ARRAY BIOPHARMA INC
Form 10-K
August 21, 2015

UNITED STATES SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-K
[ü] ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the fiscal year ended June 30, 2015
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

Array BioPharma Inc.
(Exact name of registrant as specified in its charter)

Delaware	84-1460811
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
3200 Walnut Street, Boulder, CO	80301
(Address of principal executive offices)	(Zip Code)

Registrant's telephone number, including area code: (303) 381-6600

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Name of each exchange on which registered
Common Stock, par value $0.001 per share	The NASDAQ Stock Market LLC (NASDAQ Global Market)

Securities registered pursuant to Section 12(g) of the Act: None
Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. þ 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 þ 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. þ 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). þ Yes ¨ No
Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§229.405 of this chapter) 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.

Large Accelerated Filer ¨	Accelerated Filer þ	Non-Accelerated Filer ¨ (do not check if smaller reporting company)	Smaller Reporting Company ¨

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

The aggregate market value of the voting common equity held by non-affiliates of the registrant as of December 31, 2014, was $647,473,840, based on the closing sale price of the registrant's common stock as reported on the NASDAQ Global Market on such date. Shares of the registrant's common stock held by each executive officer and director have been excluded for purposes of this calculation. This number is provided only for purposes of this Annual Report on Form 10-K and does not represent an admission that any particular person or entity is an affiliate of the registrant.

As of August 14, 2015, the registrant had 142,173,066 shares of common stock outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the Proxy Statement for the Registrant's 2015 Annual Meeting of Stockholders are incorporated by reference into Part III of this Annual Report on Form 10-K.

ARRAY BIOPHARMA INC.
ANNUAL REPORT ON FORM 10-K
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PART I

Array BioPharma Inc. and the Array BioPharma Inc. logo 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.

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 2015 refers to the fiscal year ended June 30, 2015.

FORWARD-LOOKING STATEMENTS

This Annual Report filed on Form 10-K and other documents we file with the Securities and Exchange Commission, or SEC, 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 partners; the potential for the results of ongoing preclinical or clinical trials conducted by Array or our partners 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 are 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 partners for the clinical development and commercialization of our out-licensed drug candidates; the ability of our partners 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.

Market and Industry Data

Unless otherwise indicated, information contained in this Annual Report on Form 10 K concerning the cancer market, the drug market and our other markets, including our general expectations and market position, market opportunity and market share, is based on information from independent industry analysts and third-party sources and management estimates. Management estimates are derived from publicly-available information released by independent industry analysts and third-party sources, as well as data from our internal research, and are based on

assumptions made by us based on such data and our knowledge of such industry and markets, which we believe to be reasonable.

We have not independently verified or verified with any independent source any third-party information and cannot assure you of its accuracy or completeness. In addition, while we believe the market position, market opportunity and market share information included in this Annual Report on Form 10-K is generally reliable, such

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information is inherently imprecise. Such data involves risks and uncertainties and is subject to change based on various factors, including those discussed under the heading "Item 1A. Risk Factors."

ITEM 1. BUSINESS

Our Business

Array is a biopharmaceutical company focused on the discovery, development and commercialization of targeted small molecule drugs to treat patients afflicted with cancer. Six registration studies are currently advancing. These programs include three cancer drugs, binimetinib (MEK162 / wholly-owned), encorafenib (LGX818 / wholly-owned) and selumetinib (partnered with AstraZeneca).

Our most advanced wholly-owned clinical stage drugs include:

	Proprietary Program	Indication	Clinical Status
1.	Binimetinib	MEK inhibitor for cancer	Phase 3
2.	Encorafenib	BRAF inhibitor for cancer	Phase 3
3.	Filanesib	Kinesin spindle protein, or KSP, inhibitor for multiple myeloma, or MM	Phase 2
4.	ARRY-797	p38 inhibitor for Lamin A/C-related dilated cardiomyopathy, or LMNA-DCM	Phase 2

In March 2015, Array announced the completion of the transactions contemplated by asset transfer agreements Array had entered into with Novartis under which Array regained rights to binimetinib and acquired rights to encorafenib. Also during the third quarter, we entered into a third party agreement to complete the Novartis transactions for a net consideration payment to the third party of $25 million. Along with global ownership of both assets, Array received an upfront payment of $85 million from Novartis. We believe these programs present significant opportunities for Array in the area of oncology.

Three pivotal trials of binimetinib and/or encorafenib, COLUMBUS (encorafenib in combination with binimetinib in BRAF-mutant melanoma patients), NEMO (binimetinib in NRAS-mutant melanoma patients), and MILO (binimetinib in low-grade serous ovarian cancer patients), continue to advance. Beyond the three Phase 3 trials, there are over 30 active binimetinib and/or encorafenib trials.

In April 2015, the NEMO and COLUMBUS (Part 1) Phase 3 studies completed patient enrollment. With NEMO enrollment complete, Array reaffirms a projected regulatory filing of binimetinib in NRAS melanoma during the first half of 2016. With COLUMBUS (Part 1) enrollment complete, Array reaffirms a projected regulatory filing of binimetinib in combination with encorafenib in BRAF melanoma in 2016. Patient enrollment continues in Part 2 of COLUMBUS.

The MILO Phase 3 study design was modified to incorporate a cross-over provision, allowing patients on the trial to have access to binimetinib. Array estimates the availability of top-line data from MILO in 2016 and a projected regulatory filing of binimetinib in low-grade serous ovarian cancer, or LGSOC, in 2017.

Novartis is responsible for continued conduct and funding of the COLUMBUS and NEMO trials. All other ongoing clinical trials involving binimetinib and encorafenib, including the MILO trial, continue to advance, with Novartis providing substantial financial support in the form of reimbursement to Array for all associated out-of-pocket costs and for one half of Array’s fully-burdened full-time equivalent, or FTE, costs based on an annual FTE rate. At designated points for each trial, Novartis will transition responsibility and provide this continuing financial support to Array for completing the trials.

Array continues to progress select other wholly-owned programs including two Phase 2 trials of filanesib in MM and a Phase 2 trial of ARRY-797 in a rare cardiovascular disease. In addition, we have 10 ongoing partner-funded clinical programs, including an Array-invented MEK inhibitor, selumetinib with AstraZeneca. Three registration clinical trials continue to evaluate selumetinib: SELECT-1 (second-line KRAS-mutant advanced or metastatic non-small cell lung cancer), ASTRA (differentiated thyroid cancer) and neurofibromatosis Type 1, or NF1.

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	Drug Candidate	Indication	Partner	Clinical Status
1.	Selumetinib	MEK inhibitor for cancer	AstraZeneca, PLC	Phase 3
2.	ASC08 / Danoprevir	Protease inhibitor for Hepatitis C virus	Roche Holding AG	Phase 2
3.	ASLAN001/ARRY-543	Pan-HER inhibitor for gastric or breast cancer	ASLAN Pharmaceuticals Pte Ltd.	Phase 2
4.	Ipatasertib/GDC-0068	AKT inhibitor for cancer	Genentech, Inc.	Phase 2
5.	Motolimod/VTX-2337	Toll-like receptor for cancer	VentiRx Pharmaceuticals, Inc.	Phase 2
6.	LY2606368	Chk-1 inhibitor for cancer	Eli Lilly and Company	Phase 2
7.	GDC-0575	Chk-1 inhibitor for cancer	Genentech, Inc.	Phase 1b
8.	ONT-380/ARRY-380	HER2 inhibitor for breast cancer	Oncothyreon Inc.	Phase 1b
9.	GDC-0994	ERK inhibitor for cancer	Genentech, Inc.	Phase 1
10.	LOXO-101	PanTrk inhibitor for cancer	Loxo Oncology, Inc.	Phase 1

We also have a portfolio of proprietary and partnered preclinical drug discovery programs, including inhibitors that target Trk receptors for the treatment of oncology and other indications. Our most significant discovery collaborations are with Loxo Oncology, Inc. (oncology program) and Biogen Idec (auto-immune disorder program). We may out-license other select promising candidates through research collaborations in the future.

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.

Our significant clinical stage partners include:

- ASLAN – We entered into a Collaboration and License Agreement with ASLAN in July 2011 to develop Array's pan-HER inhibitor, ASLAN001/ARRY-543, which is currently in Phase 1 and 2 clinical trials in patients with gastric cancer or breast cancer.
- 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 numerous clinical trials, including three registration trials.
- Genentech – We entered into a worldwide strategic Drug Discovery 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 drugs are ipatasertib/GDC-0068, an AKT inhibitor for cancer, which is currently in Phase 2 and GDC-0994, an ERK inhibitor for cancer, which is currently in Phase 1. We also entered into a License Agreement with Genentech in August 2011 for the development of each company's small molecule Chk-1 program in oncology. The program included Genentech's compound GDC-0425 (RG7602) and Array's compound GDC-0575 (previously known as ARRY-575). Genentech selected GDC-0575 to advance into further clinical trials in patients with cancer.
- Roche Holding AG – We entered into a Drug Discovery Collaboration Agreement with InterMune in 2002, which resulted in the joint discovery of ASC08 / danoprevir, a novel small molecule inhibitor of the Hepatitis C Virus NS3/4A protease. Roche Holding AG acquired ASC08 from InterMune in 2010 and partnered with Ascletis in 2013 to advance the program in greater China. Ascletis has announced its expectation to advance ASC08 in Phase 3 clinical trials in China and Taiwan.
- Oncothyreon – We entered into a Development and Commercialization Agreement with Oncothyreon in May 2013, to collaborate on the development and commercialization of ONT-380, an orally active, reversible and selective small-molecule HER2 inhibitor, for the treatment of cancer, including breast cancer. In December 2014, we granted Oncothyreon an exclusive license to develop, manufacture and commercialize ONT-380. The License Agreement replaces the 2013 agreement. Oncothyreon is continuing development of ONT-380 in a defined set of proof-of-concept trials in patients with metastatic breast cancer, including

patients with brain metastases.

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- Loxo – We entered into a Drug Discovery Collaboration Agreement with Loxo in July 2013 and granted Loxo exclusive rights to develop and commercialize certain Array-invented compounds targeted at the tropomyosin kinase, or Trk, family of receptors, including LOXO-101, which is currently in a Phase 1 clinical trial.
- VentiRx – We entered into a Collaboration and License Agreement with VentiRx in February 2007 and granted VentiRx exclusive worldwide rights to certain molecules from our Toll-Like Receptor, or TLR, program, including VTX-2337, which is currently in Phase 2 clinical trials.

Business History

We have received a total of $678.2 million in research funding and in up-front and milestone payments from partners from inception through June 30, 2015, including $174 million in initial payments from strategic agreements with Amgen, Celgene, Genentech, Novartis and Oncothyreon that we entered into over the last five and a half years, and we received an up-front cash payment of $85 million in March 2015 under our agreement with Novartis for the re-acquisition of binimetinib. Our existing partnered programs entitle Array to receive a total of over $2 billion in additional milestone payments if we or our partners 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 licensing or commercialization from 12 partnered clinical and discovery programs.

Our Strategy

We are building a fully-integrated, commercial-stage biopharmaceutical company that discovers, develops and will market small molecule drugs to treat patients afflicted with cancer. 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 have little or no competition, or demonstrate a competitive advantage over drugs currently on the market or in clinical development.
- Develop and commercialize our drugs to maximize their overall value. As our first drug nears approval, we plan to build a therapeutically-focused sales force to commercialize or co-promote drugs we wholly own, or for which we retain development rights in major geographic areas.
- Implement a partnering strategy in which we out-license drugs outside our therapeutic or geographic focus and partner select early-stage programs for continued research and development in exchange for research funding plus significant milestone payments and royalties.

Our out-license and collaboration agreements typically provide for up-front payments, research funding, success-based milestone payments 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.

Drug Discovery and Clinical Development Programs

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 clinical stage collaborations currently include our agreements with ASLAN, AstraZeneca, Genentech, Loxo, InterMune/Roche, Oncothyreon and VentiRx. Under our current partnered programs, our involvement in the development or research phase has ended, but we retain the right to receive clinical, regulatory and commercialization milestones and/or royalties on sales of any products covered by the collaboration. We also have research collaborations 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 collaborations, we also perform process research and development and clinical development.

Information about our partners 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 1 – Overview, Basis of Presentation and Summary of

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Significant Accounting Policies – Concentration of Business Risks to the accompanying audited financial statements included elsewhere in this Annual Report on Form 10-K.

Proprietary Programs

Below is a description of our most advanced, wholly-owned clinical programs, their stage in the drug development process and our expected future development plans for fiscal 2016.

