expected to be low, with sales across the seven major pharmaceutical markets forecasted to grow annually by 1% from \$9.5 billion in 2010 to \$10.4 billion in 2019. Market growth will be hindered by generic erosion of several key hormonal drugs, but will be offset by growth from anticipated entry of new non-hormonal therapies such as the second generation Herceptin, trastuzumab-DM1.

Tykerb, a small molecule drug that modulates HER2 and EGFR, was approved in March 2007 for the treatment of patients with metastatic HER2 positive breast cancer 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 approximately 15% of the HER2 positive subpopulation. Tykerb's sales during 2010 were \$351 million, with 2011 worldwide sales projected at \$460 million.

We believe the broad use of Herceptin in HER2 positive settings and the increasing usage of Tykerb/Xeloda combinations in metastatic HER2 positive settings suggest a high potential value for an orally active drug that regulates HER2 and can be conveniently dosed for extended periods of time. ARRY-380 is an oral, reversible and selective HER2 inhibitor currently in a Phase 1 study expansion study to evaluate the safety, pharmacokinetics and pharmacodynamics in patients with HER2 positive breast cancer. We believe ARRY-380 has the potential to treat this patient population. ARRY-380 is selective for HER2 and does not appear to have the EGFR-related side effects seen with Tykerb.

***Pain and Inflammatory Diseases Market***

Pain and inflammation are closely interrelated, yet present distinct challenges and opportunities. Pain remains one of the most pressing as well as largest therapeutic areas to address, including a wide spectrum of acute, subacute and chronic pain conditions ranging from acute postoperative pain to chronic osteoarthritis pain. Although well established, the pain field continues to evolve and specialize, as the etiology of pain is recognized as being increasingly complex. A plethora of medications, procedures and devices marketed to address different forms of pain exist, but pain remains an area of significant unmet need. In recent years, with the exception of the introduction of antidepressant drugs such as Cymbalta® (duloxetine) and the antiepileptics Neurontin® (gabapentin) and Lyrica® (pregabalin), drug development in pain has been rather limited. Instead, drug development has focused largely around reformulations and

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alternate delivery mechanisms to provide improved safety/tolerability/drug abuse prevention among the leading existing classes of opioids and nonsteroidal anti-inflammatory drugs, or NSAIDs.

Inflammation is a natural biologic response to injury or infection that, under normal conditions, resolves during healing or clearing. 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: respiratory diseases such as asthma, allergic rhinitis, and chronic obstructive pulmonary disease, or COPD; dermatological conditions such as psoriasis and atopic dermatitis; gastrointestinal disorders such as Crohn's disease and ulcerative colitis; musculoskeletal disorders such as rheumatoid arthritis, systemic lupus erythematosus, or SLE, gout, and spondyloarthropathies such as psoriatic arthritis and ankylosing spondylitis. Similar to the pain market, there are a wide range of drug treatment options and delivery mechanisms depending on the specific condition. Yet even in acknowledged "crowded" disease areas such as asthma, there still remains significant unmet need in specific populations such as those with severe, refractory and difficult-to-control asthma.

***Pain (ARRY-797 p38 inhibitor)***

Patients are treated for almost 320 million cases per year of acute and subacute pain in the U.S. alone. Acute and subacute pain occurs under a broad set of circumstances including bone fractures, postoperative pain in planned surgical or trauma/emergency settings, severe migraine attacks, arthritis flares, and breakthrough cancer pain. For example, surgical patients typically experience moderate to severe pain up to a few weeks after the procedure.

Chronic pain presents perhaps an even more significant burden, with over half of all adults experiencing chronic pain in their lifetime. According to a recent report to the U.S. Department of Health and Human Services by the Institute of Medicine, chronic pain affects an estimated 116 million adults in the U.S. and costs the nation up to \$635 billion per year in medical treatment and lost productivity. Chronic pain, variously defined as a pain condition which persists or recurs for a duration of greater than three or greater than six months depending on the specific condition, includes a wide range of conditions including arthritic pain, inflammatory pain, chronic low back pain, fibromyalgia, neuropathic pain (e.g., postherpetic neuralgia, painful diabetic neuropathy), chronic headache, and cancer pain.

The major analgesic pain therapies currently on the market, including opioids, NSAIDs and selective COX-2 inhibitors, have side effect and efficacy issues. Opioids are the most commonly prescribed drug class in the U.S., with 15% to 20% of doctor visits involving an opioid prescription, and four million Americans per year prescribed a long-acting opioid. Opioids are efficacious in the management of pain, but have considerable side effects including nausea, vomiting, constipation, respiratory depression and cognitive dysfunction. Perhaps even more significant, opioid drug abuse is a major concern; second only to car crashes as a cause of accidental death in the U.S., opioid abuse accounted for 12,000 fatalities in 2007. NSAIDs have demonstrated pain reduction which is modest but less efficacious than opioids. Although NSAIDs have overall a more favorable safety profile than opioids, renal toxicity and gastrointestinal bleeding are associated with their use. COX-2 inhibitors though possibly offering less gastrointestinal toxicity than NSAIDs, still result in other side effects associated with NSAIDs, most notably adverse cardiovascular effects. Most drugs in this class have been withdrawn from the market, with the notable exception of Celebrex® (celecoxib).

We believe there is an opportunity for a novel drug with comparable or better efficacy than NSAIDs and COX-2 inhibitors, as well as a desire for an improved safety profile compared to NSAIDs, COX-2 inhibitors or opioids. Further, there is an opportunity in several inflammatory pain conditions affecting large populations, such as RA and ankylosing spondylitis, to offer additional pain relief over and above what current targeted therapeutics, such as tumor necrosis factor alpha, or TNF $\alpha$ , inhibitors, may provide.

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Market growth of drug therapies used in acute, subacute and chronic pain settings is expected to be moderate. Sales across the seven major pharmaceutical markets for acute and subacute pain are forecasted to grow annually by 3% from \$17.4 billion in 2010 to \$22.1 billion in 2018. Sales for chronic pain are forecasted to grow annually by 4% from \$21.1 billion in 2010 to \$29.0 billion in 2018.

Few innovative pain therapeutics have successfully emerged from clinical development in recent years and there remains a significant need for safer and more efficacious drugs for the treatment of acute, subacute and chronic pain. p38 is well-known for its role in the regulation of the production of proinflammatory cytokines such as TNF and IL-1, as well as PGE2, a significant pain modifier. Based on preclinical and clinical data, we believe ARRY-797, a p38 inhibitor, has good potential to treat a broad array of pain conditions.

***Asthma (ARRY-502 CRTh2 antagonist)***

Asthma, a chronic condition of the airways, poses one of the more significant public health burdens today. According to the American Lung Association, in 2008 an estimated 23 million individuals have asthma, resulting in approximately 4,000 deaths per year and nearly \$21 billion in medical treatment and lost productivity.

Asthma is a heterogeneous disease, caused by a combination of environmental and genetic factors, which can wax and wane, with varying frequency and severity among individual patients. Most asthma patients suffer from allergic asthma, whereby the patient's immune system produces an exaggerated response to allergens (e.g. pollens, pets, dust). Mast cells, activated by IgE, release histamine and various other mediators that cause immediate bronchospasm, or a constriction of the muscles of the airway walls, and vasoconstriction, or narrowing of bronchial blood vessels, thereby resulting in coughing and difficulty breathing. Mast cells also promote tissue damage in the airways through release of other mediators, notably cytokines, chemokines, and prostanoids such as the mediator prostaglandin D2, or PGD2, which results in the attraction of more inflammatory cells to the lungs. In severe allergic asthma, there is emerging evidence suggesting that a greater presence of PGD2 and an upregulation of CRTh2, a protein receptor that is expressed on T-helper 2, or Th2, lymphocytes, eosinophils and basophils, may play a particularly important role in greater symptoms and impairment of lung function.

Currently, for chronic maintenance treatment of asthma and other respiratory tract diseases, there are a wide range of treatment options with a variety of delivery mechanisms, each of which has drawbacks. Most notably, safety concerns have arisen with inhaled long-acting beta-2 agonists, or LABAs, and the FDA has required producers of LABAs to describe these concerns on their labels and to conduct further large-scale randomized trials. These concerns impact the leading class of LABA/ICS, or inhaled corticosteroid, combination therapies as well. The most common rescue medications are short-acting beta-2 agonists.

Market growth of asthma drug therapies is expected to be flat-to-slightly-declining, with sales across the seven major pharmaceutical markets forecasted to shrink annually by less than 1% from \$13.4 billion in 2010 to \$12.7 billion in 2019. This outlook is based on the lack of any new blockbuster drug class entering the market and a potential softening of the use of LABAs in the U.S. in the short term, and ongoing price erosion due to generic entry and competitive pricing in current therapies. This will be offset somewhat by an expected uptake of once-daily LABA/ICS combination agents, once approved, and likely increased insurance coverage and expenditures due to healthcare policy changes in the U.S. from 2014 onward.

There are a number of drug classes being explored for the treatment of asthma. Array is developing a novel oral drug, ARRY-502, which is an antagonist of the CRTh2 receptor. Upregulation of CRTh2 has also been shown to result in chemotaxis and activation of eosinophils, basophils and Th2 lymphocytes, all

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key mediators of asthma and particularly severe asthma. Therefore, ARRY-502 has the potential to be an effective treatment for patients with asthma, particularly those with severe disease, who currently have few, if any, options for effective treatment.

**Research and Development for Proprietary Drug Discovery**

Our primary research efforts are centered on the treatment of cancer and inflammatory disease. 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. 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 2011, 2010 and 2009, we spent \$63.5 million, \$72.5 million and \$89.6 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.

***Drug Discovery and Development Timeline***

The drug development process is highly uncertain, is 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.

<b>Phase</b>	<b>Objective</b>	<b>Estimated Duration</b>
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 the safety and tolerability of the drug in human subjects and find the maximum tolerated dose. The pharmacokinetics of the drug are examined after single and multiple doses, the effects of food on the pharmacokinetics may be evaluated and drug metabolites may be monitored.	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



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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 initial safety and efficacy data are established.

**Our Research and Development Technologies and Expertise**

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

Discovery Research    Biology, Chemistry and Translational Medicine

Process Research, Development, Formulation and Manufacturing

Clinical Development    Clinical Science, Clinical Operations, Translational Medicine, Biostatistics & Data Management, Regulatory Affairs and Program Management

Information Technology

***Discovery 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 breadth of knowledge, refine our processes and hire key scientists who 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. To date, our average cost to invent a new chemical entity and file an IND application is \$15 million, compared to estimates of up to \$100 million spent by major pharmaceutical companies. Our discovery group has created high quality clinical candidates with every wholly-owned and to our knowledge, every partnered, drug to reach the clinic to date having been shown to modulate its mechanistic target, as measured by an appropriate clinical biomarker.

***Process Research, Development, Formulation and Manufacturing***

We have built and we continue to enhance our process research and development and cGMP manufacturing capabilities to accommodate the productivity of our research platform and support our clinical development plans. Our capabilities include formulations, physical form characterization and aspects of clinical supply manufacturing.

***Clinical Development***

Our current key capabilities within clinical development include clinical science, clinical operations, clinical pharmacology, safety monitoring, biostatistics, programming and data management, regulatory strategy and program management. This group leads the development and implementation of our clinical and regulatory strategies. 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 ensuring 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.

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Our near term focus is on bringing our most promising 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."

***Information Technology***

We believe that our information technology, or IT, capabilities provide a competitive advantage in each aspect of our business. Our IT capabilities are essential to increasing our productivity through capturing, organizing and providing appropriate information to improve decision-making. Several years ago, we accomplished our goal of creating a paperless discovery research environment, which has empowered our scientists to improve real time decision-making at the bench. Array has recently completed a clinical information system that parallels the comprehensive capabilities of our discovery system, providing company-wide access to real-time information for each clinical trial as well as the entire drug portfolio. In addition to real-time study data, the system's information includes planned and actual screening/enrollment at the site level, budget and actual costs by types of activities, important events and milestones. We believe Array now has one of the most advanced clinical IT systems in the entire drug industry.

**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 are 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 of 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 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 extensive pre- and post-market regulation by FDA, including regulations that govern the testing, manufacturing, distribution, safety, efficacy, approval, labeling, storage, record keeping, reporting, advertising and promotion of such

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products under the Federal Food, Drug, and Cosmetic Act and its implementing regulations, and by comparable agencies and laws in foreign countries. Prescription drug products are subject to rigorous preclinical and clinical testing and other approval procedures by the FDA and by foreign regulatory agencies. The FDA must approve any new drug, including a new dosage form or new use of a previously approved drug, prior to marketing in the United States. All applications for FDA approval must contain, among other things, information relating to safety and efficacy, pharmaceutical formulation, stability, manufacturing, processing, packaging, labeling and quality control information. The preclinical and clinical testing and approval process requires substantial time, effort and financial resources, and we cannot be certain that the FDA will grant approval for any of our product candidates on a timely basis, if at all. Before an application requesting FDA approval for a new drug product is submitted to the FDA, 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 even several thousand patient volunteers representing the drug's targeted population. In addition, biopharmaceutical companies may elect to conduct, or be required by the FDA to conduct, Phase 4 clinical trials to further assess the drug's safety or effectiveness after approval. Such post approval trials are typically referred to as Phase 4 clinical trials. 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., including Good Clinical Practices, or GCP, and in other countries in which we conduct development activities could result in failure to obtain approval, as well as a variety of fines and sanctions, such as warning letters, product recalls, product seizures, suspension of operations, fines and civil penalties or criminal prosecution.

