ARRAY BIOPHARMA INC
Form 10-K
September 01, 2006

U.S. SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

FORM 10-K

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

For the fiscal year ended June 30, 2006

Commission File Number: 000-31979

Array BioPharma Inc.

(Exact Name of Registrant as Specified in Its Charter)

Delaware	**84-1460811**
(State of Incorporation)	(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)

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

Securities registered pursuant to Section 12(g) of the Act:
Common Stock, Par Value $.001 Per Share

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

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

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

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

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

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

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

The aggregate market value of voting stock held by non-affiliates of the registrant as of December 31, 2005 was $249,291,478 (For this computation, the registrant has excluded the market value of all shares of its common stock reported as beneficially owned by executive officers and directors of the registrant; such exclusion shall not be deemed to constitute an admission that any such person is an affiliate of the registrant.)

Number of shares outstanding of the registrant s class of common stock as of August 25, 2006: 39,145,157

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 2006 Annual Meeting of Stockholders Part III

TABLE OF CONTENTS

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 statements do not relate to historical matters and reflect our current expectations concerning future events. Therefore 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 efforts and to create effective, commercially viable drugs, our ability to achieve and maintain profitability, the extent to which the pharmaceutical and biotechnology industries are willing to in-license drug candidates for their product pipelines and to collaborate with and fund third parties on their drug discovery activities, our ability to out-license our proprietary candidates on favorable terms, risks associated with our dependence on our collaborators for the clinical development and commercialization of our out-licensed drug candidates, the ability of our collaborators and of Array to meet objectives tied to milestones and royalties, our ability to attract and retain experienced scientists and management, and the risk factors set forth below under the caption 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.

PART I

Item 1. ***Business***

Our Business

Array BioPharma Inc. is a biopharmaceutical company focused on the discovery, development and commercialization of targeted small molecule drugs to treat debilitating and life-threatening diseases. Our proprietary drug development pipeline is primarily focused on the treatment of cancer and inflammatory disease and includes clinical candidates that are designed to regulate therapeutically important target proteins. In addition, leading pharmaceutical and biotechnology companies partner with Array to discover and develop drug candidates across a broad range of therapeutic areas.

There is tremendous opportunity in creating drugs for debilitating and life-threatening diseases, especially in cancer and inflammation. The medical community is seeking selective targeted therapies that more effectively treat disease with an improved safety profile. We believe the future of medicine will be to genetically characterize patients and treat them with these targeted therapies. Also, clinical trials aimed at a well defined patient population should show an improved response rate, increasing the chances for FDA approval. This approach may result in a greater number of marketed drugs aimed at a smaller subset of patients. Our research benefits from the evolving scientific understanding of how modulating specific protein targets can potentially treat both cancer and inflammatory disease. As a result, a drug designed to treat cancer may also be useful in treating inflammatory disease, and vice-versa.

According to analyst estimates, the worldwide market for targeted cancer drugs is expected to grow from $11 billion in 2005, to $36 billion in 2010, representing a significant shift in treating cancer patients. The inflammatory disease market is highly diverse and includes rheumatoid arthritis (or RA), osteoarthritis (or OA), chronic obstructive pulmonary disease (or COPD), cardiovascular disease, psoriasis, and kidney diseases. Targeted therapies for the RA market alone are expected to grow from $9 billion in 2005 to $17 billion in 2010, according to analyst estimates. Additionally, with the safety concerns over COX-2 inhibitors, new markets for replacement drugs to treat pain associated with RA and OA are likely to develop.

Another positive trend for Array is the escalating value of in-licensed clinical assets paid by the pharmaceutical industry. The lack of available clinical candidates to fill its clinical pipelines has increased the industry s reliance on drug discovery companies like Array. While this demand is driving higher value deal terms, it has not translated into increased market valuations for most drug discovery companies.

We have identified multiple drug candidates for the treatment of cancer and inflammatory diseases in our own proprietary programs and in collaborations with other drug companies. To date, we have advanced five programs

that are wholly owned by Array including: ErbB-2 / EGFR (cancer), in which the lead compound, ARRY-543, began a Phase 1 clinical trial in January 2006; MEK (inflammation), in which the lead compound, ARRY-162, began a Phase 1 clinical trial in April 2006; p38 (inflammation), in which the lead compound, ARRY-797, completed regulated safety assessment testing; KSP (cancer), in which our lead compound, ARRY-520, advanced into regulated safety assessment testing; and ErbB-2 (cancer), in which we are evaluating lead compounds in preclinical development. In addition, we have out-licensed proprietary cancer programs to AstraZeneca PLC, which included ARRY-886 (AZD6244), currently in a Phase 2 clinical trial, and to Genentech, Inc., which involves two programs.