1. Binimetinib and Encorafenib — MEK and BRAF Inhibitor Program

Effective March 2, 2015, Novartis' global, exclusive license to binimetinib terminated with all rights reverting to Array, and Array received global rights to encorafenib. As part of the transaction, Array received an $85 million upfront payment from Novartis and reimbursement for certain transaction-related expenses. Novartis is providing transitional regulatory, clinical development and manufacturing services as specified below and assigned or licensed to Array patent and other intellectual property rights it owns to the extent they relate to binimetinib and encorafenib. All clinical trials involving binimetinib and encorafenib sponsored by Novartis or Array at the time of the transaction, including three pivotal trials, COLUMBUS (BRAF-mutant melanoma / NCT01909453), NEMO (NRAS-mutant melanoma / NCT01763164), and MILO (LGSOC / NCT01849874), will continue to be conducted.

Other than a de minimis payment to Novartis from Array, there are no milestone payments or royalties payable between the parties under the encorafenib agreement. As part of the transactions, Array has agreed to obtain an experienced partner for global development and European commercialization of both binimetinib and encorafenib. If Array is unable to find a suitable partner in the prescribed time period, a trustee would have the right to sell such European rights.

Novartis will conduct and fund the COLUMBUS trial through the earlier of June 30, 2016 or completion of last patient first visit. At that time, Array will assume responsibility for the trial, while Novartis will reimburse Array's out-of-pocket costs along with 50% of Array's FTE costs in connection with completing the COLUMBUS trial. Novartis is responsible for conducting all other encorafenib trials until their completion or transfer to Array for a defined transition period. For all trials transferred to Array, Novartis will reimburse Array for out-of-pocket costs and 50% of FTE costs in connection with completing the trials.

Novartis will reimburse Array for all remaining out-of-pocket expenses and 50% of all remaining FTE costs associated with the MILO trial, which Array will continue to conduct. For the NEMO trial and all other ongoing and planned clinical trials for binimetinib (other than COLUMBUS, as described above), Novartis will conduct and solely fund each trial, until a mutually agreed-upon transition date to Array. Following this transition, Novartis will reimburse Array for all remaining out-of-pocket expenses and 50% of all remaining FTE costs required to complete these studies.

Novartis will remain responsible for conducting and funding development of the NRAS melanoma companion diagnostic for binimetinib until Premarket Approval is received from the U.S. Food and Drug Administration, or FDA. Following approval, Novartis will transfer the product and Premarket Approval to a diagnostic vendor of Array's designation.

Novartis also retains binimetinib and encorafenib supply obligations for all clinical and commercial needs for up to 30 months after closing and will also assist Array in the technology and manufacturing transfer of binimetinib and encorafenib. Novartis will also provide Array continued access to several Novartis pipeline compounds for use in currently ongoing combination studies, and possible future studies, including Phase 3 trials, with encorafenib and binimetinib.

Development Status: Three Phase 3 trials continue to advance: NEMO, COLUMBUS and MILO. NRAS-mutant melanoma represents the first potential indication for binimetinib, with a projected regulatory filing estimated in the first half of 2016.

- The NEMO trial began in July 2013 and will evaluate the efficacy and safety of binimetinib compared to dacarbazine in 393 patients with advanced (Stage IIIC) unresectable or metastatic (Stage IV) NRAS-

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mutant melanoma. The primary endpoint is progression free survival, or PFS, and the key secondary endpoint is overall survival. In April 2015, NEMO completed patient enrollment.

- The COLUMBUS trial began in September 2013 and will evaluate the efficacy and safety of the binimetinib/encorafenib combination and encorafenib as a single agent, in each case compared to Zelboraf® (vemurafenib) in 900 patients with advanced, unresectable or metastatic BRAF-mutant melanoma. The primary endpoint is PFS, and the key secondary endpoint is overall survival. In April 2015, COLUMBUS (Part 1) completed patient enrollment. The projected regulatory filing for binimetinib and encorafenib based on the COLUMBUS study is estimated to be in 2016.
- The MILO trial began in June 2013 and will evaluate the efficacy and safety of binimetinib compared to standard chemotherapy treatments in 360 patients with recurrent or persistent LGSOC following at least one prior platinum-based chemotherapy regimen and no more than three lines of prior chemotherapy regimens. The primary endpoint is PFS, and the key secondary endpoint is overall survival. In 2015, the MILO study design was modified to incorporate a cross-over provision, allowing all patients on the trial to have access to binimetinib. The projected regulatory filing for binimetinib based on the MILO study is estimated to be in 2017.

2. Filanesib — KSP Program for Multiple Myeloma

Filanesib is a highly selective, targeted KSP inhibitor with a mechanism of action distinct from currently available myeloma therapies such as immunomodulatory drugs, or IMiDs®, and proteasome inhibitors. Across multiple studies, filanesib has demonstrated activity in heavily pretreated MM patients, with a consistent safety profile including no drug-induced peripheral neuropathy and limited non-hematologic toxicity. Adverse events have included transient, non-cumulative and predominantly asymptomatic myelosuppression (decreases in blood counts) when supportive measures are used. Alpha 1-acid glycoprotein, or AAG, a plasma protein, is a potential patient selection marker for filanesib. AAG is undergoing further investigation in clinical trials and could represent the first patient selection marker for a myeloma therapy.

Based on data from ongoing or completed clinical trials, and discussions with the FDA, Array is developing filanesib in combination with the proteasome inhibitor Kyprolis® (carfilzomib). Two studies with filanesib continue to advance in patients with relapsed / refractory multiple myeloma (RRMM):

- The AfFIRM trial, a global Phase 2 study that began in May 2014 with single-agent filanesib in 160 patients with RRMM. While the trial includes patients regardless of AAG status, the primary endpoint is objective response rate, or ORR, in patients with low AAG levels at baseline. The AfFIRM trial is also designed to support future regulatory submissions and validation of AAG as a patient selection marker and will generate safety and pharmacological data.
- The ARRAY-520-216 trial, a randomized Phase 2 trial that began in November 2013 comparing Kyprolis plus filanesib versus Kyprolis alone in 75 RRMM patients. The primary endpoint is PFS, and this trial will provide safety and efficacy data to support the overall development plan, including data to support AAG as a patient selection marker in the combination of Kyprolis plus filanesib. To date, there are no successful drug combinations for Kyprolis in patients who have previously been treated with both Revlimid® (lenalidomide) and Velcade® (bortezomib).

During fiscal 2016, we plan to report interim results from the AfFIRM and ARRAY-520-216 studies. Data from these trials will inform next steps.

3. ARRY-797 — p38 Program for Lamin A/C-related dilated cardiomyopathy

ARRY-797 is a selective, oral inhibitor of the p38 mitogen activated protein kinase, or MAPK. LMNA-DCM is a serious cardiovascular disease caused by genetic mutations in the lamin A/C gene. These mutations lead to loss of functional lamin proteins resulting in activation of the p38 MAPK pathway and leading to structural changes in cardiac tissue such as:

- alterations to cardiomyocyte and A/V nodal cell nuclei, which leads to apoptosis and cardiac tissue remodeling, and

- sarcomere reorganization, which affects the heart’s contractile function.

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By age 45, approximately 70% of patients with LMNA-related DCM experience cardiovascular death, transplant or a major cardiac event. While other MAPK pathways have been implicated in this disease, nonclinical data suggest that the p38 pathway is a key driver.

In vivo studies of ARRY-797 in models of LMNA-DCM demonstrated reversal of cardiac remodeling and significant improvements in heart function, general well-being and survival. Data from a physician-sponsored single-patient IND application indicated that ARRY-797 treatment was associated with echocardiographic improvements and was well tolerated. Based on these encouraging data and discussions with U.S. regulatory authorities, a 12-patient Phase 2 study has been initiated to study the effectiveness and safety of ARRY-797 in patients with LMNA-DCM. The primary endpoint is the change from baseline in a 6-minute walk test at 12 weeks. Other endpoints include left and right ventricular function, quality of life assessments, safety and pharmacokinetics. Currently, we have patients on this trial past 48 weeks and ARRY-797 has been well-tolerated. Patients completing this Phase 2 trial are being enrolled in a roll-over study to continue treatment. Interim data continue to be encouraging for multiple endpoints across patients, but further data is needed to fully assess the magnitude, consistency and durability of effects.

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, and therefore may not reflect changes to any information that may have occurred since the date it was reported to us or of its public disclosure.

1. AstraZeneca — Selumetinib — MEK Program

In December 2003, we entered into a Collaboration and License 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 AZD6244, or ARRY-142886), together with two other compounds for oncology indications 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. Our research obligations ended in 2004 and AstraZeneca is responsible for all future development and commercialization of the compounds under the collaboration. To date, we have earned $26.5 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 $70 million (with $30 million specific for selumetinib) and royalties on product sales.

MEK is a key protein kinase in the RAS/RAF/MEK/ERK pathway, which signals cancer cell proliferation and survival. MEK has been shown to be frequently activated in cancer, in particular in tumors that have mutations, including BRAF and NRAS, in the RAS and RAF pathways. Selumetinib is a small molecule MEK inhibitor that targets a key position in this pathway.

Development Status: AstraZeneca is continuing to advance selumetinib in three registration trials: second-line KRAS-mutant advanced or metastatic non-small cell lung cancer, or NSCLC (SELECT-1), differentiated thyroid cancer (ASTRA) and NF1. In July 2015, AstraZeneca announced that the Phase 3 SUMIT trial in patients with metastatic uveal melanoma did not meet its primary endpoint of PFS. A full evaluation of the data is ongoing and is expected to be presented at an appropriate scientific conference. We do not believe the results from SUMIT inform the outcome of the ongoing selumetinib registration studies: SELECT-1, ASTRA or NF1. These trials are in distinct

patient populations and are being conducted in combination with different agents or are being studied as a single agent.

- The SELECT-1 trial began in September 2013 and will evaluate the efficacy and safety of selumetinib in combination with docetaxel compared to placebo and docetaxel in 634 patients with locally advanced or metastatic KRAS-mutant NSCLCs. The primary endpoint is PFS, and the key secondary endpoint is overall survival. The estimated date for top-line results is during the second half of 2016.

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- The ASTRA trial began in August 2013 and will evaluate the efficacy and safety of selumetinib with radioactive iodine therapy compared to placebo and radioactive iodine therapy in 304 patients with differentiated thyroid cancer. The primary endpoint is complete remission rate. The estimated date for top-line results is 2017.
- The Phase 2 registration trial in pediatric patients with NF1 is an expansion of the existing Phase 1 trial that began in May 2011 and will evaluate the efficacy and safety of selumetinib in 50 patients. The primary endpoint is confirmed response rate by volumetric MRI. The estimated date for top-line results is 2017. In addition, a Phase 2 registration trial in adult patients with NF1 is planned.

2. InterMune (program now owned by Roche) — ASC08 / Danoprevir Hepatitis C Virus NS3/4 Protease Program

In 2002, we entered into a Drug Discovery Collaboration Agreement with InterMune for the discovery of novel small molecule inhibitors of the Hepatitis C Virus, or HCV, NS3/4A protease. As a result of drug discovery activities under this collaboration, scientists at Array and InterMune jointly discovered ASC08 / danoprevir, which is expected to enter Phase 3 in China and Taiwan. In October 2010, Roche expanded its portfolio of investigational medicines for HCV through the purchase of ASC08 from InterMune for $175 million. InterMune thereafter ceased all further development efforts under the collaboration. Under the terms of Array's collaboration agreement with InterMune, InterMune has an obligation to make milestone payments to us based on the selection and progress of ASC08, as well as royalties on commercial sales of ASC08. To date, we have received $1.8 million in milestone payments and have the potential to earn an additional $7.5 million if all clinical and commercialization milestones for ASC08 are achieved under the agreement.

In April 2013, Roche and Ascletis announced that they will collaborate to develop and commercialize ASC08 in China. It is estimated that over 10 million patients in China are chronically infected with HCV. The majority of these patients are genotype 1b, which has been shown to be responsive to ASC08. Ascletis will fund and be responsible for the development, regulatory affairs and manufacturing of ASC08 in greater China and will receive payments upon reaching certain development and commercial milestones from Roche. Ascletis and Roche will collaborate for the clinical development and commercialization. ASC08 has been evaluated in 27 Phase 1 and seven Phase 2 clinical trials with a total of approximately 2,400 healthy volunteers and patients tested.

Development Status: In June 2015, Ascletis announced that ASC08 will enter Phase 3 trials in China and Taiwan, based on the results of the DAPSANG Phase 2 trial results.