Biopharmaceutical companies must submit the results of product development, preclinical studies and clinical trials to the FDA as part of a new drug application, or NDA. NDAs must also contain extensive information relating to the product's pharmacology, chemistry, manufacture, controls and proposed labeling, among other things. 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 comprehensive requirements under federal, state and foreign 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 or similar agencies in other countries 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 under a New Drug Application, or NDA, 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. The laws of other key markets likewise create both opportunities for exclusivity periods and patent protections and the possibility of generic competition once such periods or protections either have reached expiry or have been successfully challenged by generic entrants.

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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. Our production takes place at a manufacturing facility that complies with cGMP, which allows us to produce cGMP compliant compounds. In our facility, we have the capacity to produce Active Pharmaceutical Ingredients for early 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 other countries or of our collaborators, which may be more stringent than regulatory requirements and which can delay timely progress in our clinical development programs. 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. Other countries have similar regulatory powers. 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 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 and the recent amendments to HIPAA. Additionally, strict personal privacy laws in other countries affect pharmaceutical companies' activities in other countries. Such laws include the EU Directive 95/46-EC on the protection of individuals with regard to the processing of personal data as well as individual EU Member States, implementing laws and additional laws. Although our clinical development efforts are not barred 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 EU's disclosure standards. Failure by EU clinical trial partners to obey requirements of national laws on private personal data, including laws implementing the EU Data Protection Directive, might result in liability and/or adverse publicity. 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 frequently contract with third-party manufacturers to produce larger quantities of 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 U.S. by the FDA and in foreign jurisdictions, including, in the EU, under laws adopted by the EU Member States implementing the Community Code on Medicinal Products Directive 2001/83, as amended. These regulations generally impose various requirements on us and/or our third-party manufacturers. In some cases, for example in the EU, there are cGMP requirements that exceed the requirements of the FDA. In other cases, we must provide confirmation that we are registered with the FDA and have either a Notice of a Claimed Exception for an IND application, an approved New Drug Application or an approved Biologics License Application. Third party manufacturers may lack capacity to meet our needs go out of business or fail to perform. In addition, supplies of raw materials needed for manufacturing or formulation of clinical supplies may not be available or in shorty supply.

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We are subject to other regulations, including regulations under the Occupational Safety and Health Act, regulations promulgated by the U.S. Department of Agriculture, or USDA, and regulations under other federal, state and local laws. Violations of any of these requirements could result in penalties being assessed against us.

**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. The failure of our employees, our consultants or third parties to maintain secrecy of our drug discovery and development efforts may compromise or prevent our ability to obtain patent coverage for our invention.

Our patent strategy is designed to protect inventions, technology and improvements to inventions that are commercially important to our business. We have numerous U.S. patents and 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. Currently, none of our patents covering drugs currently under development will expire prior to 2023. 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 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

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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, 2011, we had 259 full-time employees, including 152 scientists and 44 clinical and regulatory employees, of whom 80 have PhDs or MDs. 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, 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.

Additionally, the documents we file or furnish with the SEC are available free of charge at the SEC's Public Reference Room at 100 F Street, NE, Washington D.C. 20549, or can be accessed free of charge on the website maintained by the SEC at <http://www.sec.gov>. Other information on the operation of the Public Reference Room is available by calling the SEC at (800) SEC-0330.

**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**

*If we need but are unable to obtain additional funding to support our operations, we could be required to reduce our research and development activities or curtail our operations and it may lead to uncertainty about our ability to continue to operate as a going concern.*

We have expended substantial funds to discover and develop our drug candidates and additional substantial funds will be required for further development, including preclinical testing and clinical trials of any product candidates we develop internally. Additional funds will be required to manufacture and market any products we own or retain rights to that are approved for commercial sale. Because the successful development of our products is uncertain, we are unable to precisely estimate the actual funds we will require to develop and potentially commercialize them.

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We have historically funded our operations through revenue from our collaborations and out-license transactions, the issuance of equity securities and debt financing. We currently believe that our existing cash resources will enable us to continue to fund our current operations for at least the next 12 months. However, we will continue to be dependent upon such sources for the foreseeable future. Our ability to obtain additional funding when needed, changes to our operating plans, our existing and anticipated working capital needs, the acceleration or modification of our planned research and development activities or expenditures, increased expenses or other events may affect our need for additional capital in the future and may require us to seek additional funding sooner than anticipated. Additional funding may include milestone payments under existing collaborations, up-front fees or research funding through new out-licensing transactions, sales of debt or equity securities and/or securing additional credit facilities.

If we are unable to generate enough revenue or secure additional sources of funding and/or reduce our current rate of research and development spending or further reduce our expenses, we may be required to curtail operations significantly, which could prevent us from successfully executing our operating plan and could raise substantial doubt as to our ability to continue as a going concern in future periods. Even if we are able to secure the additional sources of funding, it may not be on terms that are favorable or satisfactory to us and may result in significant dilution to our stockholders. These events may result in an inability to maintain a level of liquidity necessary to continue operating our business and the loss of all or part of the investment of our stockholders in our common stock. In addition, if we are unable to maintain certain levels of cash and marketable securities, our obligations under our credit facilities with Deerfield Private Design Fund, L.P. and Deerfield Private Design International Fund, L.P. (who we refer to collectively as Deerfield) and our loan agreement with Comerica Bank may be accelerated.

***We have a history of operating losses and may not achieve or sustain profitability.***

We have incurred significant operating and net losses and negative cash flows from operations since our inception. As of June 30, 2011, we had an accumulated deficit of \$547.2 million. We had net losses of \$56.3 million, \$77.6 million and \$127.8 million, for the fiscal years ended June 30, 2011, 2010 and 2009, respectively. We expect to incur additional losses and negative cash flows in the future, and these losses may continue or increase in part due to anticipated levels of expenses for research and development, particularly clinical development and expansion of our clinical and scientific capabilities to support ongoing development of our programs. As a result, we may not be able to achieve or maintain profitability.

***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. Several of our out-license and collaboration agreements provide for royalties on product sales. However, because 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, 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.

***We may not be successful in entering into additional out-license agreements on favorable terms, which may adversely affect our liquidity or require us to change our spending priorities on our proprietary programs.***

We are committing significant resources to create our own proprietary drug candidates and to build a commercial-stage biopharmaceutical company. We have built our clinical and discovery programs

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through spending \$464.1 million from our inception through June 30, 2011. In fiscal 2011, we spent \$63.5 million in research and development for proprietary programs, compared to \$72.5 million and \$89.6 million for fiscal years 2010 and 2009, respectively. Our proprietary drug discovery programs are in their early stage of development and are unproven. Our ability to continue to fund our planned spending on our proprietary drug programs and in building our commercial capabilities depends to a large degree on up-front fees, milestone payments and other revenue we receive as a result of our partnered programs. To date, we have entered into eight out-licensing agreements for the development and commercialization of our drug candidates, and we plan to continue initiatives during fiscal 2012 to partner select clinical candidates to obtain additional capital.

We may not be successful, however, 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. These factors include:

our ability to create valuable proprietary drugs 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;

the success or failure, and timing, of pre-clinical and clinical trials for our proprietary programs we intend to out-license; or

our ability or inability to generate proof-of-concept data and to agree with a potential partner on the value of proprietary drug candidates we are seeking to out-license, or on the related terms.

If we are unable to enter into out-licensing agreements and realize milestone, license and/or up-front fees when anticipated, it may adversely affect our liquidity and we may be forced to curtail or delay development of all or some of our proprietary programs, which in turn may harm our business and the value of our stock. In addition, insufficient funds may require us to relinquish greater rights to product candidates at an earlier stage of development or on less favorable terms to us or our stockholders than we would otherwise choose to obtain funding for our operations.

***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 further 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.



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***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 early 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, we, the FDA or an Institutional Review Board 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 program in which we have invested significant resources, we will not receive any 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.

***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

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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 to fund this additional development 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.

***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 its agreement with us, our revenue may significantly decrease.***

A relatively small number of collaborators account for a significant portion of our revenue. Amgen, Genentech, Novartis and Celgene accounted for 35.9%, 22.2%, 20.8% and 20.7%, respectively, of our total revenue for fiscal 2011; and Amgen, Genentech and Celgene accounted for 28.2%, 38.6% and 26.1%, respectively, of our total revenue for fiscal 2010. We expect that revenue from a limited number of collaborators, including Amgen, Genentech, Novartis and Celgene, will account for a large portion of our revenue in future quarters. In general, our collaborators may terminate their contracts with us upon 60 to 180 days' notice for a number of reasons. 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.

***Our debt obligations could make us more vulnerable to competitive pressures or economic downturns or have other adverse consequences to us.***

A portion of our cash flow is dedicated to the payment of interest under our existing senior secured term loan with Comerica Bank, and to the payment of principal and all or a portion of the interest on our credit facilities with Deerfield. In addition, \$150 thousand and \$14.7 million in principal amount outstanding under the senior secured term loan with Comerica Bank becomes due and payable in 2012 and 2013, respectively, and \$76.8 million in principal and \$20 million in principal under the Deerfield credit facilities becomes due and payable in 2015 and 2016, respectively. We must also make prepayments on the Deerfield credit facilities in amounts equal to a percentage of certain license and milestone payments we receive under collaboration agreements entered into after January 1, 2011, which will reduce the cash available to us from those payments for use in our operations.

In the future, if we are unable to generate cash from operations sufficient to meet these debt obligations, we will need to obtain additional funds from other sources, which may include one or more financings or the license or sale of certain of our assets, or we may be forced to curtail our operations. However, we may be unable to obtain sufficient additional funds when we need them on favorable terms or at all. In addition, if we are unable to obtain financing when needed, or to fund our operations from funds received through collaboration agreements, our level of cash, cash equivalents and marketable securities may fall below thresholds specified in our debt agreements, requiring us to pay interest at a higher interest rate. Such higher interest rates could also result in a significant increase in the estimated fair value of the embedded derivative liability, which would adversely impact our reported results of operations.

Our indebtedness could have additional negative consequences, including:

increasing our vulnerability to general adverse economic conditions;

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limiting our ability to incur additional indebtedness and to undertake certain business transactions; and

placing us at a possible competitive disadvantage to less leveraged competitors and competitors that have better access to capital resources.

If an event of default occurs under our loan documents, including in certain circumstances under the warrants issued in connection with the Deerfield credit facilities, the lenders may declare the outstanding principal balance and accrued but unpaid interest owed to them immediately due and payable, which would have a material adverse effect on our financial position. We may not have sufficient cash to satisfy this obligation. Also, if a default occurs under our secured loan, and we are unable to repay the lenders, the lenders could seek to enforce their rights under their security interests in our assets. If this were to happen, we may lose or be forced to sell some or all of our assets to satisfy our debt, which could cause our business to fail.

***Negative conditions in the financial markets could affect our ability to obtain financing for development of our proprietary drug programs and other purposes on reasonable terms and have other adverse effects on us and the market price of our common stock.***

The U.S. stock and credit markets have been experiencing significant price volatility, dislocations and liquidity disruptions, which have caused market prices of many stocks to fluctuate substantially and the spreads on prospective debt financings to widen considerably. These circumstances have materially impacted liquidity in the financial markets, making terms for certain financings less attractive and in some cases have resulted in the unavailability of financing. Continued uncertainty in the stock and credit markets may negatively impact our ability to access additional financing for our research and development activities and other purposes on reasonable terms, which may cause us to curtail or delay our discovery and development efforts and harm our business. In June 2011 and January 2009, we announced plans designed to conserve our existing capital and to allow us to obtain additional capital outside the financial markets by accelerating partnering opportunities and focusing resources on advancing the development of our most advanced clinical programs. As part of these efforts we also reduced our workforce by approximately 70 and 40 employees, respectively. A prolonged downturn in the financial markets, however, may cause us to seek alternative sources of potentially less attractive financing and may require us to make further adjustments to our business plan. These events also may make it more difficult or costly for us to raise capital through the issuance of equity or debt. The disruptions in the financial markets may have a material adverse effect on the market value of our common stock and other adverse effects on us and our business.

***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, when and if additional clinical trials will commence, 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 that may prove not to be correct for a variety of reasons, many of which are beyond our control. For example, delays in the development of drugs by Array or our collaborators may be caused by regulatory or patent issues, negative or inconclusive 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 and the development priorities of our collaborators. In addition, in preparing these estimates we rely on the timeliness and accuracy of information and estimates reported or provided to us by our collaborators concerning the timing, progress and results of clinical trials or other development activities they conduct

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under our collaborations with them. 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.

***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 259 employees as of June 30, 2011 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; R. Michael Carruthers, our Chief Financial Officer; and John R. Moore, our Vice President and General Counsel. We have employment agreements with each of these employees that are terminable upon 30 days' prior notice.