We have built our drug development pipeline, and our discovery and development capabilities, primarily through cash flow from collaborations and through sales of our equity securities. Through June 30, 2006, we have recognized $193 million in research funding, and we have generated $28 million in up-front and milestone payments from our collaborators and out-licensing partners. Under our existing collaboration agreements, we have the potential to earn over $200 million in additional milestone payments if we achieve all of the drug discovery objectives under these agreements, as well as royalties on any resulting product sales from 15 different programs.

Over the past year, we executed our strategy through the following accomplishments.

Advancing Proprietary Research Programs

- ARRY-886, our lead MEK inhibitor for cancer, entered a randomized Phase 2 clinical trial in malignant melanoma with 180 patients at 40 centers worldwide; our partner, AstraZeneca, plans on initiating additional Phase 2 trials in other tumors.

- Completed enrollment of cancer patients in a Phase 1b clinical trial for ARRY-886; we plan to report data from this trial at the European Organization for Research and the Treatment of Cancer (EORTC) annual meeting in November 2006.

- Reported Phase 1a clinical results at the annual EORTC meeting for 23 patients receiving ARRY-886. The data showed stable disease in melanoma for three out of seven patients and stable disease in one out of three non small cell lung cancer patients. Stable disease was prolonged to 10 months in some patients. ARRY-886 was well tolerated, with rash being the major dose limiting toxicity.

- Initiated a Phase 1 clinical trial on ARRY-543, our lead ErbB-2 / EGFR inhibitor, in advanced cancer patients; we plan to report interim data in 2006.

- Initiated a Phase 1 clinical trial on ARRY-162, our lead MEK inhibitor for inflammation, in healthy volunteers; we plan to report interim data in 2006.

- Completed regulated safety assessment testing on ARRY-797, our lead p38 inhibitor, to support a planned IND application filing with the FDA before the end of 2006.

- Advanced ARRY-520, our lead KSP inhibitor, into regulated safety assessment testing to support a planned IND application filing before the end of 2006.

- Evaluated and progressed lead compounds for our ErbB-2 program in preclinical development.

Growing Partnered Research

- Received $2 million in milestone payments from AstraZeneca following its selection of two additional compounds for the MEK for cancer program.

- Received a milestone payment from Genentech for nominating a clinical candidate and advancing it into regulated safety assessment testing.

- Extended and expanded our collaboration with Genentech, which will include $50 million in research funding through December 2008 and potential milestone and royalty payments.

- Initiated a collaboration with Ono Pharmaceutical Co, Ltd. that included research funding, and potential milestone payments and royalties.

- Achieved two research milestones in our collaboration with Takeda Chemical Industries, Ltd.

- Developed and delivered cGMP clinical supplies for InterMune, Inc. s HCV protease inhibitor, which InterMune expects to enter the clinic in 2006.

Strengthening Financial Position

- Achieved $45 million in revenue, while investing $33 million in our proprietary research.

- Ended the year with approximately $70 million in cash and marketable securities.

- In addition, during the first quarter of fiscal 2007 we secured expansion space through 2016 and received $32 million in net cash as a result of our sale of purchase options and lease-back of our Boulder and Longmont facilities.

Proprietary Research and Development

Array has identified cancer and inflammatory disease as our core research focus. We believe there is significant synergy between these two research areas and developing drugs in one of the areas may lead to therapies in the other area. Our research focuses on biologic functions, or pathways, which 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 against important therapeutic targets to treat patients with serious or life-threatening conditions, primarily in cancer, inflammatory disease and other large markets. In addition, we 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.