3. ASLAN — ASLAN001/ARRY-543 — Pan-HER Program

In July 2011, we entered into a Collaboration and License Agreement with ASLAN to develop Array's pan-HER inhibitor, ASLAN001/ARRY-543, which is currently in Phase 2 development in patients with gastric or breast cancer in Asia. ASLAN001 is an oral HER2/EGFR inhibitor, and has shown clinical activity in both HER2-positive and EGFR-positive tumors. Under the agreement, ASLAN is funding and developing ASLAN001 through clinical proof-of-concept. 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 of ASLAN001 under an agreed-upon development plan.

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. Data from pivotal studies of Herceptin® (trastuzumab), 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 ASLAN001 has the potential to augment or supersede the activity

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of Herceptin in this population, and in the broader population of gastric cancers that co-express both EGFR and HER2 receptors.

Development Status: Three Phase 1 or 2 trials are advancing:

- Phase 2 trial to evaluate ASLAN001 in combination with capecitabine compared with lapatinib in combination with capecitabine in patients with HER2 positive metastatic breast cancer who have failed on prior trastuzumab therapy.
- Phase 1/ 2 trial to evaluate ASLAN001 in combination with weekly paclitaxel and carboplatin in patients with HER2 positive breast cancer.
- Phase 1 trial to evaluate ASLAN001 in combination with CAPOX or mFolfox6, in patients with metastatic solid tumors, who are suitable to receive CAPOX or mFolfox6, or who have tumors that have dysregulated EGFR or HER2 signaling.

In addition, in July 2015, ASLAN and National Cancer Center Singapore announced a collaboration that includes jointly conducting preclinical and clinical studies of ASLAN001 for the treatment of gastric cancer, hepatocellular carcinoma (liver) and cholangiocarcinoma (bile duct), three common forms of gastrointestinal cancers that are particularly prevalent in Asia.

4. Genentech — Ipatasertib/GDC-0068 and GDC-0994

We entered into a Drug Discovery Collaboration Agreement with Genentech, a member of the Roche Group, 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, provided research funding and to date has paid us milestone payments for nominating a clinical candidate and advancing it into regulated safety assessment testing and a Phase 1 trial. In addition, Genentech has agreed to make additional potential development milestone payments and pay us royalties on certain 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 additional targets. Under the agreement, we received additional research funding, as well as potential research and development milestone payments and product royalties based on the success of each new program. 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 four months' written notice. Genentech has paid Array a total of $23.5 million in up-front and milestone payments, and we have the potential to earn an additional $23.0 million for all programs if Genentech continues development and achieves the remaining clinical milestones set forth in the agreement.

Development Status: Genentech is advancing one collaborative drug, ipatasertib, an AKT inhibitor, in clinical development, including four Phase 2 trials:

- Phase 2 trial with ipatasertib in combination with paclitaxel as front-line treatment for patients with metastatic triple-negative breast cancer.
- Phase 2 trial with ipatasertib in combination with paclitaxel as neoadjuvant treatment for patients with early stage triple negative breast cancer
- Phase 2 trial (JAGUAR) with ipatasertib in combination with fluoropyrimidine plus oxaliplatin in patients with advanced or metastatic gastric or gastroesophageal junction cancer.
- Phase 1b/2 trial (A.MARTIN) with ipatasertib or GDC-0980, a PI3 kinase/mTor dual inhibitor, with abiraterone acetate versus abiraterone acetate in patients with locally advanced castration-resistant prostate cancer.

In addition, Genentech is advancing a second collaborative drug, GDC-0994, an ERK inhibitor, in two Phase 1 studies in patients with locally advanced or metastatic solid tumors.

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5. Genentech — GDC-0575 — Checkpoint kinase 1, or Chk-1, Inhibitor Program

In August 2011, Array and Genentech entered into a License Agreement for the development of each company's small-molecule Chk-1 program in oncology. The programs included Genentech's compound GDC-0425 (RG7602) and Array's compound GDC-0575 (previously known as ARRY-575), both of which are being tested in Phase 1 trials in patients with cancer. Under the terms of the agreement, Genentech is responsible for all clinical development and commercialization activities. Array received an up-front payment of $28 million and is eligible to receive clinical and commercial milestone payments up to $380 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 upon a material breach by the other party that is not cured within a specified time period, and Genentech may terminate the agreement upon at least 60 days' written notice to Array. If Genentech terminates the agreement due to a material breach by Array, the license Array granted to Genentech becomes irrevocable and the royalty to Array will be reduced to a specified percentage. If the agreement is terminated by Genentech for convenience or by Array due to a material breach by Genentech, the license 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.

Development Status: In 2014, Genentech selected GDC-0575 over GDC-0425 to advance into further clinical trials. Genentech is continuing a Phase 1 multiple ascending dose trial to evaluate GDC-0575 alone and in combination with Gemzar® (gemcitabine) in approximately 90 patients with refractory solid tumors or lymphoma.

6. Lilly — LY2606368 — Chk-1 Inhibitor Program

In 1999 and 2000, Array entered into collaboration agreements involving small-molecule Chk-1 inhibitors with ICOS Corporation. LY2603618 and LY2606368 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 LY2603618 in a Phase 1 clinical trial in early 2007. The agreements provided research funding, which has now ended. Array achieved a $125 thousand milestone payment after the first patient was dosed with LY2606368 in a Phase 1 clinical trial in early 2010. Array is entitled to receive additional milestone payments totaling $3.5 million based on Lilly's achievement of clinical and regulatory milestones with the molecules.

Development Status: While there is currently one on-going LY2603618 Phase 1 clinical trial in cancer, Lilly has communicated that it does not intend to pursue further development of the drug. LY2606368 is in Phase 2 development, with three on-going trials for cancer.

7. VentiRx — Motolimod/VTX-2337 — TLR Program

In February 2007, we entered into a Collaboration and License Agreement with the privately-held biopharmaceutical company VentiRx, under which we granted VentiRx exclusive worldwide rights to certain molecules from our TLR program. The program contains a number of compounds targeting TLRs to activate innate immunity, including motolimod/VTX-2337. 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 $2.6 million in milestone payments and have the potential to earn an additional $56 million if VentiRx achieves the remaining clinical and commercial milestones under the agreement. See Note 1 — Overview, Basis of Presentation and Summary of Significant

Accounting Policies — 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.

In October 2012, VentiRx announced the formation of an exclusive, worldwide collaboration with Celgene for the development of motolimod. As part of the agreement, Celgene will retain the exclusive option to acquire VentiRx. In addition, Celgene provided a $35 million up-front payment to VentiRx to fund further research and development

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of VTX-2337 through pre-defined clinical endpoints. During the option period, VentiRx will be eligible to receive additional funding, including a potential equity investment by Celgene.

Motolimod directly activates multiple components of the innate immune system, including activation of human myeloid dendritic cells, monocytes and natural killer, or NK, cells resulting in the production of high levels of mediators known to orchestrate the integration of innate and adaptive anti-tumor responses. Results from preclinical models suggest that combining motolimod with some chemotherapies and monoclonal antibodies demonstrate a synergistic effect in stimulating a variety of immune pathways associated with anti-tumor activity including antibody-directed cellular cytotoxicity. Early data from an ongoing Phase 1 trial in squamous cell carcinoma of the head and neck, or SCCHN, demonstrated that the combination was safe and well tolerated, and demonstrated activation of NK cells following dosing with motolimod.

Development Status: Motolimod is being evaluated in the following Phase 2 trials:

- Phase 2 trial (GOG-3003) with motolimod in combination with pegylated liposomal doxorubicin, or PLD, standard second-line chemotherapy for patients with recurrent or persistent ovarian cancer versus PLD alone.
- Phase 2 trial (ACTIVE8) with motolimod in combination with a standard of care regimen, cetuximab, platinum and 5 Fluorouracil, or 5-FU, in patients with recurrent or metastatic SCCHN.
- Phase 1/2 trial of motolimod and MEDI4736 in patients with recurrent, platinum-resistant ovarian cancer for whom PLD is indicated.

8. Oncothyreon — ONT-380/ARRY-380 — HER2 Inhibitor Program

In May 2013, we entered into a Development and Commercialization Agreement with Oncothyreon Inc. to collaborate on the development and commercialization of ONT-380, an orally active, reversible and selective small-molecule HER2 inhibitor, for the treatment of cancer, including breast cancer. Under the terms of the agreement, Oncothyreon paid Array a one-time up-front fee of $10 million.

In December 2014, we granted Oncothyreon an exclusive license to develop, manufacture and commercialize ONT-380 pursuant to a License Agreement that replaced the 2013 agreement. As part of the License Agreement, Oncothyreon paid Array $20 million as an up-front fee. In addition, Oncothyreon will pay Array a significant portion of any payments received from sublicensing ONT-380 rights. If Oncothyreon is acquired within three years of the effective date of the current agreement, Array will be eligible for up to $280 million in commercial milestone payments. Array is also entitled to receive up to a double-digit royalty based on net sales of ONT-380.

The License Agreement will expire on a country-by-country basis on the later of 10 years following the first commercial sale of the product in each respective country or expiration of the last to expire patent covering the product in such country, but may be terminated earlier by either party upon material breach of the License Agreement by the other party or the other party’s insolvency, or by Oncothyreon on 180 days' notice to Array. Oncothyreon and Array have also agreed to indemnify the other party for certain of their respective warranties and obligations under the License Agreement.

Development Status: ONT-380 is being evaluated in three clinical trials:

- Phase 1 trial with ONT-380 in combination with Herceptin® (trastuzumab) in patients with brain metastases from HER2+ breast cancer (Dana Farber sponsored).
- Phase 1 trial with ONT-380 in combination with Kadcyla ® (T-DM1) in patients with HER2+ breast cancer (Oncothyreon sponsored).
- Phase 1 trial with ONT-380 in combination with Herceptin plus Xeloda ® (capecitabine) in patients with HER2+ breast cancer (Oncothyreon sponsored).

In addition, in May 2015, Oncothyreon announced plans to initiate a blinded, randomized, placebo-controlled Phase 2 trial in patients with HER2-positive metastatic breast cancer.

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9. Loxo — LOXO-101 — PanTrk Inhibitor Program

In July 2013, Array entered into a Drug Discovery Collaboration Agreement with Loxo and granted Loxo exclusive rights to develop and commercialize certain Array-invented compounds targeted at the Trk family of receptors, including LOXO-101, which is currently in a Phase 1 clinical trial. Based on evidence from this trial, including drug exposures that exceeded expectations, Loxo announced in August 2015 plans to initiate a Phase 2 trial in the second half of this year in adult cancer patients whose tumors harbor TRK fusions. In April 2014 and again in April 2015, Array and Loxo amended the agreement to expand the research activities. There is a growing body of scientific literature implicating Trk alterations in diverse tumor types, including neuroblastoma and lung, thyroid and breast cancer. Many downstream pathways important in cancer are stimulated by activated Trk, such as the PI3-kinase and MAP-kinase pathways. Drugs targeting these pathways have generated responses in both solid and hematologic tumors.

Under the terms of the amended agreement, Loxo will fund further preclinical research to be conducted by Array during a three-year discovery research phase, which may be extended by Loxo for up to two additional one-year renewal periods. In addition, Loxo will fund further discovery and preclinical research to be conducted by Array directed at other targets during the research phase of the agreement. Loxo will be responsible for all additional preclinical and clinical development and commercialization.

Array also receives advance payments for preclinical research and other services that Array is providing during the term of the discovery program and is eligible to receive up to $435 million in milestone payments if certain clinical, regulatory and sales milestones are achieved plus royalties on sales of any resulting drugs.

The Loxo agreement will continue on a country-by-country basis until the termination of the royalty payment obligations, unless terminated earlier by the parties in accordance with its terms. The agreement may be terminated by either party upon the failure of the other party to cure any material breach of its obligations under the agreement, provided that, so long as Loxo is reasonably able to pay its debts as they are due, Array will only be entitled to seek monetary damages, and will not have the right to terminate the agreement in the event of Loxo's breach after expiration of the discovery program term. Loxo also has the right to terminate the agreement or to terminate discovery research with respect to any targets under development with six months’ notice to Array. If Loxo terminates the agreement for convenience, all licenses granted to Loxo will terminate and Array will have all rights to further develop and commercialize the licensed programs. The period of exclusivity to be observed by Array under the Loxo agreement will continue as long as Loxo either has an active research and/or development program for a target and the program could result in the receipt of milestones or royalties under the program by Array, or as long as Loxo is commercializing a product for a target under the agreement.

Market Opportunity

Our proprietary pipeline is focused on targeted drugs that treat cancer. We believe there is a substantial opportunity in creating oncology drugs 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 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 $58 billion in 2014 to $131 billion in 2020.