**Risks Related to Our Clinical Development Activities and Obtaining Regulatory Approval for Our Programs**

***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 and could delay any product launch and we may never be able to develop this capacity. To the extent we are unable to 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.

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***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 decide not to proceed with clinical development or commercialization of a particular drug candidate for any 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.

***If we or our collaborators fail to adequately conduct clinical trials, regulatory approvals necessary for the sale of drugs may not be obtained when anticipated, or at all, which would reduce or eliminate our potential return on that program.***

Before any of our drug candidates can be sold commercially, we or our collaborators must conduct clinical trials that demonstrate that the 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 who 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 regulatory

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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, we are conducting and plan to conduct, further clinical trial activities in territories outside the U.S. through third-party clinical trial service providers that contract with clinical sites and enroll patients in foreign jurisdictions, including Eastern Europe and South America, and may do so in new geographic locations where our experience conducting clinical trials is more limited. Some of these foreign jurisdictions may impose requirements on us or our third-party clinical trial service providers or contract manufacturers that are more stringent than those imposed by the FDA, which may delay the development and approval of our drug candidates.

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.

***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 or products of our collaborators could significantly affect our product development costs and our ability to generate revenue from these products, including programs that we have out-licensed. 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 the ability of Array or our collaborators to do the following:

obtain regulatory approval to commence a clinical trial;

reach agreement on acceptable terms with prospective drug manufacturers, 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;

select CROs, trial sites and, where necessary, contract manufacturers that do not encounter any regulatory compliance problems;

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 or our collaborators' 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 or our collaborator, 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 (including Good Clinical Practices, or GCP) or our clinical protocols;

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inspection of the clinical trial operations, trial sites or manufacturing facility by the FDA or other regulatory authorities resulting in findings of non-compliance and the imposition of a clinical hold;

unforeseen safety issues or results that do not demonstrate efficacy; 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 the 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 Avandia(R) (rosiglitazone), regulatory authorities, members of Congress, the Government Accountability Office, medical professionals and the general public have raised concerns about potential post-marketing 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 of risk evaluations and mitigation strategies, or REMS, that may, for instance, restrict distribution of drug products and impose burdensome implementation requirements on the company. 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 than in years past. 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.

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***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, changes in labeling or distribution, or we may be required by FDA to develop and implement a REMS to ensure the safe use of our products. 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 high profile safety events with certain drug products, the FDA may require, as a condition of approval, a REMS that includes 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.



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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 APIs for clinical use in the U.S., must be operated in conformity with cGMP as established by the FDA. Similar requirements in other countries exist for manufacture of drug products for clinical use. These requirements include, among other things, quality control, quality assurance and the maintenance of records and documentation. If we or any contract manufacturers we use fail to comply with these requirements, we may not be able to continue the production of our products and we could be subject to civil and criminal 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 may be subject to periodic regulatory inspections to ensure compliance with cGMP requirements. In addition, we could be required to comply with specific requirements or specifications of other countries and/or of our collaborators, which may exceed applicable regulatory requirements. Failure on our part to comply with applicable regulations and specific requirements or specifications of other countries and/or 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 develop or commercialize the drug.

In addition, our pharmacology facility may be subject to FDA Good Laboratory Practices, or GLP, and the 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 GLP and 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.

***We or other third party manufacturers we rely on may encounter failures or difficulties in manufacturing or formulating clinical commercial supplies of drugs, which could delay the clinical development or regulatory approval of our drug candidates, or their ultimate commercial production if approved.***

We and third parties manufacture our drug candidates. We also from time to time manufacture drug candidates for our collaborators. We do not have manufacturing facilities that can produce sufficient quantities of active pharmaceutical ingredient, or API, and finished drug product for large-scale clinical trials. Accordingly, we must either develop such facilities, which will require substantial additional funds, or rely, at least to some extent, on third-party manufacturers for the production of drug candidates. Furthermore, should we obtain FDA approval for any of our drug candidates, we expect to rely, at least to some extent, on third-party manufacturers for commercial production. Our dependence on others for the manufacture of our drug candidates may adversely affect our ability to develop and deliver such drug candidates on a timely and competitive basis.

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Any performance failure on the part of us or a third-party manufacturer could delay clinical development, regulatory approval or, ultimately, sales of our or our collaborators' drug candidates. We or third-party manufacturers may encounter difficulties involving production yields, regulatory compliance, lot release, quality control and quality assurance, as well as shortages of qualified personnel. Approval of our drug candidates could be delayed, limited or denied if the FDA does not approve our or a third-party manufacturer's processes or facilities. Moreover, the ability to adequately and timely manufacture and supply drug candidates is dependent on the uninterrupted and efficient operation of the manufacturing facilities, which is impacted by many manufacturing variables including:

availability or contamination of raw materials and components used in the manufacturing process, particularly those for which we have no other source or supplier;

capacity of our facilities or those of our contract manufacturers;

facility contamination by microorganisms or viruses or cross contamination;

compliance with regulatory requirements, including Form 483 notices and Warning Letters;

changes in forecasts of future demand;

timing and actual number of production runs;

production success rates and bulk drug yields; and

timing and outcome of product quality testing.

In addition, we or our third-party manufacturers may encounter delays and problems in manufacturing our drug candidates or drugs for a variety of reasons, including accidents during operation, failure of equipment, delays in receiving materials, natural or other disasters, political or governmental changes, or other factors inherent in operating complex manufacturing facilities. Supply chain management is complex, and involves sourcing from a number of different companies and foreign countries. Commercially available starting materials, reagents and excipients may become scarce or more expensive to procure, and we may not be able to obtain favorable terms in agreements with subcontractors. We or our third-party manufacturers may not be able to operate our respective manufacturing facilities in a cost-effective manner or in a time frame that is consistent with our expected future manufacturing needs. If we or our third-party manufacturers cease or interrupt production or if our third-party manufacturers and other service providers fail to supply materials, products or services to us for any reason, such interruption could delay progress on our programs, or interrupt the commercial supply, with the potential for additional costs and lost revenues. If this were to occur, we may also need to seek alternative means to fulfill our manufacturing needs.

We may not be able to enter into agreements for the manufacture of our drug candidates with manufacturers whose facilities and procedures comply with applicable law. Manufacturers are subject to ongoing periodic unannounced inspection by the FDA, the DEA and corresponding state and foreign authorities to ensure strict compliance with CGMP and other applicable government regulations and corresponding foreign standards. We do not have control over a third-party manufacturer's compliance with these regulations and standards. If we or one of our manufacturers fail to maintain compliance, we or they could be subject to civil or criminal penalties, the production of our drug candidates could be interrupted or suspended, or our product could be recalled or withdrawn, resulting in delays, additional costs and potentially lost revenues.

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***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 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.

***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 manufacture API and drug product and 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 manufacturing or 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 U.S. by state and federal agencies and, as we begin to conduct clinical trials and other activities outside the U.S., in foreign countries. Due to escalating costs and difficulties associated with conducting certain types of clinical trials in the U.S., we conduct certain clinical trials in foreign locations where we have little experience, including countries in Eastern Europe and South America. 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 U.S., principally countries in Europe, intermediate and bulk API that are used in our development efforts and we contract with 3<sup>rd</sup> party service providers to prepare finished drug product, including packaging and labeling. As a result, we and our contractors are subject to regulations in the U.S. 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

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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.

***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 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 depend on 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 \$15 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.

#### **Risks Related to Our Drug Discovery Activities**

***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

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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 depend 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.

**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 and development.***

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 their ability to raise new capital and to continue to expand or fund existing research and development efforts. If our current or future biotechnology collaborators are unable to raise

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sufficient capital to fund research and development expenditures, we may not be able to expand or maintain current revenue.

***Health care reform, including those based on recently enacted legislation 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 March 2010, the President signed the Patient Protection and Affordable Care Act and the Health Care and Education Affordability Reconciliation Act of 2010, together the "Healthcare Reform Act." These laws substantially change the way health care is financed by both governmental and private insurers and significantly impacts the pharmaceutical industry. The Healthcare Reform Act contains a number of provisions that will be expected to impact our business and operations, in some cases in ways we cannot currently predict. Changes that may affect our business include those governing enrollment in federal healthcare programs, mandatory discounts on pharmaceuticals under federal health care programs, reimbursement changes and fraud and abuse enforcement. These changes will impact existing government healthcare programs and will result in the development of new programs, including Medicare payment for performance initiatives and improvements to the physician quality reporting system and feedback program.

Additional provisions of the Healthcare Reform Act, some of which become effective in 2011, may negatively affect any associated product revenues and prospects for continued profitability in the future. For example, the Healthcare Reform Act imposes a non-deductible excise tax on pharmaceutical manufacturers or importers that sell branded prescription drugs to U.S. government programs that may impact any associated product revenue and therefore revenue we are entitled to receive from royalties on product sales. In addition, as part of the Healthcare Reform Act's provisions closing a funding gap that currently exists in the Medicare Part D prescription drug program (commonly known as the "donut hole"), manufacturers of branded prescription drugs will be required to provide a 50% discount on drugs dispensed to beneficiaries within this donut hole. We expect that the Healthcare Reform Act and other healthcare reform measures that may be adopted in the future could have a material adverse effect on our industry generally and on the ability of Array or our collaborators to successfully commercialize product candidates or could limit or eliminate our future spending on development projects.

In addition to the Healthcare Reform Act, there will continue to be proposals by legislators at both the federal and state levels, regulators and third-party payors to keep healthcare costs down while expanding individual healthcare benefits. Certain of these changes could limit the prices that can be charged for drugs we develop or the amounts of reimbursement available for these products from governmental agencies or third-party payors, or may increase the tax obligations on pharmaceutical companies, increase our rebate liability and discount obligations and so may limit our commercial opportunity and reduce any associated revenue and profits. For example, federal laws require drug manufacturers to pay specified rebates to each state Medicaid program for medicines reimbursed by Medicaid and to provide discounts for out-patient medicines purchased by certain safety net providers and "disproportionate share" hospitals and for purchases by some federal governmental departments such as the Department of Veterans Affairs and the Department of Defense. The rebates paid to state Medicaid programs are based on pricing data reported by manufacturers on a monthly and quarterly basis to the Centers for Medicare and Medicaid Services, the federal agency which administers the Medicaid drug rebate program. These data include the average manufacturer price, or AMP, and in the case of innovator products, the best price for each drug. As a result of the enactment of the Healthcare Reform Act, rebates now also will be due on the utilization of Medicaid managed care organizations, effective March 23, 2010.

Pursuant to the Healthcare Reform Act, the amount of the Medicaid rebate for each unit of a drug has been increased. For innovator products, in general a drug marketed under a new drug application, or

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NDA, the minimum rebate has been increased from 15.1% to 23.1% of the AMP for that product, or if it is greater, the difference between the AMP and the best price for the drug. The Medicaid rebate for innovator products also includes an additional rebate amount if price increases for the drug exceed the rate of inflation since the product's launch, and in the case of certain line extension products, the additional rebate can be tied to the price of the original version of the product. The Healthcare Reform Act also caps the total rebate amount for innovator drugs at 100% of the AMP for the drug. In addition, the Healthcare Reform Act and subsequent legislation enacted in August of 2010 changed the definition of AMP. Regulations have not been adopted to implement any of the enacted statutory changes, other than to remove prior regulations that conflict with the new statutory requirements. There may be additional increases in rebates or other costs and charges from government agencies. Regulations continue to be issued and coverage expanded by various governmental agencies relating to these programs, increasing the cost and complexity of compliance.

Health reform also expanded the number of safety net providers and hospitals that receive discounted pricing on out-patient medicines. 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 due to a trend toward managed health care, the increasing influence of health maintenance organizations and additional legislative proposals. 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.

Other legislation affecting government expenditures more broadly have the potential to affect negatively our product revenues and prospects for continued profitability. For example, the Budget Control Act of 2011 that was signed into law on August 2, 2011 to reduce federal government expenditures may result in reduced payment rates for drugs under different government health care programs. The implementation of this law could decrease the price that we and our potential collaborators receive for our future products.

***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 or on a profitable 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' formularies. To the extent that our products are listed on third-party

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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 18 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 numerous U.S. patents and patent applications on file with the U.S. Patent and Trademark Office as well as 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 deemed 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



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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.

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 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. The failure by employees, consultants or advisors to maintain the secrecy of our confidential information may compromise or prevent our ability to obtain needed or meaningful patent protection. 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

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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 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 EU 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.

**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, 2011, our directors and officers beneficially owned or controlled approximately 11.6% of our issued and outstanding 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 and a significant portion of our revenue from these collaborations 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.

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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 \$3.58 and \$2.06, respectively, during fiscal 2011; \$4.45 and \$1.72, respectively, during fiscal 2010; and \$8.79 and \$2.51, respectively, during fiscal 2009. Our quarterly operating results, the success or failure of our internal drug discovery efforts, decisions to delay, modify or cease one or more of our development programs, negative data or adverse events reported on programs in clinical trials we or our collaborators are conducting, uncertainties about our ability to continue to fund our operating plan, 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:

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.