We advanced five programs during fiscal 2006 that are wholly owned and controlled by Array:

- ErbB-2/EGFR (cancer): ARRY-543 entered into a Phase 1 clinical trial in the US and Canada in January 2006;
- MEK (inflammation): ARRY-162 entered into a Phase 1 clinical trial in normal, healthy volunteers in April 2006;
- p38 (inflammation / cancer): ARRY-797 completed regulated safety assessment testing;
- KSP (cancer): ARRY-520 completed regulated safety assessment testing; and
- ErbB-2 (cancer): lead compounds evaluated in advanced preclinical development.

In addition, we have out-licensed our MEK for cancer program, including our compound ARRY-886 (AZD6244), to AstraZeneca and two cancer programs to Genentech. Our agreements with AstraZeneca and Genentech each provide for up-front payments, research funding, success-based milestone payments and royalties on product sales. We have invested approximately $91 million in our proprietary research from our inception through June 30, 2006, and we have received approximately $28 million in up-front payments and milestones resulting from this proprietary research for a net investment of approximately $63 million.

We are continuing a Phase 1 clinical trial on our ErbB-2/EGFR dual inhibitor, ARRY-543, a drug that we believe holds promise for treating breast and other types of cancer. We plan to initiate multiple Phase 2 trials during calendar 2007 for this drug. We are also continuing a Phase 1 clinical trial on our MEK inhibitor, ARRY-162, a drug that we believe holds promise for treating rheumatoid arthritis and other types of inflammatory disease. Our MEK for cancer inhibitor, ARRY-886, is in a randomized Phase 2 clinical trial in malignant melanoma patients being conducted by AstraZeneca. AstraZeneca plans to begin additional Phase 2 trials in other tumors with ARRY-886 later this year. In fiscal 2007, we anticipate filing two additional IND applications with the FDA and initiating clinical trials under them. We have several discovery programs where we are evaluating and developing compounds primarily for treating cancer and inflammatory disease.

Our Drug Development Pipeline

The following pipeline chart shows our six most advanced programs in the areas of cancer and inflammatory disease and their stage in the drug discovery process.

5

Market Opportunity

Cancer

Despite a wide range of available cancer therapies, patient responses remain limited and variable. As a result, oncologists experiment with combination therapies and drug dosing regimens tailored for individual tumor types and specific patients. Targeted therapies offer a more specific approach than first generation, cytotoxic chemotherapy drugs by regulating discrete aspects of cellular function affecting cancer cells to a greater extent than normal cells, providing an improved side effect profile and potentially increased efficacy. We believe certain cancers will eventually become chronic diseases, treated with a combination of targeted therapies. Array s research focus in the cancer market is to build a pipeline of complimentary targeted therapies.

Approximately 3.2 million people are afflicted with cancer in the U.S. and 1.4 million new cases are diagnosed each year. The following are selected new cases diagnosed annually in the U.S.:

Type	New Cases
Prostate	230,000
Breast	213,000
Lung	174,000
Colon	149,000
Melanoma	62,000
Pancreas	34,000

Worldwide, the cancer therapy market is expected to grow from $30 billion in 2005 to $62 billion in 2010, according to analyst estimates. Targeted therapies, which include small molecules and therapeutic injectable proteins, like monoclonal antibodies, represent the market s fastest growing segment.

Inflammatory Disease

Inflammation is a natural biologic response to injury or infectious attack to the human body. Unregulated inflammation results in a broad range of conditions, most of which are classified by the tissue or organ where the inflammation occurs. These conditions include RA in the joint, psoriasis in the skin, COPD in the lung, fibrotic disease in the liver and kidney, Crohn s disease in the intestine, CHF and arteriosclerosis in the arteries, among others. Currently, some of the most effective treatments for these diseases are injectable protein therapeutics, which have significant cost and patient compliance issues. IV-dosed protein therapeutics currently on the market such as Enbrel®, Remicade®, Humira® and Kineret ® bind to and/or modulate the activity of the inflammatory cytokines TNF-α or IL-1 and are utilized for the treatment of RA, psoriasis and Crohn s disease. The TNF inhibition market alone, which is dominated by these therapeutics, is expected to grow from $9 billion in 2005 to $17 billion in 2010, according to analyst estimates. There remains a significant unmet medical need for therapies to treat COPD, asthma, fibrosis and cardiovascular diseases. We believe there is a great opportunity to create orally active drugs to treat many of these often-chronic diseases. Array is developing drugs that modulate important biological targets in key intracellular pathways that control inflammation, potentially providing the ability to treat multiple diseases with a single oral agent.