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

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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. The goal of targeted therapies is to specifically address the underlying mechanisms of the disease by regulating discrete aspects of cellular function affecting cancer cells to a greater extent than normal cells. As such, targeted therapies hold the promise of being more effective 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 2015, in the U.S. there will be an estimated 1.7 million new cases of cancer in 2015 and nearly 600 thousand cancer-related deaths. The five-year relative survival rate for all cancers diagnosed between 2003 and 2009 is 68%, up from 49% in 1975-1977. The improvement in survival reflects both progress in diagnosing certain cancers at an earlier stage and improvements in treatment.

The following table shows estimated new cases diagnosed and estimated deaths in the U.S. during 2015 by major cancer types of interest to Array:

Type of Cancer	Estimated 2015 New Cases	Deaths
Lung	221,200	158,040
Breast	234,190	40,730
Colorectal	93,090	49,700
Melanoma	73,870	9,940
Thyroid	62,450	1,950
Pancreas	48,960	40,560
Ovarian	21,290	14,180
Stomach	24,590	10,720
Myeloma	26,850	11,240
Gallbladder and Other Biliary	10,910	3,700
	817,400	340,760

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 as 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 include Avastin® (bevacizumab), Xalkori® (crizotinib), Herceptin®(trastuzumab), Rituxan® (rituximab) and Zelboraf® (vemurafenib).

Lung Cancer (Binimetinib and Selumetinib — MEK inhibitors)

Lung cancer is 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 of lung cancer are NSCLC, which represents about 85%, and small cell lung cancer, or SCLC, which represents about 15% of lung cancer. In 2015, the estimated new cases and deaths from all lung cancer in the U.S. were approximately 221 thousand and 158 thousand, respectively. Globally, over 1.6 million new cases of lung cancer are diagnosed every year and nearly

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1.8 million people die as a result of this devastating disease; more than breast, colon and prostate cancer combined. The overall five-year relative survival rate for the period of 2003 to 2009 for patients with lung cancer was 17%. The five-year relative survival rate varies markedly depending on the stage at diagnosis, from 54% to 27% to 4% for patients with local, regional and distant / malignant disease, respectively.

Patients with resectable disease may be cured by surgery or surgery plus 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.

Market growth of NSCLC drug therapies is expected to grow annually by 57% from $5.4 billion in 2014 to $8.5 billion in 2023. We believe generic price erosion of key agents such as Alimta® (pemetrexed) and Tarceva® (erlotinib) will be offset by the recent approvals by the FDA of Xalkori® (crizotinib), Gilotrif® (afatinib), Zykadia™ (ceritinib), and the anticipated introduction of several novel classes of 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. Mutations in the KRAS gene are amongst the most common mutations in NSCLC, being found in approximately 26% of patients, which amounts to approximately 415 thousand patients globally. Typically, KRAS mutations activate the RAS/RAF/MEK/ERK pathway, contributing to unregulated cell growth and survival. Therapies that target this aberrant pathway, including MEK inhibitors, would therefore be expected to have therapeutic activity in patients with mutated KRAS.

Data from a double-blind, randomized Phase 2 study comparing the efficacy of selumetinib, a MEK inhibitor we licensed to AstraZeneca, in combination with docetaxel versus docetaxel alone in second-line patients with KRAS mutation-positive locally advanced or metastatic NSCLC were presented at the 2012 American Society of Clinical Oncology, or ASCO, Annual Meeting. This study showed statistically significant improvement in PFS, ORR, and alive and progression-free at six months, as well as a trend for improvement in overall survival in favor of selumetinib in combination with docetaxel versus docetaxel alone. Based on these data, AstraZeneca has initiated the pivotal Phase 3 SELECT-1 trial comparing selumetinib in combination with docetaxel versus docetaxel alone in second line patients with KRAS mutation-positive locally advanced or metastatic NSCLC.

Melanoma (Binimetinib — MEK inhibitor and Encorafenib — BRAF inhibitor)

Melanoma is the deadliest form of skin cancer. The number of new malignant melanoma cases has been increasing substantially over the past 30 years and at a rate that is among the fastest growing of any human cancer. According to the American Cancer Society, the estimated new cases and deaths from melanoma in the U.S. in 2015 are approximately 74 thousand and 10 thousand, respectively. Prognosis is heavily dependent upon stage of the disease. The outlook for patients with metastatic disease is poor, with a five-year survival rate of approximately 16%.

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. 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.

Market growth of melanoma drug therapies is expected to be strong, with sales across the seven major pharmaceutical markets forecasted to grow annually by over 92% from $1.2 billion in 2014 to $2.3 billion in 2023. This forecasted growth is driven largely by recent and anticipated launches of several novel, high-priced therapies expected to capture substantial market share over time.

Mutations that activate the RAS/RAF/MEK/ERK pathway are common in melanoma, with BRAF mutations in 40% to 60%, and NRAS mutations in 15-20% of melanoma patients, suggesting the therapeutic potential for agents that target this pathway in melanoma. Following Roche's launch of the BRAF inhibitor Zelboraf (vemurafenib) in 2011, several additional therapies that target this pathway are under study. Included amongst these are several MEK inhibitors. Both Mekinist (trametinib), a MEK inhibitor and Tafinlar (dabrafenib), a BRAF inhibitor from

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Novartis were approved by the FDA for patients with BRAF mutated melanoma, both as monotherapy and in combination.

As MEK inhibitors target the RAS/RAF/MEK/ERK pathway, which is activated with BRAF mutation, they may also have the potential for activity not only in patients with BRAF-mutant melanoma, but also in patients with tumors that harbor mutations in the NRAS gene, who currently have no adequate treatment option and poor prognosis. Data on binimetinib in an ongoing Phase 2 trial of patients with BRAF and NRAS mutated advanced melanoma was presented at the 2014 ESMO Annual Meeting. Binimetinib showed clinical activity and good tolerability in this patient population. This is the first targeted therapy to show activity in patients with NRAS mutated melanoma. Based on this data, Novartis initiated two pivotal Phase 3 trials. The NEMO trial compares binimetinib to dacarbazine in patients with NRAS mutation-positive advanced, unresectable or metastatic melanoma. The COLUMBUS trial compares binimetinib in combination with encorafenib to encorafenib as monotherapy and to vemurafenib as monotherapy in patients with newly-diagnosed BRAF inhibitor naïve, BRAF V600E or V600K mutant advanced, unresectable or metastatic melanoma.

NF1 or Plexiform Neurofibromas (Selumetinib - MEK inhibitor)

NF1 is an autosomal disorder that can cause tumors to grow on nerves throughout the body. Most of these tumors are inoperable and the disease may lead to blindness, bone abnormalities, cancer, deafness, disfigurement, learning disabilities and excruciating and disabling pain. Neurofibromatosis, or NF, affects one in every 3,000 people, which is more than cystic fibrosis, Duchenne muscular dystrophy and Huntington’s disease combined. Data on selumetinib in an ongoing Phase 2 trial of pediatric patients with NF1 was presented at the 2015 Children's Tumor Foundation NF Conference. In the study, 67% (16 of 24) of patients treated with selumetinib achieved a partial response (defined by a 20% reduction in tumor size) and all patients remain on study with a median of 18 cycles (1 cycle = 28 days, range, 6-43). Anecdotal improvement in function, and reduction in plexiform neurofibromas, or PN, related pain and disfigurement were also observed. The most frequent adverse events were acneiform rash, increased creatine kinase and gastrointestinal effects. Based on this data, a Phase 2 registration trial in pediatric patients is advancing and a Phase 2 registration trial in adult patients is planned.

Thyroid Cancer (Selumetinib — MEK inhibitor)

Thyroid cancer has become the fastest-increasing cancer in the U.S. with estimates of almost 62 thousand new cases and 1,950 deaths in 2015. The rapid increase in incidence rates is thought to be largely due to increased and earlier detection. Thyroid cancer strikes relatively young patients, with 80% of newly diagnosed thyroid cancers occurring in patients younger than 65, and 3 out of 4 cases occurring in women.

Most thyroid cancers can be treated successfully with an overall five-year survival rate of 98%. However, even when therapy is successful, the disease remains burdensome and potentially lethal; patients must be tested routinely for the rest of their life, with as many as 35% of thyroid cancers recurring, one-third of which occur more than 10 years after initial treatment.

In disease that has not metastasized, partial or total surgical excision of the thyroid gland is the primary treatment, followed by radioiodine therapy, or RAI, to kill off residual cancer cells, and usually thyroid hormone suppression therapy for maintenance to prevent recurrence. For metastatic disease, RAI is the leading therapeutic option. However, a significant number of patients have disease not receptive to RAI therapy, or RAI-refractory disease, and have few effective treatment alternatives. This remains a significant unmet need, as distant metastases are the most frequent cause of death for patients with papillary or follicular thyroid cancers which account for 90% of thyroid tumors, and decreased RAI incorporation into metastatic sites has been shown to be associated with higher mortality.

Therapies that target the RAS/RAF/MEK/ERK pathway and specific molecular abnormalities such as BRAF and NRAS mutations have a strong scientific underpinning for activity in this disease, with BRAF mutations in approximately 39%, and NRAS mutations in approximately 7% of thyroid cancers. In a pilot study published in the February 14, 2013 edition of the New England Journal of Medicine, selumetinib has shown positive therapeutic activity in patients with RAI-refractory disease. Based on these results, AstraZeneca has initiated a

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Phase 3 trial comparing selumetinib combined with single dose adjuvant radioactive iodine to single dose adjuvant radioactive iodine in patients with differentiated thyroid cancer who have had a previous thyroidectomy.

Low-Grade Serous Ovarian Cancer (Binimetinib — MEK Inhibitor)

Ovarian cancer is the ninth most common cancer among women, the fifth leading cause of cancer-related death among women and is the deadliest of gynecologic cancers. Serous ovarian cancer represents the largest group of ovarian cancer and is considered to consist of two main subtypes: low-grade and high-grade. LGSOC represents up to 10% of ovarian cancer diagnoses and it is estimated that over 10 thousand women are living with the disease in the U.S. and Europe.

Women diagnosed with LGSOC are generally diagnosed at a younger age and live longer, but have a lower response rate to conventional chemotherapy compared to high-grade serous ovarian cancer patients. Treatment for these patients involves surgery and multiple anti-cancer regimens for advanced disease. Following first-line treatment with a platinum-based regimen, less than 4% of patients show a response to additional rounds of chemotherapy. Historic data suggest a median PFS of only seven months for this population. This along with the relative chemo-resistant nature of this disease underscores the high unmet need among these patients.

At the 2012 American Association for Cancer Research Annual Meeting, proof-of-concept data on selumetinib was presented showing an ORR of 15% and clinical benefit rate of 81% in patients with platinum-resistant LGSOC. When compared with historic data related to chemotherapy and hormonal therapy, two commonly used treatments for LGSOC, treatment with a MEK inhibitor demonstrated improved clinical activity and in a more heavily pre-treated population.

Based on this data and other research, Array has advanced binimetinib in this high unmet need patient population with the MILO study. In the MILO study, binimetinib will be compared to physicians choice chemotherapy (paclitaxel, topotecan, or liposomal doxorubicin) in patients with recurrent or persistent low-grade serous carcinomas of the ovary, fallopian tube or primary peritoneum who have received prior platinum containing therapy.

Lamin A/C-Related Dilated Cardiomyopathy (ARRY-797 — p38 inhibitor)

LMNA-DCM is a rare, degenerative cardiovascular disease caused by genetic mutations in the lamin A/C gene. These mutations lead to loss of functional lamin proteins resulting in activation of the p38 MAPK pathway and leading to structural changes in cardiac tissue such as alterations to cardiomyocyte and A/V nodal cell nuclei, which leads to apoptosis and cardiac tissue remodeling, and sarcomere reorganization, which affects the heart’s contractile function. While other MAPK pathways have been implicated in this disease, nonclinical data suggest that the p38 pathway is a key driver.

Patients with LMNA-DCM typically begin experiencing symptoms in their twenties or thirties, and by age 45 nearly 70% have undergone a heart transplant, experienced a major cardiac event or have died. Currently, there are no disease-specific treatments approved for LMNA-DCM. Treatment is limited to symptomatic and supportive care, and a significant unmet medical need remains for therapies that can halt disease progression or improve cardiac function. Patients diagnosed with LMNA-DCM are treated using the same practices as patients diagnosed with dilated cardiomyopathy arising from other causes. It is estimated that 5,000 to 9,000 patients are living with LMNA-DCM, but due to infrequent genetic testing, far fewer are actually diagnosed. No available treatments are curative, and given the relentless progression of disease and poor prognosis of LMNA-DCM, novel drugs that can target the molecular mechanism underlying cardiac dysfunction in this disease are warranted. Thus, there is a high unmet need for patients who are diagnosed with LMNA-DCM, and inhibition of p38 MAPK may offer an important therapeutic option for these patients.