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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. As of June 30, 2011, we are utilizing 58 thousand square feet in our Longmont facility as discussed further under *Note 9 Restructuring Charges* contained elsewhere in this Annual Report. We also lease 11 thousand square feet of office space in Morrisville, North Carolina under a lease that expires in October 2014. We have options to extend each of the leases for up to two terms of five years each.

**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. REMOVED AND RESERVED**

Table of Contents**PART II****ITEM 5. MARKET FOR THE REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES****Common Stock Sales Prices**

Our common stock trades on the NASDAQ Global Market under the symbol "ARRY." 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.

<b>Fiscal Year Ended June 30, 2011</b>	<b>High</b>	<b>Low</b>
First Quarter	\$ 3.44	\$ 2.67
Second Quarter	\$ 3.58	\$ 2.98
Third Quarter	\$ 3.29	\$ 2.70
Fourth Quarter	\$ 3.21	\$ 2.06

<b>Fiscal Year Ended June 30, 2010</b>	<b>High</b>	<b>Low</b>
First Quarter	\$ 4.45	\$ 2.38
Second Quarter	\$ 2.81	\$ 1.72
Third Quarter	\$ 2.83	\$ 2.24
Fourth Quarter	\$ 4.02	\$ 2.66

As of August 5, 2011, there were approximately 66 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 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.

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, 2011. The graph assumes that \$100 was invested on June 30, 2006 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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Among Array BioPharma Inc., the NASDAQ Composite Index,  
the NASDAQ Pharmaceutical Index and the NASDAQ Biotechnology Index

	<b>Array BioPharma Inc.</b>	<b>NASDAQ Composite Index</b>	<b>NASDAQ Pharmaceutical Index</b>	<b>NASDAQ Biotechnology Index</b>
6/30/2006	\$ 100.00	\$ 100.00	\$ 100.00	\$ 100.00
9/30/2006	\$ 99.07	\$ 104.76	\$ 104.12	\$ 104.85
12/31/2006	\$ 150.23	\$ 113.05	\$ 107.35	\$ 108.01
3/31/2007	\$ 147.67	\$ 113.26	\$ 102.24	\$ 105.19
6/30/2007	\$ 135.70	\$ 122.33	\$ 104.58	\$ 109.89
9/30/2007	\$ 130.58	\$ 127.57	\$ 112.48	\$ 117.91
12/31/2007	\$ 97.91	\$ 124.95	\$ 102.62	\$ 110.40
3/31/2008	\$ 81.51	\$ 107.02	\$ 98.67	\$ 107.15
6/30/2008	\$ 54.65	\$ 108.31	\$ 101.46	\$ 109.17
9/30/2008	\$ 89.30	\$ 96.96	\$ 104.98	\$ 112.58
12/31/2008	\$ 47.09	\$ 74.39	\$ 96.85	\$ 103.86
3/31/2009	\$ 30.70	\$ 72.15	\$ 87.65	\$ 96.39
6/30/2009	\$ 36.51	\$ 86.75	\$ 95.54	\$ 104.37
9/30/2009	\$ 27.67	\$ 100.42	\$ 106.45	\$ 115.55
12/31/2009	\$ 32.67	\$ 107.90	\$ 105.93	\$ 117.31
3/31/2010	\$ 31.86	\$ 113.87	\$ 114.33	\$ 128.31
6/30/2010	\$ 35.47	\$ 100.42	\$ 96.21	\$ 108.44
9/30/2010	\$ 37.56	\$ 112.96	\$ 106.15	\$ 118.19
12/31/2010	\$ 34.77	\$ 126.64	\$ 112.21	\$ 124.60
3/31/2011	\$ 35.58	\$ 132.89	\$ 118.51	\$ 131.05
6/30/2011	\$ 26.05	\$ 132.75	\$ 127.07	\$ 138.55

Table of Contents**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:

	<b>Years Ended June 30,</b>				
	<b>2011</b>	<b>2010</b>	<b>2009</b>	<b>2008</b>	<b>2007</b>
<b>Revenue</b>					
License and milestone revenue	\$ 53,426	\$ 32,485	\$ 7,754	\$ 7,295	\$ 6,864
Collaboration revenue	18,475	21,395	17,228	21,513	30,106
Total revenue	71,901	53,880	24,982	28,808	36,970
<b>Operating expenses</b>					
Cost of revenue	28,916	28,322	19,855	21,364	24,936
Research and development for proprietary drug discovery	63,498	72,488	89,560	90,347	57,464
General and administrative	16,261	17,121	18,020	15,591	13,644
Total operating expenses	108,675	117,931	127,435	127,302	96,044
<b>Loss from operations</b>	(36,774)	(64,051)	(102,453)	(98,494)	(59,074)
<b>Other income (expense)</b>					
Realized gains (losses) on auction rate securities, net	1,891	1,305	(17,742)	(1,872)	-
Loss on prepayment of long-term debt, net	(6,340)	-	-	-	-
Interest income	406	864	2,116	6,064	4,610
Interest expense	(15,507)	(15,749)	(10,024)	(1,986)	(979)
Total other income (expense), net	(19,550)	(13,580)	(25,650)	2,206	3,631
<b>Loss before income taxes</b>	(56,324)	(77,631)	(128,103)	(96,288)	(55,443)
Income tax benefit	-	-	288	-	-
<b>Net loss</b>	\$ (56,324)	\$ (77,631)	\$ (127,815)	\$ (96,288)	\$ (55,443)
<b>Weighted average shares outstanding - basic and diluted</b>					
	55,447	50,216	47,839	47,309	40,717

**Net loss per share - basic and diluted**                    \$    (1.02) \$    (1.55) \$    (2.67) \$    (2.04) \$    (1.36)

	<b>2011</b>	<b>2010</b>	<b>2009</b>	<b>2008</b>	<b>2007</b>
Cash and cash equivalents, marketable securities and restricted cash	\$ 64,708	\$ 128,869	\$ 57,488	\$ 125,531	\$ 141,331
Working capital (deficit)	\$ 754	\$ 39,367	\$ (5,378)	\$ 66,346	\$ 120,827
Total assets	\$ 89,374	\$ 159,179	\$ 95,055	\$ 163,077	\$ 174,974
Long-term debt, net of discount	\$ 91,390	\$ 112,825	\$ 68,170	\$ 35,355	\$ 15,000
Total stockholders' equity (deficit)	\$ (130,858)	\$ (116,678)	\$ (73,701)	\$ 38,027	\$ 107,701

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

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 drug discovery activities conducted by Array and by our collaborators, our ability to obtain additional capital to fund our operations and/or reduce our research and development spending, realizing new revenue streams and obtaining future out-licensing collaboration agreements that include up-front milestone and/or royalty payments, our ability to realize up-front milestone and royalty payments under our existing or any future agreements, future research and development spending and projections relating to the level of cash we expect to use in operations, our working capital requirements and our future headcount requirements. In some cases, forward-looking statements can be identified by the use of terms such as "may," "will," "expects," "intends," "plans," "anticipates," "estimates," "potential," or "continue," or the negative thereof or other comparable terms. These statements are based on current expectations, projections 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 for the fiscal year ended June 30, 2011. All forward looking statements are made as of the date hereof and, unless required by law, we undertake no obligation to update any forward-looking statements.

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 annual report. Our fiscal year ends on June 30. When we refer to a fiscal year or quarter, we are referring to the year in which the fiscal year ends and the quarters during that fiscal year. Therefore, fiscal 2011 refers to the fiscal year ended June 30, 2011.

**Overview**

We are a biopharmaceutical company focused on the discovery, development and commercialization of targeted small molecule drugs to treat patients afflicted with cancer and inflammatory diseases. Our proprietary drug development pipeline includes clinical candidates that are designed to regulate therapeutically important target pathways. In addition, leading pharmaceutical and biotechnology companies partner with us to discover and develop drugs across a broad range of therapeutic areas.

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The five most advanced wholly-owned programs that we are developing internally are:

Program	Indication	Clinical Status
1. ARRY-520	Kinesin spindle protein, or KSP, inhibitor for multiple myeloma	Phase 2
2. ARRY-614	p38/Tie-2 dual inhibitor for myelodysplastic syndrome, or MDS	Phase 1
3. ARRY-380	HER2 inhibitor for breast cancer	Phase 1
4. ARRY-797	p38 inhibitor for pain	Phase 2
5. ARRY-502	CRTh2 antagonist for allergic inflammation	Phase 1

In addition to these development programs, our most advanced partnered drugs in clinical development are:

Drug Candidates	Indication	Partner	Clinical Status
1. Selumetinib and AZD8330	MEK inhibitors for cancer	AstraZeneca, PLC	Phase 2
2. MEK162 and MEK300	MEK inhibitors for cancer	Novartis International Pharmaceutical Ltd.	Phase 2
3. Danoprevir	Hepatitis C virus (HCV) protease inhibitor	InterMune (now being developed by Roche Holding AG)	Phase 2
4. ARRY-543	HER2/EGFR inhibitor for solid tumors	ASLAN Pharmaceuticals Pte Ltd.	Phase 2
5. LY2603618	ChK-1 inhibitor for cancer	Eli Lilly and Company	Phase 2
6. AMG 151	Glucokinase activator for Type 2 diabetes	Amgen Inc.	Phase 1b
7. GDC-0068	AKT inhibitor for cancer	Genentech Inc.	Phase 1b
8. VTX-2337	Toll-like receptor for cancer	VentiRx Pharmaceuticals, Inc.	Phase 1b
9. VTX-1463	Toll-like receptor for allergy	VentiRx Pharmaceuticals, Inc.	Phase 1b
10. ARRY-382	cFMS inhibitor for cancer	Celgene Corporation	Phase 1

11. ARRY-575 and  
GDC-0425

ChK-1 inhibitor for cancer

Genentech Inc.

Phase 1

*Any information we report about the development plans or the progress or results of clinical trials or other development activities of our partners is based on information that is publicly disclosed.*

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Under our partnered drug discovery programs, we are generally entitled to receive payments upon achievement of clinical development and commercialization milestones and royalties based on sales of any resulting drugs. Under our existing partnered program agreements, we have the potential to earn over \$3.5 billion in additional milestone payments if we or our collaborators achieve the drug discovery, development and commercialization objectives detailed in those agreements. We also have the potential to earn royalties on any resulting product sales or share in the proceeds from development or commercialization arrangements resulting from 12 drug research and development programs.

Additionally, we have a portfolio of proprietary and partnered drug discovery programs generated by our internal discovery efforts. Our internal drug discovery programs include inhibitors that target Trk receptors for the treatment of pain and G-protein-coupled receptor 119, or GPR-119 for the treatment of diabetes. We may choose to out-license select promising candidates through research partnerships.

We have built our clinical and discovery pipeline programs through spending \$464.1 million from our inception in 1998 through June 30, 2011. In fiscal 2011, we spent \$63.5 million in research and development expenses for proprietary drug discovery, compared to \$72.5 million and \$89.6 million for fiscal years 2010 and 2009, respectively. Over the past 20 months through the date of filing this Annual Report, we signed strategic collaborations with Amgen, Genentech and Novartis. Together these collaborations entitled Array to \$133 million in initial payments, over \$2.2 billion in potential milestone payments if all clinical and commercialization milestones under the agreements are achieved, double digit royalties and/or commercial co-detailing rights. We have received a total of \$523.3 million in research funding and in up-front and milestone payments from our collaboration partners since inception through June 30, 2011.

Our significant and / or recent collaborators under our partnered programs include:

*Amgen* We entered into a worldwide strategic collaboration with Amgen in December 2009 to develop and commercialize our glucokinase activator, AMG 151, and to discover potential back-up compounds for AMG 151.

*ASLAN Pharmaceuticals* We entered into a collaboration and license agreement with ASLAN Pharmaceuticals in July 2011 to develop Array's HER2 / EGFR inhibitor, ARRY-543, which is currently entering Phase 2 development for solid tumors.

*AstraZeneca* In December 2003, we entered into a collaboration and license agreement with AstraZeneca under which AstraZeneca received a license to three of our MEK inhibitors for cancer, including selumetinib, which is currently in multiple Phase 2 clinical trials.

*Celgene* We entered into a worldwide strategic collaboration agreement with Celgene in September 2007 focused on the discovery, development and commercialization of novel therapeutics in cancer and inflammation. The most advanced drug is ARRY-382, a cFMS inhibitor for cancer, which is currently in a Phase 1 clinical trial.

*Genentech* We entered into a worldwide strategic collaboration agreement with Genentech in January 2003, which was expanded in 2005, 2008, and 2009, and is focused on the discovery, development and commercialization of novel therapeutics. The most advanced drug is GDC-0068, an AKT inhibitor for cancer currently in a Phase 1b trial. The other programs under this collaboration are in preclinical development. In August 2011, we entered into an oncology partnership with Genentech for the development of each company's small-molecule Checkpoint kinase 1 (ChK-1) program. The programs include Genentech's compound GDC-0425 (RG7602),

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currently in Phase 1, and Array's compound, ARRY-575, which is being prepared for an investigational new drug application to initiate a Phase 1 trial in cancer patients.

*Novartis* We entered into a worldwide strategic collaboration with Novartis in April 2010 to develop and commercialize our MEK inhibitor, MEK162, and other MEK inhibitors identified in the agreement.