Our Drug Development Programs

ARRY-886 (AZD6244) / MEK for Cancer

We initiated an anti-cancer research program targeting MEK in July 2001, and within 17 months identified ARRY-886, an orally active clinical candidate. ARRY-886 has shown tumor suppressive or regressive activity in multiple preclinical models of human cancer including melanoma, pancreatic, colon, lung, and breast cancers. The MEK inhibitors advantages over current therapies include potential improved efficacy linked to novel mechanism and cost effectiveness.

In December 2003, we entered into an out-licensing and collaboration agreement with AstraZeneca to develop our MEK program solely in the field of oncology. We retain the rights to all MEK compounds not selected by AstraZeneca for development.

We initiated Phase 1 clinical testing in June 2004. The trial evaluated tolerability and pharmacokinetics of ARRY-886 following oral administration to patients with advanced cancer. In addition, the trial examined

patients for indications of biological activity as well as pharmacodynamic and tumor biomarkers. Phase 1a clinical results on 23 patients showed stable disease in three out of seven melanoma cases and one out of three non-small cell lung cancer (or NSCLC) cases. ARRY-886 was well tolerated, with rash being the dose-limiting toxicity. We initiated Phase 1b clinical testing in August 2005 and have completed enrollment. We expect to report Phase 1b results at the November 2006 EORTC annual meeting.

In June 2006, AstraZeneca initiated a Phase 2 study for ARRY-886 in malignant melanoma and we subsequently earned a $3 million milestone payment. The trial is a randomized Phase 2 study that will compare ARRY-886 to temozolomide in the treatment of stage III / IV melanoma. AstraZeneca expects to enroll up to 180 patients at approximately 40 centers worldwide. AstraZeneca has planned additional Phase 2 studies, in a range of other tumors, to start later this year.

ARRY-543 / ErbB-2 / EGFR for Cancer

ErbB-2 and EGFR are receptor kinase targets that are over-expressed in breast cancer, and EGFR is over-expressed in other cancers including lung, pancreas, and head / neck. We believe the concurrent inhibition of both ErbB-2 and EGFR provide enhanced efficacy in cancer treatment. Currently, there is no single drug on the market that inhibits both ErbB-2 and EGFR. Herceptin® is an IV-dosed protein therapeutic currently on the market that modulates ErbB-2. Recently, Herceptin has been reported to show promising therapeutic benefits in an expanded patient population, including post-surgery breast cancer patients being treated chronically or patients with chemotherapy-induced ErbB-2 over-expression. We believe these results suggest a high potential value in an orally active drug that can be conveniently dosed for extended periods of time. Erbitux™, an IV-dosed protein therapeutic, and Tarceva®, a small molecule inhibitor, are drugs currently on the market that modulate EGFR only.

We have identified ARRY-543, a novel orally active dual inhibitor of EGFR and ErbB-2. The compound behaves as a reversible ATP-competitive inhibitor with nanomolar potency both *in vitro* and in cell-based proliferation assays. Selectivity against a panel of kinases has been demonstrated *in vitro*. In preclinical models, ARRY-543 demonstrated significant dose related tumor growth inhibition when administered orally. ARRY-543 demonstrated significant dose related tumor growth inhibition when administered orally. ARRY-543 has demonstrated efficacy in certain preclinical models where Tarceva® or Herceptin® are not active and we believe has shown equivalent or improved efficacy compared to the most clinically advanced competitors.

We initiated a Phase 1 clinical trial in both the United States and Canada in January 2006. We expect to report interim data in 2006.

ARRY-XXX / ErbB-2 for Cancer

Our lead small molecule ErbB-2 inhibitors have shown potency, excellent drug characteristics and a low side effect profile in preclinical models of human cancer. Our lead inhibitors advantages include improved efficacy versus Herceptin® in preclinical models of human breast cancer, projected improved tissue penetration, inhibition of ErbB-family heterodimer activation, inhibition of the truncated p95 ErbB-2 target, ease of use for an orally active drug and cost effectiveness for long-term adjuvant treatment. We are currently evaluating our lead inhibitors in preclinical development.