Array is currently developing ARRY-797, a selective, oral inhibitor of the p38 MAPK pathway. Based on data from a single-patient IND and discussions with U.S. regulatory authorities, a 12-patient Phase 2 study has been initiated to study the effectiveness and safety of ARRY-797 in patients with LMNA-DCM.

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Multiple Myeloma, or Myeloma (Filanesib — KSP inhibitor)

MM is a hematological cancer characterized by the neoplastic proliferation of plasma cells which accumulate in the bone marrow and produce a monoclonal immunoglobulin (Ig) - heavy and/or light chain (paraprotein, M-protein). Plasma cells normally produce antibodies to fight infection and disease. In MM, plasma cells proliferate in the bone marrow, which often leads to extensive bone destruction, including osteolytic lesions, osteopenia, hypercalcemia, fractures and myelosuppression. Myelosupression can lead to anemia, recurrent bacterial infections and bleeding. The deposition of immunoglobulin (M-protein) can lead to renal failure.

MM is the second most common hematologic malignancy, and treatments garner significant sales due to the cost of treatment regimens and relatively long life expectancies of patients. Despite advances in therapy over the last decade, it remains an incurable, fatal disease in nearly all patients. 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 48 thousand in the seven major global markets (U.S., France, Germany, Italy, Spain, the U.K. and Japan) with approximately 24 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 over 89 thousand patients with MM in the U.S. in 2012.

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 5.6% from $3.6 billion in 2010 to $6.2 billion in 2020. This growth is projected to be driven by three factors:

1. Increased efficacy of current treatments, notably the leading targeted therapies, including the proteasome inhibitor Velcade® (bortezomib), and the IMiDs, Revlimid® (lenalidomide) and Thalomid® (thalidomide), 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 Kyprolis® (carfilzomib) and Pomalyst® (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.

Filanesib targets KSP, a novel mechanism of action in MM, distinct from the approved proteasome inhibitors and IMiDs. Preclinically, filanesib showed significant single-agent activity in disease models resistant to standard-of-care drugs. Furthermore, filanesib was active in vivo in preclinical MM models, and demonstrated synergy with proteasome inhibitors and IMiDs, suggesting the potential to combine filanesib with these standard-of-care therapies. In clinical trials, filanesib has shown single-agent activity in heavily pretreated patients; it is one of the few non-IMiD or proteasome inhibitor drugs to show single-agent activity in this patient population. Filanesib has also shown clinical activity in MM patients when combined with dexamethasone, Kyprolis or Velcade in disease refractory to Revlimid and Velcade. This clinical activity supports the potential for further development of filanesib in patients refractory to other therapies.

Research and Development for Proprietary Drug Discovery

Our primary research efforts during fiscal 2015 were focused on development of our hematology/oncology programs. 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. 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

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characteristics, including efficacy, tolerability or dosing to provide safer, more effective drugs. During fiscal years 2015, 2014 and 2013, we spent $54.4 million, $49.8 million and $59.4 million, respectively, on research and development for proprietary drug discovery, which consist of costs associated with our proprietary drug programs for, among other things, salaries and benefits for scientific personnel, consulting and outsourced services, laboratory supplies, allocated facilities costs and depreciation.

Drug Discovery and Development Timeline

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

Phase	Objective	Estimated Duration
Discovery	Lead identification and target validation.	2 to 4 years
Preclinical	Initial toxicology for preliminary identification of risks for humans; gather early pharmacokinetic data.	1 to 2 years
Phase 1	Evaluate 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	Evaluate effectiveness of the drug and its optimal dosage in patients; continue safety evaluation.	2 to 4 years
Phase 3	Confirm efficacy, dosage regime and safety profile of the drug in patients	2 to 4 years
NDA Preparation, Review and Approval	FDA review and approval to sell and market the drug under the approved labeling	1 to 2 years

Some non-clinical studies, including animal studies, are often conducted during the course 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 three integrated areas of expertise:

- Discovery Research — Biology, Pharmacology, Toxicology, Chemistry and Translational Medicine;
- Process Research, Development, Formulation and Manufacturing (through collaborations, including with Accuratus Lab Services, Inc.); and
- Clinical Development — Clinical Science, Clinical Operations, Drug Safety, Translational Medicine, Biostatistics and Data Management, Regulatory Affairs and Program Management.

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 engage key scientists who enhance our current capabilities. Our translational medicine team 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. Our discovery group has created high quality clinical candidates for our proprietary and partnered programs that have been shown to modulate their mechanistic target, as measured by an appropriate clinical biomarker.

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Process Research, Development, Formulation and Manufacturing

In June 2015, we entered into an Asset Purchase Agreement with Accuratus Lab Services, Inc., where Accuratus acquired Array's chemistry, manufacturing and controls activities. This group will continue to provide expert support to Array's drug discovery and development programs. Their capabilities include formulations, physical form characterization and aspects of clinical supply manufacturing. Array will also utilize other service providers for its Process Research, Development, Formulation and Manufacturing needs.

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.

Our near-term focus is on bringing our most promising drugs through proof-of-concept and Phase 3 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."

Competitors

The pharmaceutical and biotechnology industries are characterized by rapid and continuous technological innovation. We compete with companies worldwide that are engaged in 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, or CROs, 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 partners are conducting, which may limit the number of patients who meet the criteria for enrollment and delay or prevent us or our partners 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, including regulation governing the testing, development, manufacturing, quality control, distribution, safety, effectiveness, approval, labeling, storage, record keeping, reporting, advertising and promotion, and import and

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export of such products under the Federal Food, Drug, and Cosmetic Act, or the FDC Act, and its implementing regulations, and by comparable agencies and laws in foreign countries. Failure to comply with applicable foreign regulatory agency or FDA requirements may result in enforcement action, including warning letters, fines, civil or criminal penalties, suspension or delays in clinical development, recall or seizure of products, partial or total suspension of production or withdrawal of a product from the market. Although the discussion below focuses on regulation in the U.S., which is our primary initial focus, we and our partners anticipate seeking approval to market our products in other countries. Generally, our activities in other countries will be subject to regulation that is similar in nature and scope as that imposed in the U.S., although there can be important differences.

Development and Approval

In the U.S., prescription drug products are subject to rigorous preclinical and clinical testing and other approval procedures by the FDA. Under the FDC Act, 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 U.S. Typically, approval requires extensive studies and submission of a large amount of data by the company. The 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.

Preclinical Testing. Before testing any drug candidate in human subjects in the U.S., a company must develop extensive preclinical data. Preclinical testing generally includes laboratory evaluation of product chemistry and formulation, as well as toxicological and pharmacological studies in several animal species to assess the quality and safety of the product. Certain animal studies must be performed in compliance with the FDA's Good Laboratory Practice, or GLP, regulations and the U.S. Department of Agriculture's Animal Welfare Act.

IND Application. Human clinical trials cannot commence until an IND application is submitted and becomes effective. A company must submit, among other information, preclinical testing results to the FDA as part of the IND, and the FDA must evaluate whether there is an adequate basis for testing the drug candidate in initial clinical studies in human volunteers. Unless the FDA raises concerns, the IND becomes effective 30 days following its receipt by the FDA.

Clinical Trials. Clinical trials involve the administration of the drug to healthy human volunteers or to patients under the supervision of a qualified investigator. The conduct of clinical trials is subject to extensive regulation, including compliance with the FDA's bioresearch monitoring regulations and Good Clinical Practice, or GCP, requirements, which establish standards for conducting, recording data from, and reporting the results of clinical trials, and are intended to assure that the data and reported results are credible and accurate, and that the rights, safety, and well-being of study participants are protected. Clinical trials must be conducted under protocols that detail the study objectives, parameters for monitoring safety, and the efficacy criteria, if any, to be evaluated. FDA reviews each protocol that is submitted to the IND. In addition, each clinical trial must be reviewed and approved by, and conducted under the auspices of, an Institutional Review Board, or IRB, for each institution conducting the clinical trial. Companies sponsoring the clinical trials, investigators, and IRBs also must comply with regulations and guidelines for obtaining informed consent from the study subjects, complying with the protocol and investigational plan, adequately monitoring the clinical trial, and timely reporting adverse events. Foreign studies conducted under an IND must meet the same requirements that apply to studies being conducted in the U.S. Data from a foreign study not conducted under an IND may be submitted in support of an NDA if the study was conducted in accordance with GCP and, if necessary, the FDA is able to validate the data through an on-site inspection, if the agency deems such inspection necessary.

Human clinical trials typically are conducted in three sequential phases, although the phases may overlap with one another. Phase 1 clinical trials involve the initial introduction of a drug in humans on a small scale, and are generally intended to develop data regarding metabolism, pharmacologic action and safety, as well as helping determine the

maximum tolerated dose. They also may provide early information regarding effectiveness. Phase 2 trials typically are controlled studies conducted in larger numbers of patients to gather initial effectiveness and safety data for specific indications. Phase 3 studies usually are intended to develop additional effectiveness and safety data, in order to allow evaluation of the drug's overall benefit/risk profile and provide a basis for labeling.

During any of these phases, the sponsoring company, the FDA, or an IRB may suspend or terminate a clinical trial at any time for a variety of reasons, including a finding that the subjects or patients are being exposed to an

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unacceptable health risk. Further, success in early-stage clinical trials does not assure success in later-stage clinical trials. Data obtained from clinical activities are not always conclusive and may be subject to alternative interpretations that could delay, limit or prevent regulatory approval.

NDA Submission and Review. After completing clinical testing of an investigational drug, a sponsor must prepare and submit an NDA for review and approval by the FDA. When an NDA is submitted, the FDA conducts a preliminary review to determine whether the application is sufficiently complete to be accepted for filing. If it is not, the FDA may refuse to file the application and request additional information, in which case the application must be resubmitted with the supplemental information, and review of the application is delayed.

As part of its review, the FDA may refer an NDA to an advisory committee for evaluation and a recommendation as to whether the application should be approved. Although the FDA is not bound by the recommendation of an advisory committee, the agency usually has followed such recommendations. Under the Pediatric Research Equity Act, certain applications for approval must include an assessment, generally based on clinical study data, of the safety and effectiveness of the subject drug or biological product in relevant pediatric populations. The FDA may waive or defer the requirement for a pediatric assessment, either at the company's request or by the agency's initiative. The FDA may determine that a Risk Evaluation and Mitigation Strategy, or REMS, is necessary to ensure that the benefits of a new product outweigh its risks. A REMS may include various elements, ranging from a medication guide or patient package insert to limitations on who may prescribe or dispense the drug, depending on what the FDA considers necessary for the safe use of the drug.

Before approving an NDA, the FDA will inspect the facilities at which the product is to be manufactured. The FDA will not approve the product unless it determines that the manufacturing processes and facilities are in compliance with cGMP requirements and adequate to assure consistent production of the product within required specifications.

If the FDA concludes that an NDA does not meet the regulatory standards for approval, the FDA typically issues a Complete Response letter communicating the agency's decision not to approve the application and outlining the deficiencies in the submission. The Complete Response letter also may request further information, including additional preclinical or clinical data. Even if such additional information and data are submitted, the FDA may decide that the NDA still does not meet the standards for approval.

Data from clinical trials are not always conclusive and the FDA may interpret data differently than the sponsor. Obtaining regulatory approval often takes a number of years, involves the expenditure of substantial resources, and depends on a number of factors, including the nature of the disease or condition the drug is intended to address, the availability of alternative treatments, and the risks and benefits demonstrated in clinical trials. Additionally, as a condition of approval, the FDA may impose restrictions that could affect the commercial success of a drug or require post-approval commitments, including the completion within a specified time period of additional clinical studies, which often are referred to as "Phase 4" or "post-marketing" studies.

Certain post-approval modifications to the drug product, such changes in indications, labeling, or manufacturing processes or facilities, may require a sponsor to develop additional data or conduct additional preclinical or clinical trials, to be submitted in a new or supplemental NDA, which would require FDA approval.

Post-Approval Regulation

Even if regulatory approvals are granted, a marketed product is subject to continuing comprehensive requirements under federal, state and foreign laws and regulations, including requirements and restrictions regarding adverse event reporting, recordkeeping, marketing, and compliance with cGMP. Adverse events reported after approval of a drug can result in additional restrictions on the use of a drug or requirements for additional post-marketing studies or clinical trials. The FDA or similar agencies in other countries may also require labeling changes to products at any time based on new safety information. If ongoing regulatory requirements are not met or if safety problems occur after the product reaches the market, the FDA or similar agencies in other countries may at any time withdraw product approval or take actions that would suspend marketing or approval.