*InterMune (program acquired by Roche)* We entered into a collaboration with InterMune in 2002, which resulted in the joint discovery of danoprevir, a novel small molecule inhibitor of the Hepatitis C Virus NS3/4A protease. Roche acquired danoprevir from InterMune in 2010. Danoprevir is currently in Phase 2b clinical trials.

**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 general, our collaborators may terminate their collaboration agreements with 90 to 180 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. Amgen may terminate its agreement with us at any time upon notice of 60 or 90 days depending on the development activities going on at the time of such notice.

Additional information related to the concentration of revenue among our collaborators is reported in *Note 2 Segments, Geographic Information and Significant Collaborations* to the audited financial statements included elsewhere in this Annual Report.

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

**Critical Accounting Policies and Estimates**

Management's discussion and analysis of 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 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 from our collaborators for research funding, up-front or license fees and milestone payments derived from discovering and developing drug candidates. Our agreements with collaboration partners include fees based on annual rates for full-time-equivalent employees, or FTEs, working on a program and may also include non-refundable license and up-front fees, non-refundable milestone

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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 the sale of compounds on a per-compound basis. We report FTE fees for discovery and the development of proprietary drug candidates that we out-license as Collaboration Revenue. License and Milestone Revenue is combined and consists of the portion of up-front fees and ongoing milestone payments from collaborators that are recognized during the applicable period.

We recognize revenue in accordance with Staff Accounting Bulletin No. 104, *Revenue Recognition* ("SAB 104"), which establishes four criteria, each of which must be met, in order to recognize revenue for 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.

Collaboration agreements that include a combination of discovery research funding, up-front or license fees, milestone payments and/or royalties are evaluated to determine whether each deliverable under the agreement has value to the customer on a stand-alone basis and whether reliable evidence of fair value for the deliverable exists. Deliverables in an arrangement that do not meet this separation criteria are treated as a single unit of accounting, generally applying applicable revenue recognition guidance for the final deliverable to the combined unit of accounting in accordance with SAB 104.

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 estimated research or development term. These advance payments are deferred and recorded as Deferred Revenue upon receipt, pending recognition, and are classified as a short-term or long-term liability in the accompanying Balance Sheets.

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 or development term, the existence, or likelihood of achievement of development commitments and any other significant commitments of ours.

Most of our agreements provide for milestone payments. In certain cases, 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 or development term that has elapsed to the total estimated research and/or development term. In other cases, when the milestone payment is attributed to future development obligations of Array, the revenue is recognized on a straight-line basis over the estimated remaining development period. Certain milestone payments are for activities for which there are no future obligations and as a result, are recognized when earned in their entirety.

We periodically review the expected performance periods under each of our agreements that provide for non-refundable up-front payments and license fees and milestone payments and adjust the amortization periods when appropriate to reflect changes in assumptions relating to the duration of expected performance periods. Revenue recognition for non-refundable license fees and up-front payments and milestone payments could be accelerated in the event of early termination of programs or alternatively, decelerated, if programs are extended. While changes to such estimates have no impact on our reported cash flows, our reported revenue is significantly influenced by our estimates of the period over which our obligations are expected to be performed.

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***Cost of Revenue and Research and Development Expenses for Proprietary Programs***

We incur costs in connection with performing research and development activities which consist mainly of compensation, associated fringe benefits, share-based compensation, preclinical and clinical outsourcing costs and other collaboration-related costs, including supplies, small tools, facilities, depreciation, recruiting and relocation costs and other direct and indirect chemical handling and laboratory support costs. We allocate these costs between Cost of Revenue and Research and Development Expenses for Proprietary Programs based upon the respective time spent by our scientists on development conducted for our collaborators and for our internal proprietary programs. Cost of Revenue represents the costs associated with research and development, including preclinical and clinical trials, conducted by us for our collaborators. Research and Development for Proprietary Programs consists of direct and indirect costs for our specific proprietary programs. We do not bear any risk of failure for performing these activities and the payments are not contingent on the success or failure of the research program. Accordingly, we expense these costs when incurred.

Where our collaboration agreements provide for us to conduct research and development 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 its research and development costs to Cost of Revenue based on the percentage of total programs under the agreement that we conclude is likely to continue to be funded by the partner. These costs may not be incurred equally across all programs. In addition, we continually evaluate the progress of development activities under these agreements and if events or circumstances change in future periods that we reasonably believe would make it unlikely that a collaborator would continue to fund the same percentage of programs, we will adjust the allocation accordingly. See *Note 6 Deferred Revenue*, for further information about our collaborations.

***Accrued Outsourcing Costs***

Substantial portions of our preclinical studies and clinical trials are performed by third-party laboratories, medical centers, contract research organizations and other vendors (collectively "CROs"). These CROs generally bill monthly or quarterly for services performed or bill based upon milestone achievement. For preclinical studies, we accrue expenses based upon estimated percentage of work completed and the contract milestones remaining. For clinical studies, expenses are accrued based upon the number of patients enrolled and the duration of the study. We monitor patient enrollment, the progress of clinical studies and related activities to the extent possible through internal reviews of data reported to us by the CROs, correspondence with the CROs and clinical site visits. Our estimates depend on the timeliness and accuracy of the data provided by the 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.

***Marketable Securities***

We have designated our marketable securities as of each balance sheet date as available-for-sale securities and account for them at their respective fair values as discussed further below under the heading "*Fair Value Measurements*." 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. Marketable securities that are readily available for use in current operations are classified as short-term available-for-sale securities and are reported as a component of current assets in the accompanying Balance Sheets. Marketable securities that are not considered available for use in current operations (including when active markets for such securities do not exist) are classified as long-term available-for-sale securities and are reported as a component of long-term assets in the accompanying Balance Sheets.

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Securities that are classified as available-for-sale are carried at fair value, including accrued interest, with temporary unrealized gains and losses reported as a component of Stockholders' Deficit until their disposition. We review all available-for-sale securities each period to determine if they remain available-for-sale based on our then current intent and ability to sell the security if we are required to do so. The amortized cost of debt securities in this category is adjusted for amortization of premiums and accretion of discounts to maturity. Such amortization is included in Interest Income in the accompanying Statements of Operations and Comprehensive Loss. Realized gains and losses on auction rate securities, or ARS, we held along with declines in value judged to be other-than-temporary are reported in Realized Gains on Auction Rate Securities, Net in the accompanying Statements of Operations and Comprehensive Loss when recognized. The cost of securities sold is based on the specific identification method.

We sold our remaining ARS during the quarter ended March 31, 2011. Prior to their disposition, we measured the ARS under the fair value hierarchy described below under the heading "*Fair Value Measurements*," using Level III, or unobservable inputs, as there was no active market for the securities. The most significant unobservable inputs used in this method are estimates of the amount of time until an event resulting in the liquidity of the ARS will occur and the discount rate, which incorporates estimates of credit risk and a liquidity premium (discount). Due to the inherent complexity in valuing these securities, we engaged a third-party valuation firm to perform an independent valuation of the ARS as part of our overall fair value analysis beginning with the first quarter of fiscal 2009 and continuing through the quarter ended December 31, 2010.

See *Note 3 Marketable Securities* in the notes to the audited financial statements included elsewhere in this Annual Report on Form 10-K for additional information about our investments in ARS.

***Fair Value Measurements***

Our financial instruments are recognized and measured at fair value in our financial statements and primarily consist of cash and cash equivalents, marketable securities, long-term investments, trade receivables and payables, long-term debt, embedded derivatives associated with the long-term debt and warrants. We measure the fair value of assets and liabilities based on a three-level hierarchy that reflects market information available and the level of judgment involved in estimating fair values for various types of assets and liabilities. The valuation techniques we use to measure fair value are discussed in more detail in *Note 1 Overview and Basis of Presentation* to the financial statements included elsewhere in this Annual Report.

Considerable judgment is required in interpreting market and other data to develop estimates of fair value for assets or liabilities for which there are no quoted prices in active markets, which include our ARS, warrants issued by us in connection with our long-term debt and the embedded derivatives associated with the long-term debt. The use of different assumptions and/or estimation methodologies may have a material effect on their estimated fair value. Accordingly, the fair value estimates we disclose may not be indicative of the amount that we or holders of the instruments could realize in a current market exchange.

We periodically review the realizability of each investment when impairment indicators exist with respect to the investment. If an other-than-temporary impairment of the value of an investment is deemed to exist, the cost basis of the investment is written down to its then estimated fair value.

***Long-term Debt and Embedded Derivatives***

The terms of our long-term debt are discussed in detail in *Note 5 Long-term Debt* to our audited financial statements included elsewhere in this Annual Report on Form 10-K. The accounting for these



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arrangements is complex and is based upon significant estimates by management. We review all debt agreements to determine the appropriate accounting treatment when the agreement is entered into and review all amendments to our debt agreements to determine if the changes require accounting for the amendment as a modification, or as an extinguishment and new debt. We also review each long-term debt arrangement to determine if any feature of the debt requires bifurcation and/or separate valuation. These may include hybrid instruments, which are comprised of at least two components ((1) a debt host instrument and (2) one or more conversion features), warrants and other embedded derivatives, such as puts and other rights of the debt holder.

We currently have two embedded derivatives related to our long-term debt with Deerfield. One of the embedded derivatives is a variable interest rate structure that constitutes a liquidity-linked variable spread feature. The other is a significant transaction contingent put option relating to Deerfield's ability to accelerate the repayment of the debt in the event of certain changes in control of our company. Such event would occur if the acquirer did not meet certain financial conditions, based on size and credit worthiness. Collectively, they are referred to as the "Embedded Derivatives." Under the fair value hierarchy, we measure the fair value of the Embedded Derivatives using Level III, or unobservable inputs, as there is no active market for them, and calculate fair value using a combination of a discounted cash flow analysis and the Black-Derman-Toy interest rate model.

The fair value of the variable interest rate structure is based on our estimate of the probable effective interest rate over the term of the Deerfield credit facilities. Because the applicable interest rate is based on our cash position during the term of the loan, the determination of the probably effective interest rate requires us to estimate our cash flow forecasts, which include our expectations of future cash inflows from up-front fees, milestone payments and issuances of equity. The fair value of the put option is based on our estimate of the probability that a change in control that triggers Deerfield's right to accelerate the debt will occur. With those inputs, the fair value of each Embedded Derivative is calculated as the difference between the fair value of the Deerfield credit facilities if the Embedded Derivatives are included and the fair value of the Deerfield credit facilities if the Embedded Derivatives are excluded.

Due to the inherent complexity in valuing the Deerfield credit facilities and the Embedded Derivatives, we engaged a third-party valuation firm to perform the valuation as part of our overall fair value analysis. The assumptions used in determining the estimated fair value of the Embedded Derivatives were based on management's judgment and the use of different assumptions could result in significantly different estimated fair values.

The fair value of the Embedded Derivatives is recorded as a component of Other Long-term Liabilities in the accompanying Balance Sheets. We recorded fair values for the Embedded Derivatives of \$540 thousand and \$825 thousand at June 30, 2011 and 2010, respectively. The initial fair value of the Embedded Derivatives was recorded as Derivative Liabilities and as Debt Discount in our Balance Sheets. Each quarter, we determine whether any adjustments to the fair value of the Embedded Derivatives based on management's then current assumptions are necessary and record any changes in value to Derivative Liabilities in the Balance Sheets and Interest Expense in the accompanying Statements of Operations and Comprehensive Loss.

Warrants that we have issued in connection with our long-term debt arrangements have been classified as equity. We value the warrants at issuance based on a Black-Scholes option pricing model and then allocate a portion of the proceeds under the debt to the warrants based upon their relative fair values. The warrants are recorded in Stockholders' Equity with the offset to Debt Discount. The Debt Discount is being amortized from the respective draw dates to the end of the term of the Deerfield credit facilities using the effective interest method and recorded as Interest Expense in the accompanying Statements of Operations and Comprehensive Loss.

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Transaction fees paid in connection with our long-term debt arrangements that qualify for capitalization are recorded as Other Long-Term Assets in the Balance Sheets and amortized to Interest Expense in the accompanying Statements of Operations and Comprehensive Loss using the effective interest method over the term of the underlying debt agreement.

**Results of Operations*****License and Milestone Revenue***

License and Milestone Revenue is combined and consists of up-front license fees and ongoing milestone payments from collaborators.

Below is a summary of our license and milestone revenue (dollars in thousands):

	Years Ended June 30,			Change 2011 vs.		Change 2010 vs.	
	2011	2010	2009	\$	%	\$	%
License revenue	\$ 42,477	\$ 27,489	\$ 6,475	\$ 14,988	54.5%	\$ 21,014	324.5%
Milestone revenue	10,949	4,996	1,279	5,953	119.2%	3,717	290.6%
<b>Total license and milestone revenue</b>	<b>\$ 53,426</b>	<b>\$ 32,485</b>	<b>\$ 7,754</b>	<b>\$ 20,941</b>	<b>64.5%</b>	<b>\$ 24,731</b>	<b>318.9%</b>

*Fiscal 2011 compared to Fiscal 2010* During fiscal 2011, license revenue increase by approximately \$15.0 million, or 54.5%. We recognized \$9.0 million and \$8.0 million during the current fiscal year in additional license revenue under our collaborations with Amgen and Novartis, respectively. The fiscal 2011 amounts represented a full year of revenue compared to only six and three months of revenue, respectively, recognized under the these collaborations during fiscal 2010 as the collaborations were not in place for the full year. This increased revenue was partially offset by decreased revenue of \$1.6 million recognized under our collaboration with Celgene due to the longer period over which revenue is recognized following our conclusion that the remaining estimated performance period under the collaboration with Celgene extended from September 2011 to March 2012 effective October 1, 2010 (see Note 6 *Deferred Revenue Celgene Corporation* to the accompanying financial statements).