ARRY-520 / KSP for Cancer

Several members of the kinesin family of microtubule motor proteins play essential roles in mitotic spindle function and are potential targets for the discovery of novel antimitotic cancer therapies. Kinesin Spindle Protein (KSP), also known as Eg5, plays an essential role in the formation of a bipolar mitotic spindle and is required for cell cycle progression through mitosis. Currently, the most clinically advanced competitor compound in multiple Phase 2 trials has been reported to show preliminary efficacy in breast cancer, but limited activity elsewhere.

Our compound, ARRY-520, is a KSP inhibitor with sub-nanomolar potency in both enzymatic and cellular assays. These inhibitors are anti-mitotic, leading to cancer cell death. *In vivo*, ARRY-520 caused marked tumor regression in preclinical models of human cancer at tolerated doses, often leading to complete durable responses. In comparator studies against the most clinically advanced competitor compound, ARRY-520 has shown superior efficacy in multiple xenograft models. These highly soluble inhibitors can be delivered intravenously without requiring enabling formulations. We have completed regulated safety assessment testing and plan to file an IND application with the FDA by the end of 2006.

7

ARRY-162 / MEK for Inflammation

MEK is a kinase target that has been demonstrated to have a role in the biosynthesis of TNF, IL-6 and IL-1. Our scientists have discovered MEK inhibitors that interfere with these biosynthetic processes. We have also advanced one MEK inhibitor, ARRY-886, into clinical development for the treatment of cancer. Given our experience with the safety profile of MEK inhibitors, we believe inhibition of MEK will have applications in diseases driven by IL-1 and TNF. ARRY-162, an orally active MEK inhibitor, has shown potency and good drug characteristics in preclinical models of human arthritis and other inflammatory diseases. We believe this compound may provide broad therapeutic benefits in the treatment of inflammatory and chronic degenerative diseases.

We initiated Phase 1 clinical testing in normal, healthy volunteers in April 2006. We plan to report interim data at the Inflammation Research Association meeting in October 2006.

ARRY-797 / p38 for Inflammation and Cancer

p38 is a kinase target that regulates the production of numerous pro-inflammatory cytokines, in particular, TNF, IL-6 and IL-1. IV-dosed protein therapeutics currently on the market, including Enbrel®, Remicade®, Humira® and Kineret®, bind to and modulate the activity of the cytokines TNF or IL-1. Additionally, several cancers have show up-regulation of TNF and IL-6, including prostate, ovarian and multiple myeloma; p38 may be involved as part of a resistance mechanism. ARRY-797, an orally active p38 inhibitor, has shown potency, unique drug characteristics and a low side effect profile in preclinical models of human arthritis and certain cytokine-driven cancers. We plan to file an IND application with the FDA by the end of 2006.

Partnered Research and Development

We have research partnerships with leading pharmaceutical and biotechnology companies that include design, creation and optimization of drug candidates, preclinical testing and process research and development, across a broad range of therapeutic areas. These partnerships involve either continued research and development on programs we have out-licensed or drug discovery and development on targets selected by our partners. These collaborations provide research funding and, in a number of our current agreements, up-front fees, milestone payments and/or royalties based upon the success of the program. Our partners, from whom we are receiving research funding or have the potential for future milestones or royalties, include Amgen, AstraZeneca, Genentech, ICOS Corporation, InterMune, Inc., Japan Tobacco Inc., Ono Pharmaceutical Co., Ltd., and Takeda Pharmaceutical Company, Ltd. We have delivered candidate compounds in 13 programs for preclinical development.

Our research team s productivity has yielded more early-stage discovery assets than we can develop internally. During the next three years, we intend to out-license certain of these assets through research partnerships of higher value than our traditional collaborations. We believe this strategy will create opportunities for greater financial upside while continuing to provide a revenue stream and will allow us to maintain a critical mass of scientists required for a world-class research platform.

Below are summaries of four of our most significant partnered programs.

AstraZeneca MEK for Cancer Program / ARRY-886

In December 2003, we entered into an out-licensing and collaboration agreement with AstraZeneca to develop our MEK program solely in the field of oncology. Under the agreement, AstraZeneca acquired exclusive worldwide rights to our clinical development candidate, ARRY-886, together with two second-generation compounds we developed during the collaboration, for oncology indications. We retain the rights to all non-oncology therapeutic indications for MEK compounds not selected by AstraZeneca for development. As of July 2006, we have earned a total of $19.5 million in upfront and milestone payments and have recognized $16.5 million of these payments as revenue from the inception of the agreement through fiscal 2006. The agreement also provided for research funding, which is now complete, and potential additional development milestone payments of over $75 million and royalties on product sales. AstraZeneca is responsible for additional clinical development and commercialization for ARRY-886, and for clinical development and commercialization for the other two compounds it licensed.