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Good Manufacturing Practices. Companies engaged in manufacturing drug products or their components must comply with applicable cGMP requirements and product-specific regulations enforced by the FDA and other regulatory agencies. If, after receiving approval, a company makes a material change in manufacturing equipment, location, or process (all of which are, to some degree, incorporated in the NDA), additional regulatory review and approval may be required. The FDA also conducts regular, periodic visits to re-inspect equipment, facilities, and processes following the initial approval of a product. Failure to comply with applicable cGMP requirements and conditions of product approval may lead the FDA to seek sanctions, including fines, civil penalties, injunctions, suspension of manufacturing operations, operating restrictions, withdrawal of FDA approval, seizure or recall of products, and criminal prosecution.

Advertising and Promotion. The FDA and other federal regulatory agencies closely regulate the marketing and promotion of drugs through, among other things, standards and regulations for advertising, promotion to physicians and patients, communications regarding unapproved uses, and industry-sponsored scientific and educational activities. Failure to comply with applicable FDA requirements and other restrictions in this area may subject a company to adverse publicity and enforcement action by the FDA, the Department of Justice, the Office of the Inspector General of the Department of Health and Human Services, and state authorities, as well as civil and criminal fines and agreements that may materially restrict the manner in which a company promotes or distributes drug products.

Other Requirements. In addition, companies that manufacture or distribute drug products or that hold approved NDAs must comply with other regulatory requirements, including submitting annual reports, reporting information about adverse drug experiences, submitting establishment registrations and drug listings, and maintaining certain records.

Hatch-Waxman Act

If drug candidates we develop are approved for commercial marketing under an 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 establishes two abbreviated approval pathways for drug products that are in some way follow-on versions of already approved NDA products. In addition, the Hatch-Waxman Act provides companies with marketing exclusivity for new chemical entities, allows companies to apply to extend for up to five additional years of patent term lost during product development and FDA review of an NDA, and provides for a period of marketing exclusivity for products that are not new chemical entities if the NDA (or supplemental NDA) contains data from new clinical investigations that were necessary for approval. 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 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 have either expired or have been successfully challenged by generic entrants.

Orphan Drug Exclusivity

The Orphan Drug Act established incentives for the development of drugs intended to treat rare diseases or conditions, which generally are diseases or conditions affecting less than 200 thousand individuals in the U.S. at the time of the request for orphan designation. If a sponsor demonstrates that a drug is intended to treat a rare disease or condition and meets other applicable requirements, the FDA grants orphan drug designation to the product for that use. The FDA has granted orphan drug designation for the following products for the identified intended uses: i) filanesib for use in treating MM in May 2014; ii) ARRY-797 for use in treating LMNA-DCM in May 2014; iii) binimetinib for use in treating LGSOC in July 2014; iv) binimetinib for use in treating stage IIB-IV melanoma in November 2013; and v) binimetinib and encorafenib for treatment of stage IIB-IV melanoma that is positive for BRAF mutation in November 2013. The benefits of orphan drug designation include tax credits for clinical testing expenses and exemption from user fees. A drug that is approved for the orphan drug designated use typically is granted seven years of orphan drug exclusivity. During that period, the FDA generally may not approve any other application for the same product for the same indication, although there are exceptions, most notably when the later product is shown to be clinically superior to the product with exclusivity.

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Pediatric Exclusivity

Section 505A of the FDC Act provides for six months of additional exclusivity if an NDA sponsor submits pediatric data that fairly respond to a written request from the FDA for such data. The data do not need to show the product to be safe and effective in the pediatric population studied; rather, if the clinical trial is deemed to fairly respond to the FDA's request, the additional protection is granted. If reports of requested pediatric studies are submitted to and accepted by the FDA within the statutory time limits, whatever statutory or regulatory periods of exclusivity or Orange Book listed patent protection that cover the drug are extended by six months. This is not a patent term extension, but it effectively extends the regulatory period during which the FDA cannot approve an ANDA or 505(b)(2) application owing to regulatory exclusivity or listed patents. If any of our product candidates is approved, we anticipate seeking pediatric exclusivity when it is appropriate.

Fast Track and Breakthrough Therapy Designations

Certain of our product candidates may qualify for Fast Track designation. The Fast Track program is intended to expedite or facilitate the process for reviewing new drugs that demonstrate the potential to address unmet medical needs involving serious or life-threatening diseases or conditions. If a drug receives Fast Track designation, the FDA may consider reviewing sections of the NDA on a rolling basis, rather than requiring the entire application to be submitted to begin the review. Products with Fast Track designation also may be eligible for more frequent meetings and correspondence with the FDA about the product's development. Certain of our product candidates may benefit from other FDA programs intended to expedite development and review, such as priority review (i.e., a six-month review goal, rather than the standard 10-month timeframe) and accelerated approval (i.e., approval on the basis of a surrogate endpoint that is reasonably likely to predict clinical benefit).

Certain of our product candidates also may qualify for Breakthrough Therapy designation, which is intended to expedite the development and review of drugs for serious or life-threatening conditions and where preliminary clinical evidence shows that the drug may have substantial improvement on at least one clinically significant endpoint over available therapy. If a drug receives Breakthrough Therapy designation, it will be eligible for all of the benefits of Fast Track designation. In addition, Breakthrough Therapy-designated drugs are eligible for more intensive guidance from the FDA on an efficient drug development program and a commitment from the agency to involve senior FDA managers in such guidance.

Even if a product qualifies for Fast Track designation or Breakthrough Therapy designation, the FDA may later decide that the product no longer meets the conditions for qualification, and/or may determine that the product does not meet the standards for approval.

Companion Diagnostics

Diagnostic tests are regulated as medical devices under the FDC Act. Unless an exemption applies, diagnostic tests require marketing clearance or approval from the FDA prior to commercial distribution. The two primary types of FDA marketing authorization applicable to a medical device are premarket notification, also called 510(k) clearance, and premarket approval, or PMA approval. The diagnostic test being developed by Novartis for NRAS-mutant melanoma is subject to the PMA approval process.

PMA applications must be supported by valid scientific evidence, which typically requires extensive data, including technical, preclinical, clinical and manufacturing data, to demonstrate to the FDA's satisfaction the safety and effectiveness of the device. For diagnostic tests, a PMA application typically includes data regarding analytical and clinical validation studies. As part of its review of the PMA, the FDA will conduct a pre-approval inspection of the manufacturing facility or facilities to ensure compliance with the Quality System Regulation, or QSR, which requires manufacturers to follow design, testing, control, documentation, and other quality assurance procedures. FDA is required by statute to complete its review of an initial PMA application within six to ten months, although the process typically takes longer, and may require several years to complete. If FDA's evaluations of both the PMA application

and the manufacturing facilities are favorable, the FDA will either issue an approval letter or an approvable letter. The latter usually contains a number of conditions that must be met in order to secure final approval of the PMA. If the FDA's evaluation of the PMA or manufacturing facilities is not favorable, the FDA will deny approval of the PMA or issue a not approvable letter. A not approvable letter will outline the deficiencies in the application and, where practical, will identify what is necessary to make the PMA

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approvable. The FDA may also determine that additional clinical trials are necessary, in which case the PMA approval may be delayed for several months or years while the trials are conducted and the data are submitted in an amendment to the PMA. Once granted, PMA approval may be withdrawn by the FDA if compliance with post approval requirements, conditions of approval, or other regulatory standards is not maintained or problems are identified following initial marketing.

We anticipate that meetings with the FDA regarding our product candidate binimetinib for use in NRAS-mutant melanoma and its associated companion diagnostic product candidate will include representatives from FDA's Center for Drug Evaluation and Research and Center for Devices and Radiological Health to ensure that the NDA and PMA submissions are coordinated so that FDA can conduct parallel review of both submissions. In 2014, the FDA issued its final guidance document addressing the development and approval process for in vitro companion diagnostic devices. According to the guidance, for novel therapeutic products such as our product candidate binimetinib, the companion diagnostic device generally should be approved or cleared contemporaneously with the drug candidate, although the guidance allows for certain exceptions. We believe our program for the development of binimetinib and its NRAS companion diagnostic is consistent with this guidance.

Biological Samples

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.
Privacy

Most health care providers, including research institutions from which we or our partners obtain patient information, are subject to privacy and security regulations promulgated under the Health Insurance Portability and Accountability Act of 1996, or HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, or HITECH. Our clinical research efforts are not directly regulated by HIPAA. However, depending on the facts and circumstances, we could face substantial criminal penalties if we knowingly receive individually identifiable health information from a health care provider or research institution that has disclosed that information in violation of HIPAA. In addition, international data protection laws including the European Union, or EU, Directive 95/46/EC on the protection of individuals with regard to the processing of personal data and on the free movement of such data (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, other privacy and data security laws and regulations and genetic testing laws and regulations, including U.S. federal and state privacy and data security laws and regulations, may apply directly to our operations and/or those of our partners and may impose a number of obligations and restrictions, including restrictions on the use and disclosure of individuals' health information and other sensitive personal information. Finally, a security breach affecting sensitive personal information, including health information, could result in significant legal and financial exposure and reputational damages that could potentially have an adverse effect on our business.

United States Healthcare Reform

In March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, together the Healthcare Reform Act, was adopted in the U.S. This law substantially changes the way healthcare is financed by both governmental and private insurers, and significantly impacts the pharmaceutical industry. The Healthcare Reform Act contains a number of provisions that are expected to impact our business and operations, in some cases in ways we cannot currently predict. Changes that may affect our business if we or our partners commercialize our products in the future include those governing enrollment in federal healthcare

programs, reimbursement changes, rules regarding prescription drug benefits under the health insurance exchanges, and fraud and abuse and enforcement. In addition, continued implementation of the Healthcare Reform Act may result in the expansion of new programs such as Medicare payment for performance initiatives, and may impact existing government healthcare programs, such as by improving the physician quality reporting system and feedback program.

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Additional provisions of the Healthcare Reform Act, some of which became effective in 2011, may negatively affect our revenues from products that we or our partners commercialize in the future. For example, as part of the Healthcare Reform Act's provisions closing a coverage gap that currently exists in the Medicare Part D prescription drug program, manufacturers of branded prescription drugs are required to provide a 50% discount on branded prescription drugs dispensed to beneficiaries within this coverage gap. Medicare Part D is a prescription drug benefit available to all Medicare beneficiaries. It is a voluntary benefit that is implemented through private plans under contractual arrangements with the federal government. Similar to pharmaceutical coverage through private health insurance, Part D plans negotiate discounts from drug manufacturers and pass on some of those savings to Medicare beneficiaries. The Healthcare Reform Act also makes changes to the Medicaid Drug Rebate Program, discussed in more detail below, including increasing the minimum rebate from 15.1% to 23.1% of the average manufacturer price for most innovator products. The Centers for Medicare & Medicaid Services, or CMS, the federal agency that administers the Medicaid program, currently is expected to issue a final regulation later in 2015 to implement changes made to the Medicaid Drug Rebate Program by the Healthcare Reform Act.

Many of the Healthcare Reform Act's most significant reforms did not take effect until 2014 or thereafter, and the resulting new programs and requirements will continue to evolve in the next few years. Some states have chosen not to expand their Medicaid programs by raising the income limit to 133% of the federal poverty level. In part because not all states have expanded their Medicaid programs, it is unclear whether there will be more uninsured patients in 2015 than anticipated when Congress passed the Healthcare Reform Act. For each state that has opted not to expand its Medicaid program, there will be fewer insured patients overall. An increase in the proportion of uninsured patients who are prescribed products resulting from our proprietary or partnered programs could impact the future sales of any products that are commercialized in the future and our business and results of operations.

Pharmaceutical Pricing and Reimbursement

In U.S. markets, our ability and that of our partners to commercialize our products successfully, and to attract commercialization partners for our products, depends in significant part on the availability of adequate financial coverage and reimbursement from third-party payors, including, in the U.S., governmental payors such as the Medicare and Medicaid programs, managed care organizations, and private health insurers.

Once we have an approved drug, we intend to participate in the Medicaid Drug Rebate Program. Under the Medicaid Drug Rebate Program, we will be required to pay a rebate to each state Medicaid program for our covered outpatient drugs that are dispensed to Medicaid beneficiaries and paid for by a state Medicaid program as a condition of having federal funds being made available to the states for our drugs under Medicaid and Medicare Part B. Those rebates are based on pricing data that would be reported by us on a monthly and quarterly basis to CMS. Federal law requires that any company that participates in the Medicaid Drug Rebate Program also participate in the Public Health Service’s 340B drug pricing discount program, or the 340B program, in order for federal funds to be available for the manufacturer’s drugs under Medicaid and Medicare Part B. The 340B program requires participating manufacturers to agree to charge statutorily-defined covered entities no more than the 340B “ceiling price” for the manufacturer’s covered outpatient drugs. The ceiling price can represent a significant discount and is based on the pricing data reporting to the Medicaid Drug Rebate Program.