Milestone revenue increased in fiscal 2011 by \$6.0 million, or 119.2%, over the prior year. This increase consisted of \$4.0 million in additional revenue from our collaboration with Novartis resulting from the \$10.0 million milestone payment received in the fourth quarter of fiscal 2011 and from additional milestone revenue recognized under the full year of the agreement in fiscal 2011. We also recognized an additional \$2.5 million in revenue under our collaboration with Celgene from the \$10.0 million milestone payment received in the second quarter of fiscal 2011.

*Fiscal 2010 compared to Fiscal 2009* During fiscal 2010, we received \$100 million in upfront payments from new collaborations with Amgen and Novartis and \$9.8 million in milestone payments. License revenue increased approximately \$21.0 million in fiscal 2010 compared to fiscal 2009 as a result of approximately \$10.8 million in revenue for our new collaboration with Amgen, \$2.2 million in revenue for our new collaboration with Novartis and \$7.4 million in additional revenue recognized under the Celgene collaboration due to our conclusion that the remaining estimated performance period decreased from five to two years effective September 30, 2009 (see Note 6 *Deferred Revenue Celgene Corporation* to the accompanying financial statements).

Milestone revenue increased in fiscal 2010 by \$3.7 million over the prior year. The increase includes \$3.8 million in milestones recognized for the advancement of certain research programs under our collaboration with Genentech, compared with \$280 thousand of milestone revenue under our Genentech

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collaboration recognized in fiscal 2009. Additionally, we recognized \$1 million in milestone revenue from InterMune during fiscal 2010 and similarly, recognized \$1 million in milestone revenue from VentiRx during fiscal 2009.

**Collaboration Revenue**

Collaboration Revenue consists of revenue for our performance of drug discovery and development activities in collaboration with partners, which include co-development of proprietary drug candidates we out-license as well as screening, lead generation and lead optimization research, custom synthesis and process research and to a small degree the development and sale of chemical compounds.

Below is a summary of our collaboration revenue (dollars in thousands):

	Years Ended June 30,			Change 2011 vs.		Change 2010 vs.	
	2011	2010	2009	2010	2010	2009	2009
				\$	%	\$	%
Collaboration revenue	\$ 18,475	\$ 21,395	\$ 17,228	\$ (2,920)	(13.6%)	\$ 4,167	24.2%

*Fiscal 2011 compared to Fiscal 2010* Collaboration Revenue decreased by \$2.9 million, or 13.6%, in fiscal 2011. The decrease was primarily due to fewer scientists engaged on our collaboration with Genentech during the second half of fiscal 2011, which resulted in \$5.0 million less revenue compared to fiscal 2010. This decrease was partially offset by increased revenue of \$1.7 million and \$700 thousand from funded research under our collaborations with Amgen and Novartis, respectively.

*Fiscal 2010 compared to Fiscal 2009* The increase in Collaboration Revenue of \$4.2 million, or 24.2%, for the year ended June 30, 2010 was from \$4.4 million of revenue from our new collaboration with Amgen and \$500 thousand of additional revenue under our collaboration with Genentech, of which \$1 million that was recorded in the first quarter of fiscal 2010 was for the finalization of contract rates for services rendered in the prior fiscal year. This increase was offset by fewer scientists engaged on the Genentech program beginning in the third quarter of fiscal 2010 and \$800 thousand less revenue due to the expiration of our research term with VentiRx.

**Cost of Revenue**

Cost of Revenue represents costs attributable to discovery and development including preclinical and clinical trials we may conduct for our collaborators and the cost of chemical compounds sold from our inventory. These costs consist mainly of compensation, associated fringe benefits, share-based compensation, preclinical and clinical outsourcing costs and other collaboration-related costs, including supplies, small tools, travel and meals, facilities, depreciation, recruiting and relocation costs and other direct and indirect chemical handling and laboratory support costs.

Below is a summary of our Cost of Revenue (dollars in thousands):

	Years Ended June 30,			Change 2011 vs.		Change 2010 vs.	
	2011	2010	2009	2010	2010	2009	2009
				\$	%	\$	%
Cost of revenue	\$ 28,916	\$ 28,322	\$ 19,855	\$ 594	2.1%	\$ 8,467	42.6%
Cost of revenue as a percentage of total revenue	40.2%	52.6%	79.5%				

*Fiscal 2011 compared to Fiscal 2010* During fiscal 2011, Cost of Revenue increased \$594 thousand, or 2.1%, but decreased as a percentage of total revenue. The increase in absolute dollars was related to the

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restructuring charges incurred during the fourth quarter as discussed under *Note 9 Restructuring Charges Fiscal 2011 Restructuring* to the financial statements contained elsewhere in this Annual Report. We recorded \$1.3 million to Cost of Revenue from the reduction in force. In addition, related to the restructuring, we vacated a portion of one of our significant laboratory facilities at our Longmont facility and recorded \$339 thousand to Cost of Revenue in accelerated depreciation on leasehold improvements. This increase was partially offset by reduced outsourcing costs to advance our partnered programs with Amgen and Novartis through clinical trials, as our partners now bear all or an increased share of the development costs compared to the prior year. The decrease as a percentage of revenue is the result of increased License and Milestone Revenue recognized during the year which did not have a direct impact on our expenses.

*Fiscal 2010 compared to Fiscal 2009* Cost of Revenue increased in absolute dollars and decreased as a percentage of total revenue for fiscal 2010 compared to the prior year. The increase in absolute dollars was for discovery, preclinical and clinical costs for the advancement of certain collaboration programs, including Celgene and our new programs with Amgen and Novartis. These increases were offset by the change in the estimate for the Celgene cost allocation from 50% to Cost of Revenue and 50% to Research and Development Expenses for Proprietary Drug Discovery to 33.3% and 67.7%, respectively, as discussed further in *Note 6 Deferred Revenue Celgene Corporation* to the accompanying Financial Statements. In addition, there were fewer scientists engaged on our collaboration with Genentech and our research term with VentiRx, which expired in September 2009. The decrease as a percentage of total revenue was because of greater License and Milestone Revenue recognized during the 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 and clinical personnel, supplies, inventory, equipment, small tools, travel and meals, depreciation, 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.

Below is a summary of our research and development expenses by categories of costs for the periods presented (dollars in thousands):

	Years Ended June 30,			Change 2011 vs.		Change 2010 vs.	
	2011	2010	2009	\$	%	\$	%
Salaries, benefits and share-based compensation	\$ 29,082	\$ 31,358	\$ 37,887	\$ (2,276)	(7.3%)	\$ (6,529)	(17.2%)
Outsourced services and consulting	13,843	19,131	28,761	(5,288)	(27.6%)	(9,630)	(33.5%)
Laboratory supplies	9,328	10,734	10,256	(1,406)	(13.1%)	478	4.7%
Facilities and depreciation	9,702	9,697	10,649	5	0.1%	(952)	(8.9%)
Other	1,543	1,568	2,007	(25)	(1.6%)	(439)	(21.9%)
Total research and development for proprietary drug discovery	\$ 63,498	\$ 72,488	\$ 89,560	\$ (8,990)	(12.4%)	\$ (17,072)	(19.1%)

*Fiscal 2011 compared to Fiscal 2010* Research and Development Expenses for Proprietary Drug Discovery for fiscal 2011 decreased by \$9.0 million because our development costs for AMG 151 and MEK162 both shifted out of Research and Development Expenses for Proprietary Drug Discovery to Cost

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of Revenue as a result of partnering those programs with Amgen and Novartis during the third and fourth quarters of fiscal 2010, respectively. Those decreases were partially offset by the increased development costs from continuing to progress our most advanced wholly-owned drug programs through the clinic. Also included in fiscal 2011 Research and Development Expenses for Proprietary Drug Discovery were restructuring charges incurred during the fourth quarter as discussed in *Note 9 Restructuring Charges Fiscal 2011 Restructuring* within the notes to the financial statements contained elsewhere in this Annual Report. We recorded \$2.1 million and \$1.5 million to Research and Development Expenses for Proprietary Drug Discovery from the reduction in force and accelerated depreciation on leasehold improvements, respectively.

*Fiscal 2010 compared to Fiscal 2009* Research and Development Expenses for Proprietary Drug Discovery for fiscal 2010 decreased from the prior year because our development costs for AMG 151 and MEK162 shifted out of Research and Development Expenses for Proprietary Drug Discovery to Cost of Revenue as a result of partnering these programs under our collaboration agreements with Amgen and Novartis. Additionally, we reduced overall spending as we focused on the development efforts for our most advanced programs and reduced resources devoted to early discovery research, which occurred after the second quarter of fiscal 2009.

**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 Expenses for Proprietary Drug Discovery and include other management, business development, accounting, information technology and administration costs, including patent filing and prosecution, recruiting and relocation, consulting and professional services, travel and meals, sales commissions, facilities, depreciation and other office expenses.

Below is a summary of our General and Administrative Expenses (dollars in thousands):

	Years Ended June 30,			Change 2011 vs.		Change 2010 vs.	
	2011	2010	2009	2010	2009	2010	2009
				\$	%	\$	%
General and administrative	\$ 16,261	\$ 17,121	\$ 18,020	\$ (860)	(5.0%)	\$ (899)	(5.0%)

*Fiscal 2011 compared to Fiscal 2010* General and Administrative Expenses decreased \$860 thousand, or 5.0%, in fiscal 2011 compared to fiscal 2010 primarily as the result of a \$760 thousand decrease in stock compensation expense from fully vested options as well as a \$575 thousand decrease in the estimated liability for our fiscal 2011 performance bonus compared to the prior year. We also incurred approximately \$400 thousand additional expense during fiscal 2011 to obtain and protect our patents.

*Fiscal 2010 compared to Fiscal 2009* General and Administrative Expenses decreased \$899 thousand, or 5%, in fiscal 2010 compared to fiscal 2009 primarily as a result of lower patent costs.

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Below is a summary of our Other Income (Expense) (dollars in thousands):

	Years Ended June 30,			Change 2011 vs.		Change 2010 vs.	
	2011	2010	2009	2010		2009	
	\$	\$	\$	\$	%	\$	%
Realized gains (losses) on auction rate securities, net	\$ 1,891	\$ 1,305	\$ (17,742)	\$ 586	44.9%	\$ 19,047	(107.4%)
Loss on prepayment of long-term debt, net	(6,340)	-	-	(6,340)		-	
Interest income	406	864	2,116	(458)	(53.0%)	(1,252)	(59.2%)
Interest expense	(15,507)	(15,749)	(10,024)	242	(1.5%)	(5,725)	57.1%
<b>Total other income (expense), net</b>	<b>\$ (19,550)</b>	<b>\$ (13,580)</b>	<b>\$ (25,650)</b>	<b>\$ (5,970)</b>	<b>44.0%</b>	<b>\$ 12,070</b>	<b>(47.1%)</b>

Summaries of the gains and losses recorded related to our ARS are reported in *Note 5 Marketable Securities* to the accompanying financial statements.

A summary of the loss on prepayment of long-term debt, net related to the modification of the Deerfield credit facilities in May 2011 and Interest Expense are reported in *Note 8 Long-term Debt* of the accompanying financial statements.

**Income Tax Benefit**

A summary of our Income Tax Benefit follows (dollars in thousands):

	Years Ended June 30,			Change 2011 vs.		Change 2010 vs.	
	2011	2010	2009	2010		2009	
	\$	\$	\$	\$	%	\$	%
Income tax benefit	\$ -	\$ -	\$ 288	\$ -	-	\$ (288)	-

During fiscal 2009, we recorded an income tax receivable and benefit related to a research and experimentation federal income tax credit. The \$288 thousand credit relates to research expenditures we made in years prior to 2008.

**Liquidity and Capital Resources**

We have incurred operating losses and an accumulated deficit as a result of ongoing research and development spending since inception. As of June 30, 2011, we had an accumulated deficit of \$547.2 million. We had net losses of \$56.3 million, \$77.6 million and \$127.8 million for the years ended June 30, 2011, 2010 and 2009, respectively.

We have historically funded our operations from up-front fees and license and milestone payments received under our collaboration and out-licensing transactions, from the issuance and sale of equity securities and through debt provided by our credit facilities. For example, the Company has received \$132 million in the last nineteen months, including the following payments under its collaborations:

In December 2009, we received a \$60 million up-front payment from Amgen Inc. under a Collaboration and License Agreement.

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In April 2010, we received \$45 million in up-front and milestone payments under a License Agreement with Novartis Pharmaceutical International Ltd.