Genentech Oncology Programs

We entered into a licensing and collaboration agreement with Genentech in December 2003 to develop small molecule drugs against multiple therapeutic targets in the field of oncology. We initiated this collaboration with Genentech 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 to us, provides research funding and paid a milestone payment to us for nominating a clinical candidate and advancing it into regulated safety assessment testing. In addition, Genentech has agreed to pay us additional potential development milestone payments and royalties on any resulting product sales. Genentech is responsible for clinical development and commercialization of the resulting products.

In April 2005, we expanded our collaboration agreement with Genentech to develop clinical candidates directed against an additional cancer target. Under the expanded agreement, Array receives additional research funding, as well as potential research and development milestone payments and product royalties based on the success of the new program. Genentech has the sole responsibility for clinical development and commercialization of any resulting products. In October 2005, we further expanded our collaboration with Genentech; under the current agreement, we expect to receive $50 million in research funding through December 2008, plus milestone and royalty payments based on success of the programs. Genentech may terminate its agreement with us upon 120 days notice.

InterMune Hepatitis C Virus Programs

Array and InterMune scientists have collaborated since 2002 to discover novel small molecule inhibitors of the Hepatitis C Virus (HCV) NS3/4 protease. During fiscal 2005, this collaboration was extended and expanded. Under the terms of the agreement, InterMune funds drug discovery, preclinical testing, process development and cGMP manufacturing conducted by Array and will make milestone payments to Array based on the selection and progress of clinical drug candidates, as well as royalties on sales of any products derived from the collaboration. As a result of Array s research progress, we received our first milestone payment from InterMune in June 2004.

We designed compounds under this program using computational modeling techniques and optimized them to achieve superior efficacy and targeted tissue penetration. Preclinical plasma pharmacokinetic analysis following intravenous and oral administration was then used in conjunction with other *in vitro* assays and stability studies to choose optimal development candidates. Preclinical data was presented in May 2006 at the Digestive Disease Week conference. During fiscal 2006, we developed and delivered cGMP clinical supplies for the HCV protease inhibitor. InterMune expects to initiate a Phase 1 clinical trial later in 2006, which will trigger a milestone payment to Array.

We also commenced a second drug discovery collaboration with InterMune in April 2005 to create small molecule drugs focused on hepatitis. InterMune funds drug discovery research conducted by Array based on the number of Array scientists working on the research phase of the agreement and will be responsible for all further development and commercialization. Array is entitled to receive milestone payments based on the selection and progress of clinical drug candidates, as well as royalties on net sales of any products derived from the collaborative efforts. Research funding under these agreements with InterMune ends June 30, 2007, but may be extended at InterMune s option.

Ono Pharmaceutical Research Program

We entered into a drug discovery collaboration with Ono Pharmaceutical in October 2005 to create small molecule drug candidates against a series of kinases selected by Ono. Ono provides research funding and milestone and royalty payments based on the success of the program. Ono is responsible for clinical development and commercialization of any resulting products. The research funding for this program ends May 1, 2008.

Array s Research and Development Technologies and Expertise

Our scientists use the Array Discovery Platform, an integrated suite of drug discovery technologies, to create drug candidates and conduct preclinical and clinical development. A critical capability within the Array Discovery Platform is our proprietary software, which enables our scientists to share information across our company, analyze databases of existing drugs, generate novel predictive databases and design novel drugs with potential competitive advantages over current therapies. We use *in vitro* and *in vivo* predictive pharmacodynamic and pharmacokinetic

models to select compounds for potential development. Early in the drug discovery process, our scientists engineer into a drug candidate desirable drug characteristics, such as improved potency, specificity and dosing regimen and reduced side effect profile. The resulting compounds are tested for safety, efficacy and metabolism to select the most promising clinical candidates. We believe our drug discovery approach can significantly improve on the industry s existing clinical attrition rates through our use of:

- Proprietary chemoinformatic databases that relate chemical structure to compound development potential;
- Multiple lead generation strategies including high throughput screening of our lead generation library of up to 400,000 compounds, virtual screening and proprietary *de novo* design software;
- State-of-the-art protein x-ray crystallography, structural databases and computational modeling;
- An extensive battery of *in vivo* and *in vitro* metabolic and safety drug profiling assays;
- A company-wide electronic laboratory notebook that enables our scientists to collect, analyze and share information across the organization; and
- Innovative clinical trial designs, incorporating markers of biological activity.