The Healthcare Reform Act expanded the 340B program to include additional entity types: certain free-standing cancer hospitals, critical access hospitals, rural referral centers and sole community hospitals, each as defined by the Healthcare Reform Act. The Healthcare Reform Act exempts drugs designated under section 526 of the FDC Act as “orphan drugs” from the ceiling price requirements for these newly-eligible entities. On July 21 2014, HRSA issued an “interpretive” rule that interprets the orphan drug exception narrowly and exempts orphan drugs from the ceiling price requirements for the newly-eligible entities only when the orphan drug is used for its orphan indication. Under the interpretive rule, the newly-eligible entities are entitled to purchase orphan drugs at the ceiling price when the orphan

drug is not used for its orphan indication. A pending legal challenge to the validity of this interpretive rule has made the application of the statutory orphan drug exception uncertain. The uncertainty regarding how the statutory orphan drug exception will be applied will increase the complexity of compliance, will make compliance more time-consuming, and could negatively impact our results of operations.

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The Healthcare Reform Act also obligates HRSA to create regulations and processes to improve the integrity of the 340B program and to update the agreement that manufacturers must sign to participate in the 340B program. HRSA has issued a proposed regulation and is currently expected to issue additional proposed regulations and guidance in 2015 that will address many aspects of the 340B program. Any final regulations and guidance could affect our obligations under the 340B program in ways we cannot anticipate. In addition, legislation may be introduced that, if passed, would further expand the 340B program to additional covered entities or otherwise expand the 340B program.

Federal law also requires that for a drug manufacturer's products to be eligible for payment with federal funds under the Medicaid and Medicare Part B programs and to be purchased by certain federal agencies and grantees, the manufacturer must participate in the Department of Veterans Affairs Federal Supply Schedule, or FSS, pricing program, established by Section 603 of the Veterans Health Care Act of 1992. Manufacturers that participate in the FSS pricing program must submit non-federal average manufacturer price data. In addition, if our products become available in the retail pharmacy setting when they are commercialized, we would be required to provide rebates to the Department of Defense for prescriptions dispensed to Tricare beneficiaries from Tricare retail network pharmacies under the Tricare Retail Refund Program. These programs obligate the manufacturer to pay rebates and offer its drugs at certain prices to certain federal purchasers. To the extent we choose to participate in these government healthcare programs, these and other requirements may affect our ability to profitably sell any product candidate for which we obtain marketing approval.

Pricing and rebate calculations vary among products and programs. The calculations are complex and will often be subject to interpretation by us, governmental or regulatory agencies and the courts. If we become aware that our reporting of pricing data for a prior quarter was incorrect, we will be obligated to resubmit the corrected data. For the Medicaid Drug Rebate Program, corrected data must be submitted for a period not to exceed 12 quarters from the quarter in which the data originally were due. Such restatements and recalculations increase our costs for complying with the laws and regulations governing the Medicaid Drug Rebate Program and other governmental pricing programs.

We may be liable for errors associated with our submission of pricing data. If we are found to have knowingly submitted false pricing data to the Medicaid program or the FSS pricing program, we may be liable for civil monetary penalties in the amount of up to $100,000 per item of false information. Our failure to submit pricing data to the Medicaid program or the FSS pricing program on a timely basis could result in a civil monetary penalty of $10,000 per day for each day the information is late. Such failure also could be grounds for CMS to terminate our Medicaid drug rebate agreement, which is the agreement under which we would participate in the Medicaid Drug Rebate Program. In the event that CMS terminates our rebate agreement, federal payments may not be available under Medicaid or Medicare Part B for our covered outpatient drugs. We cannot assure you that our submissions will not be found to be incomplete or incorrect.

Third-party payors decide which drugs they will pay for and establish reimbursement and co-pay levels. Third-party payors are increasingly challenging the prices charged for medical products and services and examining their cost effectiveness, in addition to their safety and efficacy. We may need to conduct expensive pharmacoeconomic studies in order to demonstrate the cost effectiveness of our products. Even with such studies, any of our products that are commercialized may be considered less safe, less effective or less cost-effective than other products, and third-party payors may not provide coverage and reimbursement, in whole or in part, for our products.

Political, economic and regulatory influences are subjecting the healthcare industry in the U.S. to fundamental changes. There have been, and we expect there will continue to be, legislative and regulatory proposals to change the healthcare system and reimbursement systems in ways that could impact our ability and that of our partners to profitably sell commercialized products.

Payors also are increasingly considering new metrics as the basis for reimbursement rates, such as average sales price, average manufacturer price and actual acquisition cost. It is difficult to project the impact of these evolving reimbursement mechanics on the willingness of payors to cover any of our products that are commercialized.

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In addition, we anticipate that a significant portion of our or our partners' revenue from sales of commercialized products will be obtained through government payors, including Medicaid, and any failure to qualify for reimbursement for products we are able to commercialize under those programs would have a material adverse effect on revenues and royalties from sales of such products.

Interactions with Healthcare Providers

Healthcare providers, physicians and others often play a primary role in the recommendation and prescription of pharmaceutical products. Manufacturers of branded prescription drugs are subject to broadly applicable fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which manufacturers market, sell and distribute the products for which they obtain marketing approval. Some of the laws and regulations that may affect our ability to operate are described below.

Anti-Kickback Laws

The federal Anti-Kickback Statute prohibits, among other things, persons from knowingly and willfully offering, paying, soliciting, or receiving remuneration, directly or indirectly, in cash or in kind, to induce or reward the purchasing, leasing, ordering or arranging for the purchase, lease, or order of any health care item or service reimbursable under federal healthcare programs such as Medicare and Medicaid. The term “remuneration” has been broadly interpreted to include anything of value, and the government can establish a violation of the Anti-Kickback Statute without proving that a person or entity had actual knowledge of the law. This statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on the one hand and prescribers, purchasers and formulary managers on the other. There are a number of statutory exceptions and regulatory safe harbors protecting certain common activities from prosecution or other regulatory sanctions, however, the exceptions and safe harbors are drawn narrowly. Failure to meet all of the requirements of a particular statutory exception or regulatory safe harbor does not make the conduct per se illegal under the Anti-Kickback Statute, but the legality of the arrangement will be evaluated on a case-by-case basis based on the totality of the facts and circumstances. A number of states also have anti-kickback laws that establish similar prohibitions that may apply to items or services reimbursed by government programs, as well as any third-party payors, including commercial payors.

False Claims Act

The federal civil False Claims Act prohibits, among other things, individuals or entities from knowingly presenting, or causing to be presented false or fraudulent claims for payment of government funds and knowingly making, or causing to be made or used, a false record or statement to get a false claim paid. Federal Anti-Kickback Statute violations and certain marketing practices, including off-label promotion, may implicate the federal civil False Claims Act. In addition, the Healthcare Reform Act amended the Social Security Act to provide that a claim including items or services resulting from a violation of the Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the False Claims Act. Actions under the False Claims Act may be brought by the government or as a qui tam action by a private individual in the name of the government. There are also criminal penalties, including imprisonment and criminal fines, for making or presenting a false or fictitious or fraudulent claim to the federal government. False Claims Act liability is potentially significant in the healthcare industry because the statute provides for treble damages and mandatory penalties of $5,500 to $11,000 per false claim or statement. Because of the potential for large monetary exposure, healthcare companies often resolve allegations without admissions of liability for significant and sometimes material amounts to avoid the uncertainty of treble damages and per claim penalties that may awarded in litigation proceedings. They may be required, however, to enter into corporate integrity agreements with the government, which may impose substantial costs on companies to ensure compliance.

Health Insurance Portability and Accountability Act

The federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, created federal criminal statutes that prohibit among other actions, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, including private third-party payors, knowingly and willfully embezzling or stealing from a healthcare benefit program, willfully obstructing a criminal investigation of a healthcare offense,

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and knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items or services.

Other Regulations

There also has been a recent trend of increased federal and state regulation of payments and transfers of value provided to healthcare professionals or entities. The federal Physician Payment Sunshine Act, which requires manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program to report annually (with certain exceptions) to the Centers for Medicare & Medicaid Services, or CMS, information related to payments or other ''transfers of value'' made to physicians and teaching hospitals, and requires applicable manufacturers and group purchasing organizations to report annually to CMS ownership and investment interests held by physicians and their immediate family members and payments or other ''transfers of value'' to such physician owners. Certain states also mandate implementation of commercial compliance programs, impose restrictions on device manufacturer marketing practices and require tracking and reporting of gifts, compensation and other remuneration to healthcare professionals and entities.

Foreign Corrupt Practices Act

U.S. Foreign Corrupt Practices Act, or FCPA, prohibits U.S. corporations and their representatives and intermediaries from offering, promising, authorizing or making payments to any foreign government official, government staff member, political party or political candidate in an attempt to obtain or retain business abroad. The scope of the FCPA includes interactions with certain healthcare professionals in many countries. Other countries have enacted similar anti-corruption laws and/or regulations.

Efforts to ensure that business activities and business arrangements comply with applicable healthcare laws and regulations can be costly for manufacturers of branded prescription products. If a manufacturer's operations, including activities conducted by its sales team, are found to be in violation of any of these laws or any other governmental regulations that apply to the company, the company may be subject to significant civil, criminal and administrative sanctions, including imprisonment, monetary penalties, damages, fines, exclusion from participation in federal healthcare programs, such as Medicare and Medicaid, and the curtailment or restructuring of operations.
Other Regulatory Requirements

We are also subject to regulation by other regional, national, state and local agencies, including the U.S. Department of Justice, the Office of Inspector General of the U.S. Department of Health and Human Services and other regulatory bodies. Our current and future partners are subject to many of the same requirements.

In addition, 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, the Toxic Substance Control Act, the Resource Conservation and Recovery Act, and regulations under other federal, state and local laws.

Violations of any of the foregoing 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.

Our patent strategy is designed to protect inventions, technology and improvements to inventions that are commercially important to our business in countries where we believe it is commercially reasonable and advantageous to do so. We have numerous U.S. patents and patent applications related to our clinical-stage programs as well as numerous patent applications and counterpart patent filings which relate to our preclinical

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programs and proprietary technologies. These patents and patent applications include claims directed to compositions of matter, pharmaceutical compositions, methods of treatment, and methods of making these compositions for multiple applications.

We have two issued U.S patents covering filanesib and related molecules, and their equivalent counterparts issued or pending in dozens of countries. These patents include composition of matter, method of treatment and combination therapy claims, which will expire on various dates in 2025. We believe that patent term extension under the Hatch-Waxman Act could be available to extend our patent exclusivity for filanesib to at least 2030 in the United States depending on timing of our first approval. In Europe, we believe that patent term extension under a supplementary protection certificate could be available for an additional five years to at least 2030. Additionally, other patent applications are directed to methods of using filanesib and other combination therapies, which, if issued, have expiration dates between 2033 and 2034, excluding any patent term adjustment.

We have issued U.S. patents covering binimetinib, selumetinib and related molecules and their equivalent counterparts issued or pending in dozens of countries. These patents include composition of matter, method of treatment and synthetic method claims, which will expire on various dates in 2023 and 2024. We have also filed patent applications directed to methods of manufacturing, and to intermediates useful for manufacturing, binimetinib and selumetinib, which will expire on various dates in 2026 and 2027. Additionally, AstraZeneca has filed other patent applications directed to selumetinib, including patent applications of which we are not aware. Patent term extension under the Hatch-Waxman Act in the United States and in Europe under a supplementary protection certificate could be available for each of our partners to extend patent exclusivity for these clinical candidates. AstraZeneca is entitled to decide which patent covering its product candidate will be subject to such efforts and whether to file other patent applications directed at its product candidate. Our partners do not share information with us about the status or results of their respective efforts to seek additional patent protection. Therefore, information we report regarding the patent status of these partnered drug development programs is limited to our efforts to obtain patent protection.

In addition, we have several hundred additional patents and patent applications filed worldwide, substantially all of which pertain to our product development programs. Any patents that may issue from our pending patent applications would expire no earlier than 2023, excluding any patent term extension. These patents and patent applications disclose compositions of matter, pharmaceutical compositions, methods of use and synthetic methods, as well as various salt and polymorphic forms of clinical candidates.

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 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.

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The source code for our proprietary software programs is protected both as a trade secret and as a copyrighted work. 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.

Employees

As of June 30, 2015, we had 156 full-time employees. 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 and 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

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products is uncertain, we are unable to precisely estimate the actual funds we will require to develop and potentially commercialize them.