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In December 2010, we received a \$10 million milestone payment under a License Agreement with Celgene Corporation.

In May 2011, we received a \$10 million milestone payment under a License Agreement with Novartis Pharmaceutical International Ltd.

However, until we can generate sufficient levels of cash from our operations, which we do not expect to achieve in the foreseeable future, we will continue to utilize our existing cash, cash equivalents and marketable securities, and will continue to be dependent upon funds provided from the sources mentioned above, which may not be available or forthcoming.

Prior to the reduction in force in June 2011, we were using approximately \$20 million per quarter to fund our operations. Our estimates indicate we will save approximately \$4 million per quarter from this reduction. These savings may be partially offset by increased development costs with third parties as our wholly owned development programs progress into Phase 2 and Phase 3. Such increased spending for development costs could be reduced or eliminated if sufficient funds are not available when needed. We believe that the cash, cash equivalents and marketable securities we hold as of June 30, 2011, as well as the \$28 million upfront payment from Genentech related to the license agreement that we entered into on August 5, 2011, discussed in *Note 16 Subsequent Event* to the financial statements included elsewhere in this Annual Report, will enable us to continue to fund our operations for at least the next 12 months. Our ability to maintain sufficient liquidity to fund our operations beyond that period is dependent upon factors which may be outside our control. We believe we will continue to obtain funding through milestone payments from existing collaborations and plan to continue to satisfy most or all of our interest payment obligations under the credit facilities with Deerfield with the proceeds from sales of our common stock pursuant to the Equity Distribution Agreement with Piper Jaffray & Co. discussed in *Note 8 Equity Distribution Agreement*, or through the issuance of shares of common stock to Deerfield in accordance with our Facility Agreements with Deerfield. We may also fund operations through the sale of our debt or equity securities. Although we are currently in active licensing discussions with a number of potential partners on select programs, there can be no assurance, that we will successfully close new collaborations that provide for additional up-front fees. Furthermore, sufficient funds may not be available to us when needed from existing or future collaborations or from the proceeds of debt or equity financings.

If we are unable to obtain additional funding from these or other sources when needed or to the extent needed, it may be necessary to significantly reduce our current rate of spending through additional reductions in staff and delaying, scaling back, or stopping certain research and development programs. Insufficient funds may also require us to relinquish greater rights to product candidates at an earlier stage of development or on less favorable terms to us or our stockholders than we would otherwise choose in order to obtain up-front license fees needed to fund our operations. These events could prevent us from successfully executing our operating plan and could raise substantial doubt as to our ability to continue as a going concern in future periods.

Our ability to realize milestone or royalty payments under existing collaboration agreements and to enter into new partnering arrangements that generate additional revenue through up-front fees and milestone or royalty 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 may not be successful in generating proof-of-concept data to create partnering opportunities and, even if we are, 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 and, therefore, we may not receive milestone, royalty or other payments when anticipated or at all;



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The drug candidates we develop may not obtain regulatory approval;

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; and

The spending priorities and willingness of pharmaceutical companies to in-license drugs for further development and commercialization.

Our assessment of our future need for funding 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:

Our ability to enter into agreements to out-license, co-develop or commercialize our proprietary drug candidates and the timing of payments under those agreements throughout each candidate's development stage;

The number and scope of our research and development programs;

The progress and success of our preclinical and clinical development activities;

The progress and success of the development efforts of our collaborators;

Our ability to maintain current collaboration agreements;

The costs involved in enforcing patent claims and other intellectual property rights;

The costs and timing of regulatory approvals; and/or

The 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.

***Cash, Cash Equivalents and Marketable Securities***

Cash equivalents are 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.

Short-term marketable securities consist primarily of U.S. government agency obligations with maturities of greater than 90 days when purchased. Long-term marketable securities as of June 30, 2010 consisted primarily of our investments in ARS, all of which we have sold as of March 31, 2011. See *Note 3 Marketable Securities* to the accompanying financial statements for more information regarding our ARS.

Long-term marketable securities as of June 30, 2011 primarily related to our Deferred Compensation Plan.

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

	2011	June 30, 2010	2009	Change 2011 vs. 2010		Change 2010 vs. 2009	
				\$	%	\$	%
Cash and cash equivalents	\$ 48,099	\$ 32,846	\$ 33,202	\$ 15,253	46.4%	\$ (356)	(1.1%)
Marketable securities - short-term	15,986	78,664	7,296	(62,678)	(79.7%)	71,368	978.2%

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Marketable securities - long-term	623	17,359	16,990	(16,736)	(96.4%)	369	2.2%
Total	\$ 64,708	\$ 128,869	\$ 57,488	\$ (64,161)	(49.8%)	\$ 71,381	124.2%

Table of Contents**Cash Flow Activities**

Below is a summary of our cash flows (dollars in thousands):

	Years Ended June 30,		
	2011	2010	2009
Cash flows provided by (used in):			
Operating activities	\$ (65,940)	\$ 17,558	\$ (92,939)
Investing activities	74,073	(69,063)	29,005
Financing activities	7,120	51,149	40,688
<b>Total</b>	<b>\$ 15,253</b>	<b>\$ (356)</b>	<b>\$ (23,246)</b>

*Fiscal 2011 compared to Fiscal 2010* Net cash (used in) operating activities in fiscal 2011 was \$(65.9) million, compared to \$17.6 million of cash provided by operating activities in fiscal 2010. In fiscal 2010, we received \$105 million from Amgen and Novartis in up-front and initial milestone payments under our collaboration agreements with them which decreased our net loss compared to fiscal 2011.

Net cash provided by (used in) investing activities was \$74.1 million and \$(69.1) million in fiscal 2011 and 2010, respectively. During fiscal 2011, we invested approximately \$650 thousand more in property and equipment than we did in the prior year. Additionally, our net cash proceeds from sales of marketable securities increased by \$144 million in fiscal 2011 compared to the prior year, including increased proceeds related to sales of our ARS in the amount of \$9.3 million.

Net cash provided by financing activities was \$7.1 million and \$51.1 million for fiscal 2011 and 2010, respectively. This decrease was primarily due to receiving net proceeds of \$39.0 million from the Deerfield credit facilities in fiscal 2010. Additionally, we received approximately \$5.5 million more from sales of shares of our common stock under our Equity Distribution Agreement with Piper Jaffray & Co during fiscal 2010.

*Fiscal 2010 compared to Fiscal 2009* Net cash provided by (used in) operating activities for fiscal 2010 was \$17.6 million, compared to \$(92.9) million for fiscal 2009. The \$105 million received in fiscal 2010 from Amgen and Novartis in up-front and initial milestone payments under our collaboration agreements with them was offset by reduced spending on advancing our own proprietary programs, which decreased our net loss. Net cash provided by (used in) operating activities was also higher due to the issuance of stock as payment of 2009 employee bonuses during fiscal 2010 compared to the cash bonus distribution during the prior year.

Net cash provided (used in) by investing activities was \$(69.1) million and \$29.0 million in fiscal 2010 and 2009, respectively. During the fiscal 2010, we invested \$1.6 million less in property and equipment than we did in the prior year because of our plan to reduce overall spending. During the first quarter of fiscal 2010, we liquidated our non-ARS marketable securities as they matured. During the fourth quarter of fiscal 2010, we began investing again in longer term U.S. government backed securities.

Net cash provided by financing activities was \$51.1 million and \$40.7 million for fiscal 2010 and 2009, respectively. This increase was primarily due to receiving net proceeds of \$11.0 million from sales of shares of our common stock under our Equity Distribution Agreement with Piper Jaffray & Co. Both years include net proceeds of \$39.0 million from the Deerfield credit facilities.

Table of Contents**Obligations and Commitments**

The following table shows our contractual obligations and commitments as of June 30, 2011 (dollars in thousands):

	<b>Less Than 1 Year</b>	<b>1 to 3 Years</b>	<b>4 to 5 Years</b>	<b>Over 5 Years</b>	<b>Total</b>
Debt obligations <sup>(1)</sup>	\$ 150	\$ 14,700	\$ 96,762	\$ -	\$ 111,612
Interest on debt obligations <sup>(3) (4)</sup>	7,233	14,136	8,250	-	29,619
Operating lease commitments <sup>(2)</sup>	8,059	16,433	16,487	368	41,347
Purchase obligations <sup>(2)</sup>	9,148	5,486	-	-	14,634
<b>Total</b>	<b>\$ 24,590</b>	<b>\$ 50,755</b>	<b>\$ 121,499</b>	<b>\$ 368</b>	<b>\$ 197,212</b>

(1) Reflected in the accompanying Condensed Balance Sheets.

(2) These obligations are not reflected in the accompanying Condensed Balance Sheets.

(3) Interest on the variable debt obligations under the Term Loan with Comerica Bank is calculated at 3.25%, the interest rate in effect as of June 30, 2011.

(4) Interest on the variable debt obligation under the credit facilities with Deerfield is calculated at 7.5%, the interest rate in effect as of June 30, 2011.

We are obligated under non-cancelable operating leases for all of our facilities and to a limited degree, equipment leases. Original lease terms for our facilities in effect as of June 30, 2011 were five to 10 years and generally require us to pay the real estate taxes, certain insurance and other operating costs. Equipment lease terms generally range from three to five years.

Purchase obligations totaling \$7.0 million are for outsourced services for clinical trials and other research and development costs. Purchase obligations totaling \$2.6 million are for software related expenses. The remaining \$5.0 million is for all other purchase commitments.

**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 and fluctuations in interest rates. Following the disposition of our remaining ARS in the quarter ended March 31, 2011, we no longer have liquidity risk associated with our ARS/marketable securities. 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, 2011, we have had little or no exposure to market risk from changes in foreign currency or exchange rates.

Our investment portfolio is comprised primarily of readily marketable, high-quality securities diversified and structured to minimize market risks. We target our average portfolio maturity at one year or less. Our exposure to market risk for changes in interest rates relates primarily to our investments in marketable securities. Marketable securities held in our investment portfolio are subject to changes in market value in response to changes in interest rates and liquidity. A significant change in market interest rates could have a material impact on interest income earned from our investment portfolio. A theoretical 100 basis point change in interest rates and security prices would impact our annual net loss positively or negatively by \$647 thousand based on the current balance of \$64.7 million of investments classified as cash and cash equivalents and short-term and long-term marketable securities available for sale.

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As of June 30, 2011, we had \$111.6 million of debt outstanding, exclusive of the debt discount of \$20.0 million. The term loan under our senior secured Term Loan with Comerica Bank of \$14.8 million is variable rate debt. Assuming constant debt levels, a theoretical change of 100 basis points on our current interest rate of 3.25% on the Comerica debt as of June 30, 2011 would result in a change in our annual interest expense of \$148 thousand. The interest rate on our long-term debt under the credit facilities with Deerfield is variable based on our total cash, cash equivalents and marketable securities balances. However, as long as our total cash, cash equivalents and marketable securities balances remain above \$50 million, our interest rate is fixed at 7.5%. Assuming constant debt levels, a theoretical change of 100 basis points on our current rate of interest of 7.5% on the Deerfield credit facilities as of March 31, 2011 would result in a change in our annual interest expense of \$968 thousand.

Historically and as of June 30, 2011, we have not used foreign currency 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 as of June 30, 2011 to ensure that information we are required to disclose in reports that we file or furnish under the Securities Exchange Act of 1934: (1) is recorded, processed and summarized effectively 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.

**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 our internal control over financial reporting as part of this Annual Report on Form 10-K for the year ended June 30, 2011. Our independent registered public accounting firm also audited and reported on the effectiveness of our internal control over financial reporting. Management's report and the independent registered public accounting firm's attestation

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report are included under the captions entitled "Management's Report on Internal Control Over Financial Reporting" and "Report of Independent Registered Public Accounting Firm" in Item 15 of this Annual Report on Form 10-K and are incorporated herein by reference.

**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 year ended June 30, 2011 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**

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The information required by Part III is omitted from this report because we will file a definitive proxy statement within 120 days after the end of our 2011 fiscal year pursuant to Regulation 14A for our 2011 Annual Meeting of Stockholders to be held on October 26, 2011 (the "2011 Proxy Statement"), and the information referenced below to be included in this Part III is incorporated by reference from the 2011 Proxy Statement.

**ITEM 10. DIRECTORS, EXECUTIVE OFFICERS OF THE REGISTRANT AND CORPORATE GOVERNANCE**

The information required by this item concerning our executive officers and our directors and nominees for director, our audit committee and audit committee financial expert, and compliance with the reporting requirements of Section 16(a) is incorporated by reference from the information in the 2011 Proxy Statement under the captions "Proposal 1 Election of Directors," "Executive Officers" and "Section 16(a) Beneficial Ownership Reporting Compliance."

**Code of Ethics**

We have adopted a Code of 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 Conduct is posted under the Investor Relations portion of our website at [www.arraybiopharma.com](http://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 Conduct by posting such information on our website at [www.arraybiopharma.com](http://www.arraybiopharma.com) and, to the extent required by the NASDAQ Stock 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 captions "Executive Compensation," "Compensation Committee Report," "Compensation of Directors" and "Compensation Committee Interlocks and Insider Participation" contained in the 2011 Proxy Statement.