Our Strategy

We are building a fully integrated, commercial-stage biopharmaceutical company that invents, develops and markets safe and effective small molecule drugs to treat patients with debilitating and life threatening diseases, primarily in cancer and inflammation. We intend to accomplish this through the following strategies:

- Inventing targeted small molecule drugs that demonstrate a competitive advantage over existing therapies to fill our clinical pipeline;
- Commercializing drugs requiring a therapeutically directed sales force;
- Partnering late-stage co-development and commercialization of drugs that will be marketed to primary care physicians and that require broad distribution;
- Partnering continued research and development of select early-stage programs under which we would receive research funding, plus significant milestones and royalties; and
- Evaluating opportunities to in-license later stage clinical or commercial programs to accelerate our transition to a commercial stage biotech company.

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 Arena Pharmaceuticals Inc.; Arqule; Cytokinetics Inc.; deCODE genetics, Inc.; Exelixis Inc.; Incyte Corporation.; Theravance, Inc.; and Vertex Pharmaceuticals Incorporated. 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.

Research and Development Expenses

Research and development expenses consist of costs associated with our proprietary drug programs for salaries and benefits of scientific personnel, consulting and outsourced services, laboratory supplies, allocated facilities costs and depreciation. Research and development expenses were $33.4 million for the year ended June 30, 2006, compared to $22.9 million for fiscal 2005 and $15.9 million for fiscal 2004.

Government Regulation

Biopharmaceutical companies are subject to substantial regulation by governmental agencies in the United States and other countries. Virtually all pharmaceutical products are subject to rigorous preclinical and clinical testing and other approval procedures by the FDA and by foreign regulatory agencies. Before a drug product is approved by the FDA for commercial marketing, three phases of human clinical trials are usually conducted to test the safety and effectiveness of the product. Phase 1 clinical trials most typically involve testing the drug on a small number of healthy volunteers to assess the safety profile of the drug at different dosage levels. Phase 2 clinical trials, which also enroll a relatively small number of 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 volunteers representing the drug s targeted population. During any of these phases, the clinical trial can be placed on clinical hold, or temporarily or permanently stopped for a variety of reasons, principally for safety concerns.

The approval process is time-consuming and expensive, and there are no assurances that approval will be granted on a timely basis, or at all. Even if regulatory approvals are granted, a marketed product is subject to continual review under federal and state laws and regulations. Post-marketing requirements include reporting adverse events, recordkeeping, compliance with current good manufacturing practices (cGMP) and marketing requirements.

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

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

In the course of our business, we handle, store and dispose of chemicals and biological samples. We are subject to various federal, state and local laws and regulations relating to the use, manufacture, storage, handling and disposal of hazardous materials and waste products. These environmental laws generally impose liability 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 (HIPAA). Although our clinical development efforts are not directly regulated by these privacy regulations, we could face substantial criminal penalties if we knowingly receive individually identifiable health information from a health care provider that has not satisfied HIPPA s disclosure standards. In addition, certain state 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.

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

Intellectual Property

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

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

Our patent strategy is designed to protect technology, inventions and improvements to inventions that are commercially important to our business. We currently have eight issued United States patents and numerous patent applications on file with the United States 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.

United States patents issued from applications filed on or after June 8, 1995, have a term of 20 years from the application filing date or earlier claimed priority. All of our patent applications were filed after June 8, 1995. Patents in most other countries have a term of 20 years from the date of filing of the patent application. Because the time from filing patent applications to issuance of patents is often several years, this process may result in a period of patent protection significantly shorter than 20 years, which may adversely affect our ability to exclude competitors from our markets. Our success will depend in part upon our ability to develop proprietary products and technologies and to obtain patent coverage for these products and technologies. We intend to continue to file patent applications covering newly developed products and technologies. We may not, however, commercialize t