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

The information relating to security ownership of certain beneficial owners and management required by this item is incorporated by reference from the information under the caption "Principal Stockholders" contained in the 2011 Proxy Statement and the information relating to securities authorized for issuance under our equity compensation plans is incorporated by reference from the information under the caption "Proposal 2 Approval of Amendment to Employee Stock Purchase Plan" contained in the 2011 Proxy Statement.

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

The information required by this item relating to related party transactions is incorporated by reference from the information under the caption "Certain Relationships and Transactions" contained in the 2011 Proxy Statement and relating to director independence is incorporated by reference from the information

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under the caption "Proposal 1 Election of Directors Meetings of the Board of Directors and Committees of the Board of Directors" contained in the 2011 Proxy Statement.

**ITEM 14. PRINCIPAL ACCOUNTING 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 2011 Proxy Statement.



**PART IV**

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**ITEM 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES**

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

1.

*Financial Statements*

Reference is made to the Index to the financial statements as 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 pertinent 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.

Table of Contents**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 12, 2011.

ARRAY BIOPHARMA INC.

By: /s/ ROBERT E. CONWAY

Robert E. Conway  
Chief Executive Officer

**KNOW ALL PERSONS BY THESE PRESENTS**, that each person whose signature appears below constitutes and appoints Robert E. Conway, R. Michael Carruthers and John R. Moore, and each or any one of them, his true and lawful attorney-in-fact and agent, with full power of substitution and resubstitution, for him and in his name, place and stead, in any and all capacities, to sign any and all amendments (including post-effective amendments) to this report on Form 10-K, and to file the same, with all exhibits thereto, and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents, and each of them, full power and authority to do and perform each and every act and thing requisite and necessary to be done in connection therewith, as fully to all intents and purposes as he might or could do in person, hereby ratifying and confirming all that said attorneys-in-fact and agents, or any of them, or their or his substitutes or substitute, may lawfully do or cause to be done by virtue hereof.

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

<b>SIGNATURE</b>	<b>TITLE</b>	
/s/ ROBERT E. CONWAY _____ Robert E. Conway	Chief Executive Officer and Director (Principal Executive Officer)	August 12, 2011
/s/ KYLE A. LEFKOFF _____ Kyle A. Lefkoff	Chairman of the Board of Directors	August 12, 2011
/s/ R. MICHAEL CARRUTHERS _____ R. Michael Carruthers	Chief Financial Officer (Principal Financial And Accounting Officer)	August 12, 2011
/s/ FRANCIS J. BULLOCK _____ Francis J. Bullock, Ph.D.	Director	August 12, 2011
/s/ MARVIN H. CARUTHERS _____ Marvin H. Caruthers, Ph.D.	Director	August 12, 2011
/s/ KEVIN KOCH _____ Kevin Koch, Ph.D.	Director	August 12, 2011
/s/ DAVID L. SNITMAN _____ 	Director	August 12, 2011



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<b>SIGNATURE</b>	<b>TITLE</b>	
<u>/s/ GIL J. VAN LUNSEN</u> Gil J. Van Lunsen	Director	August 12, 2011
<u>/s/ DOUGLAS E. WILLIAMS</u> Douglas E. Williams, Ph.D.	Director	August 12, 2011
<u>/s/ JOHN L. ZABRISKIE</u> John L. Zabriskie, Ph.D.	Director	August 12, 2011

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**INDEX TO THE FINANCIAL STATEMENTS**

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<u>Report of Independent Registered Public Accounting Firm</u>	<u>F-4</u>
<u>Balance Sheets as of June 30, 2011 and 2010</u>	<u>F-5</u>
<u>Statements of Operations and Comprehensive Loss for the years ended June 30, 2011, 2010 and 2009</u>	<u>F-6</u>
<u>Statements of Stockholders' Equity (Deficit) for the years ended June 30, 2011, 2010 and 2009</u>	<u>F-7</u>
<u>Statements of Cash Flows for the years ended June 30, 2011, 2010 and 2009</u>	<u>F-8</u>
<u>Notes to the Financial Statements</u>	<u>F-9</u>

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**MANAGEMENT'S REPORT ON INTERNAL CONTROL OVER FINANCIAL REPORTING**

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Exchange Act Rules 13a-15(f) and 15d-15(f). Our internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles.

All internal control systems, no matter how well designed, have inherent limitations. Therefore even those systems determined to be effective can provide only reasonable assurance with respect to financial statement preparation and presentation. Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, we conducted an evaluation of the effectiveness of our internal control over financial reporting as of June 30, 2011 based on the framework set forth in Internal Control – Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). Based on that evaluation, our management concluded that, as of June 30, 2011, our internal control over financial reporting was effective.

KPMG LLP, our independent registered public accounting firm, has issued an attestation report on the effectiveness of our internal control over financial reporting as of June 30, 2011, as stated in their report, which is included elsewhere herein.

/s/ ROBERT E. CONWAY

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Robert E. Conway  
Chief Executive Officer

August 12, 2011

/s/ R. MICHAEL CARRUTHERS

---

R. Michael Carruthers  
Chief Financial Officer

August 12, 2011

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**REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM**

The Board of Directors and Stockholders  
Array BioPharma Inc.:

We have audited Array BioPharma Inc.'s internal control over financial reporting as of June 30, 2011, based on criteria established in *Internal Control - Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). Array BioPharma Inc.'s management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting, included in the accompanying *Management's Report on Internal Control over Financial Reporting*. Our responsibility is to express an opinion on the Company's internal control over financial reporting based on our audit.

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

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

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

In our opinion, Array BioPharma Inc. maintained, in all material respects, effective internal control over financial reporting as of June 30, 2011, based on criteria established in *Internal Control - Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the balance sheets of Array BioPharma Inc. as of June 30, 2011 and 2010, and the related statements of operations and comprehensive loss, stockholders' equity (deficit) and cash flows for each of the years in the three-year period ended June 30, 2011, and our report dated August 12, 2011 expressed an unqualified opinion on those financial statements.

/s/ KPMG LLP

Boulder, Colorado  
August 12, 2011

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**REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM**

The Board of Directors and Stockholders  
Array BioPharma Inc.:

We have audited the accompanying balance sheets of Array BioPharma Inc. as of June 30, 2011 and 2010, and the related statements of operations and comprehensive loss, stockholders' equity (deficit) and cash flows for each of the years in the three-year period ended June 30, 2011. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

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

In our opinion, the financial statements referred to above present fairly, in all material respects, the financial position of Array BioPharma Inc. as of June 30, 2011 and 2010, and the results of its operations and its cash flows for each of the years in the three-year period ended June 30, 2011, in conformity with U.S. generally accepted accounting principles.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), Array BioPharma Inc.'s internal control over financial reporting as of June 30, 2011, based on the criteria established in *Internal Control - Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO), and our report dated August 12, 2011 expressed an unqualified opinion on the effectiveness of the Company's internal control over financial reporting.

/s/ KPMG LLP

Boulder, Colorado  
August 12, 2011



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**ARRAY BIOPHARMA INC.**  
**Balance Sheets**  
**(Amounts in Thousands, Except Share and Per Share Amounts)**

	<b>June 30,</b>	
	<b>2011</b>	<b>2010</b>
<b>ASSETS</b>		
<b>Current assets</b>		
Cash and cash equivalents	\$ 48,099	\$ 32,846
Marketable securities	15,986	78,664
Prepaid expenses and other current assets	6,477	5,788
Total current assets	70,562	117,298
<b>Long-term assets</b>		
Marketable securities	623	17,359
Property and equipment, net	15,698	21,413
Other long-term assets	2,491	3,109
Total long-term assets	18,812	41,881
Total assets	\$ 89,374	\$ 159,179
<b>LIABILITIES AND STOCKHOLDERS' DEFICIT</b>		
<b>Current liabilities</b>		
Accounts payable	\$ 4,460	\$ 5,634
Accrued outsourcing costs	5,248	4,907
Accrued compensation and benefits	6,431	10,013
Other accrued expenses	2,312	1,723
Deferred rent	3,333	3,180
Deferred revenue	47,874	52,474
Current portion of long-term debt	150	-
Total current liabilities	69,808	77,931
<b>Long-term liabilities</b>		
Deferred rent	14,968	18,301
Deferred revenue	39,306	65,177
Long-term debt, net	91,390	112,825
Derivative liabilities	540	825
Other long-term liabilities	4,220	798
Total long-term liabilities	150,424	197,926
Total liabilities	220,232	275,857
<b>Commitments and contingencies</b>		
<b>Stockholders' deficit</b>		
	-	-

Series A junior participating convertible preferred stock, \$0.001 par value; 500,000 shares authorized, no shares issued or outstanding		
Series B convertible preferred stock, \$.001 par value; 10,135 authorized, issued and outstanding as of June 30, 2011; no shares issued or outstanding as of June 30, 2010	30,000	-
Common stock, \$0.001 par value; 120,000,000 shares authorized; 57,020,003 and 53,224,248 shares issued and outstanding, as of June 30, 2011 and 2010, respectively	57	53
Additional paid-in capital	346,853	332,277
Warrants	39,385	36,296
Accumulated other comprehensive gain	3	5,528
Accumulated deficit	(547,156)	(490,832)
Total stockholders' deficit	(130,858)	(116,678)
Total liabilities and stockholders' deficit	\$ 89,374	\$ 159,179

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

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**ARRAY BIOPHARMA INC.**  
**Statements of Operations and Comprehensive Loss**  
**(Amounts in Thousands, Except Per Share Data)**

	Years Ended June 30,		
	2011	2010	2009
<b>Revenue</b>			
License and milestone revenue	\$ 53,426	\$ 32,485	\$ 7,754
Collaboration revenue	18,475	21,395	17,228
Total revenue	71,901	53,880	24,982
<b>Operating expenses</b>			
Cost of revenue	28,916	28,322	19,855
Research and development for proprietary drug discovery	63,498	72,488	89,560
General and administrative	16,261	17,121	18,020
Total operating expenses	108,675	117,931	127,435
<b>Loss from operations</b>	(36,774)	(64,051)	(102,453)
<b>Other income (expense)</b>			
Realized gains (losses) on auction rate securities, net	1,891	1,305	(17,742)
Loss on early repayment of long-term debt, net	(6,340)	-	-
Interest income	406	864	2,116
Interest expense	(15,507)	(15,749)	(10,024)
Total other income (expense), net	(19,550)	(13,580)	(25,650)
<b>Loss before income taxes</b>	(56,324)	(77,631)	(128,103)
Income tax benefit	-	-	288
<b>Net loss</b>	\$ (56,324)	\$ (77,631)	\$ (127,815)
Change in unrealized gains (losses) on marketable securities	(5,525)	2,294	5,171
<b>Comprehensive loss</b>	\$ (61,849)	\$ (75,337)	\$ (122,644)
<b>Weighted average shares outstanding - basic and diluted</b>	55,447	50,216	47,839
<b>Net loss per share attributable to Array Biopharma common stockholders - basic and diluted</b>	\$ (1.02)	\$ (1.55)	\$ (2.67)

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



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**ARRAY BIOPHARMA INC.**  
**Statements of Stockholders' Equity (Deficit)**  
**(All Numbers in Thousands)**

	Preferred Stock		Common Stock			Additional Paid-in Capital	Warrants	Accumulated Other Comprehensive Income Accumulated Deficit		Total
	Shares	Amounts	Shares	Amounts	(Loss)			Deficit		
<b>Balance as of June 30, 2008</b>	\$ -		47,545	\$ 48	\$ 304,713	\$ 20,589	\$ (1,937)	\$ (285,386)	\$ 38,027	
Issuance of common stock under stock option and employee stock purchase plans	-	-	580	-	1,688	-	-	-	1,688	
Share-based compensation expense	-	-	-	-	5,948	-	-	-	5,948	
Repricing of warrants for common stock						3,280			3,280	
Recognition of unrealized loss out of accumulated other comprehensive income (loss) to earnings	-	-	-	-	-	-	1,939	-	1,939	
Change in unrealized gain (loss) on marketable securities	-	-	-	-	-	-	3,232	-	3,232	
Net loss	-	-	-	-	-	-	-	(127,815)	(127,815)	
<b>Balance as of June 30, 2009</b>	-	-	48,125	48	312,349	23,869	3,234	(413,201)	(73,701)	
Issuance of common stock under stock option and employee stock purchase plans	-	-	797	1	1,175	-	-	-	1,176	
Share-based compensation expense	-	-	-	-	5,372	-	-	-	5,372	
Issuance of common stock for cash, net of offering	-	-	3,302	3	10,970	-	-	-	10,973	

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costs									
Issuance of common stock warrants	-	-	-	-	-	12,427	-	-	12,427
Payment of employee bonus with stock	-	-	1,000	1	2,411	-	-	-	2,412
Recognition of unrealized gain out of accumulated other comprehensive income to earnings	-	-	-	-	-	-	(915)	-	(915)
Change in unrealized gain on marketable securities	-	-	-	-	-	-	3,209	-	3,209
Net loss	-	-	-	-	-	-	-	(77,631)	(77,631)
<b>Balance as of June 30, 2010</b>	-	-	-	-	-	-	-	-	-