We have historically funded our operations from up-front fees and license and milestone payments received under our drug collaborations and license agreements, the sale of equity securities, and debt provided by convertible debt and other credit facilities. Management believes that our cash, cash equivalents and marketable securities as of June 30, 2015 will enable us to continue to fund operations in the normal course of business for at least the next 12 months. Until we can generate sufficient levels of cash from current operations, which we do not expect to achieve in the foreseeable future, and because sufficient funds may not be available to us when needed from existing collaborations, we expect that we will be required to continue to fund our operations in part through the sale of debt or equity securities and through licensing select programs that include up-front and/or milestone payments. 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.

Our ability to successfully raise sufficient funds through the sale of debt or equity securities or from debt financing from lenders when needed is subject to many risks and uncertainties and, even if we are successful, future equity issuances would result in dilution to our existing stockholders. We also may not successfully consummate new collaboration or license agreements that provide for up-front fees or milestone payments, or we may not earn milestone payments under such agreements when anticipated, or at all. Our ability to realize milestone or royalty payments under existing agreements and to enter into new 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. For example, in August 2013, we reduced our workforce by approximately 20% as part of our efforts to fund our discovery organization with strategic collaborations and focus internally on progressing our hematology and oncology programs to later stage development. If we are unable to generate enough revenue from our existing or new collaborations when needed or secure additional sources of funding, it may be necessary to significantly reduce our current rate of spending through further reductions in staff and delaying, scaling back or stopping certain research and development programs, including more costly Phase 2 and Phase 3 clinical trials on our wholly-owned or co-development programs as these programs progress into later stage development. 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 a part of the investment of our stockholders in our common stock and may result in a reduction in the value of our 3.00% Convertible Senior Notes due 2020. In addition, if we are unable to maintain certain levels of cash and marketable securities, our obligations under 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, 2015, we had an accumulated deficit of $708.6 million. We had net income of $9.4 million for the fiscal year ended June 30, 2015, including the impact of the net gain related to the return of binimetinib and acquisition of encorafenib, as well as realized gains from the sale of marketable securities, and net losses of $85.3 million and $61.9 million for the fiscal years ended June 30, 2014 and 2013, 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 and license 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 collaboration and license 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 may never realize much of the milestone revenue provided for in our collaboration and license agreements and we do not expect to receive any royalty revenue for several

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years, if at all. 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 or our partners 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 partners 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. If one of our partners terminates a program, we will not receive any future milestone payments or royalties relating to that program under our agreement with that party. 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 partners have substantial control and discretion over the timing and the continued development and marketing of drug candidates we have licensed to them and, therefore, over the timing and whether we receive anticipated milestone payments and/or royalties.

Our partners have significant discretion in determining the efforts and amount of resources that they dedicate to our collaborations and, therefore, whether we will receive milestone payments and any royalties when anticipated, or at all. Our partners 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 receipt of milestone payments and royalties from our partners depends on their 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 partners 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. In addition, we may not be apprised of the development or commercialization activities or strategies of our partners and, as a result, our assumptions regarding the anticipated receipt of milestone payments or royalties may be incorrect.

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

- partners 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;
- partners may not commit sufficient resources to the testing, marketing, distribution or other development of our drug candidates;
- partners may not properly maintain or defend intellectual property rights we license to them 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;
- partners 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);
- partners are subject to many of the risks described under the heading below "Risks Related to Our Industry" and any adverse effects on our partners in connection with their regulatory obligations could have a material adverse effect on our business, financial condition and ability to commercialize our products; and
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disputes may arise between us and our partners 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 partners to act in their own self-interest and not in the interest of holders of our securities.

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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 through spending $720.9 million from our inception through June 30, 2015, including our investment in binimetinib while co-developed with Novartis and subsequently returned to us pursuant to the Binimetinib Agreement. In fiscal 2015, we spent $54.4 million in research and development for proprietary programs, compared to $49.8 million and $59.4 million for fiscal years 2014 and 2013, respectively. Our proprietary drug discovery programs are in 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. We have 10 ongoing partner-funded clinical programs, and we plan to continue initiatives to partner select clinical and preclinical stage programs to obtain additional capital or fund further development.

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-promotion 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;
- strategic decisions to allocate more of our resources to the further development of our proprietary programs and building our commercialization capabilities as our drugs advance;
- 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 preclinical 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 and our 3% Convertible Senior Notes due 2020. 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 holders of our securities 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.

An 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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Servicing our debt requires a significant amount of cash, and we may not have sufficient cash flow from our business to pay our substantial debt.

In June 2013, we issued $132.3 million aggregate principal amount of 3.00% Convertible Senior Notes due 2020, or the 2020 Notes, to investors pursuant to an effective shelf registration statement filed with the SEC. Interest is payable on the 2020 Notes semi-annually and the 2020 Notes mature on June 1, 2020, unless redeemed or converted prior to that date. In addition, if an event considered a Fundamental Change under the 2020 Notes occurs, holders of the 2020 Notes may require us to purchase for cash all or any portion of their 2020 Notes at a purchase price equal to 100% of the principal amount of the 2020 Notes to be purchased plus accrued and unpaid interest, if any, to, but excluding, the Fundamental Change purchase date. As of June 30, 2015, all $132.3 million principal amount of the 2020 Notes remained outstanding. We also have a term loan outstanding with Comerica Bank under which $14.6 million is outstanding as of June 30, 2015.

Our ability to make scheduled payments of interest and principal on our indebtedness, including the 2020 Notes, or to pay the redemption price for the 2020 Notes on a Fundamental Change, depends on our future performance, which is subject to economic, financial, competitive and other factors beyond our control. We may not have sufficient cash in the future to service our debt and make necessary capital expenditures. If we are unable to generate such cash flow or secure additional sources of funding, we may be required to adopt one or more alternatives, such as significantly reducing our current rate of spending through further reductions in staff, delaying, scaling back or stopping certain research and development programs, restructuring debt or obtaining additional equity capital on terms that may be onerous or highly dilutive. Our ability to refinance our indebtedness will depend on the capital markets and our financial condition at such time. We may not be able to engage in any of these activities or engage in these activities on desirable terms, which could result in a default on our debt obligations.

Many of 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. Many of our drug candidates are in the early stages of development. Although our most advanced drug candidates are in Phase 3 studies, 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 studies and clinical trials. At any time, we, the FDA, an IRB or other regulatory body may temporarily or permanently stop the trial, for a variety of reasons, principally for safety concerns. We or our partners 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;
- existence of alternative therapeutics that are more effective; and
- if a drug candidate requires a companion diagnostic test for approval, failure to obtain approval for the companion diagnostic test.

As our product candidates advance to later stage clinical trials, it is customary that various aspects of the development program, such as manufacturing, formulation and other processes, and methods of administration, may be altered to optimize the candidates and processes as part of scale-up necessary for later stage clinical

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trials and potential approval and commercialization. These changes may not produce the intended optimization, including production of drug substance and drug product of a quality and in a quantity sufficient for Phase 3 clinical stage development or for commercialization, which may cause delays in the initiation or completion of clinical trials and greater costs. We may also need to conduct "bridging studies" to demonstrate comparability between newly manufactured drug substance and/or drug product for commercialization relative to previously manufactured drug substance and/or drug product for clinical trials. Demonstrating comparability may require us to incur additional costs or delay initiation or completion of clinical trials and, if unsuccessful, could require us to complete additional preclinical studies or clinical trials.

Our capital requirements could significantly increase if we choose to develop more of our proprietary programs internally.

We believe that the maximum value for certain proprietary drug candidates is best achieved by retaining the rights to develop and commercialize the candidate and not seeking a partner or by waiting until later in the development process to seek a partner to co-develop and commercialize or co-promote a product. It is difficult to predict which of our proprietary programs are likely to yield higher returns if we elect to develop them further before seeking a partner or to not seek a partner at all as a result of many factors, including the competitive position of the product, our capital resources, the perceived value among potential partners of the product and other factors outside of our control. Therefore, we may undertake and fund, solely at our expense, further development, clinical trials, manufacturing and marketing activities for a greater number of proprietary candidates than we planned, which may not result in a greater return to Array than if we had chosen to out-license those programs. 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 partners for a significant portion of our revenue, if one or more of our major partners terminates or reduces the scope of its agreement with us, our revenue may significantly decrease.

A relatively small number of partners account for a significant portion of our revenue. Oncothyreon, Loxo and Novartis accounted for 42%, 18% and 16%, respectively, of our total revenue for fiscal 2015. In fiscal 2014, Novartis, Loxo and AstraZeneca accounted for 29%, 23% and 12%, respectively, of our total revenue. We expect that revenue from a limited number of partners, including Biogen, Celgene and Loxo will account for a large portion of our revenue in future quarters. In general, our partners may terminate their contracts with us upon 60 to 180 days’ notice for a number of reasons or no reason, which would eliminate future milestone or royalty revenue under the collaboration. In addition, certain of our partners do not generate revenue or sufficient revenue to cover their operating expenses and their ability to continue to fund milestone and other payments under our agreements with them depends on their ability to raise funds through the issuance of debt or equity securities or from other sources. To the extent such funding is not available to these partners when needed, they may not be able to fund their obligations to us and we would therefore not realize revenue when anticipated or at all under our agreement with them.

If our drug discovery and development programs do not progress as anticipated, our revenue, stock price and the value of the 2020 Notes 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. 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 partners 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 partners. In addition, in preparing these estimates we rely on the timeliness and accuracy of information and estimates reported or provided to us by our partners concerning the timing, progress and results of clinical

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trials or other development activities they conduct under our collaborations with them. If we or our partners do not achieve milestones when anticipated, or if our partners choose to terminate a program, we may not achieve our planned revenue, our expenses could be higher than anticipated 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 156 full-time employees as of June 30, 2015, 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 partners 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. In addition, we periodically review our existing workforce in light of the current and anticipated needs of our business and may make strategic changes to its size and scope in an effort to use our capital more efficiently.

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 Ron Squarer, our Chief Executive Officer; Dr. Victor Sandor, our Chief Medical Officer; Dr. Nicholas Saccomano, our Chief Scientific Officer; Andrew Robbins, our Chief Operating 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 began a Phase 3 trial in June 2013 on binimetinib in LGSOC, but we have not previously 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. In addition, in deciding to pursue development of ovarian cancer in the Phase 3 MILO study, we relied on broad-based activity that has been shown for binimetinib in other indications and known prior results with other inhibitors, including MEK inhibitors that have shown activity in ovarian cancer. Consequently, we do not have direct clinical information that binimetinib will be effective in treating the proposed patient population. We expect to spend significant amounts to recruit and retain high quality personnel with clinical development experience. 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. 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 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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If we or our partners 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 partners 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 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 several years completing certain trials. Further, the time within which we or our partners 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 partners 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 approvals and associated delays in drug candidates reaching the market. Patients may also suffer adverse medical events or side effects in the course of clinical trials that may delay or prohibit regulatory approval of our drug candidates. Even if we or our partners successfully conduct clinical trials, we or our partners may not obtain favorable clinical trial results and may not be able to obtain regulatory approval on this basis.

In addition, we 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 partners 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 partners may fail to gain approval for our drug candidates altogether. If we or our partners are unable to market and sell our drug candidates or are unable to obtain approvals in the time frame 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 partners, including any Phase 3 or pivotal trials for binimetinib and/or encorafenib, filanesib, selumetinib (partnered with AstraZeneca) and danoprevir (partnered with Intermune/Roche Holding AG), could significantly affect our product development costs and our ability to generate revenue. We do not know whether the FDA will agree with the trial designs for ongoing and planned clinical trials or 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 partners to do the following:

- provide sufficient safety, efficacy or other data regarding a drug candidate to support the commencement of a Phase 3 or other clinical trial;
- reach agreement on acceptable terms with prospective contract manufacturers, CROs and trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different third parties;
- 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 IRB approval to conduct a clinical trial at a prospective site;

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- recruit and enroll patients to participate in clinical trials, which can be impacted by many factors outside our or our partners' control, including competition from other clinical trial programs for the same or similar indications;
- 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; and
- develop and validate a companion diagnostic test for a drug candidate that requires one.

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 partner, the FDA, an IRB, a clinical trial site 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 GCP, or our protocols;
- 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, we or our partners may need to amend clinical trial protocols for a variety of reasons, including to reflect changes in regulatory requirements and guidance. Such amendments may require us to, for example, 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 partners or on our own may not receive regulatory approval.

The development and commercialization of drug candidates with our partners and through 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. For a drug candidate that requires a companion diagnostic test, we may not be able to obtain approval for the drug if the FDA does not approve or clear its corresponding companion diagnostic test. 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 partners 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, changes in regulatory policy during the period of clinical trials in humans and regulatory review, or the availability of alternative treatments. None of our partners has 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 partners cannot obtain this approval, we will not realize milestone or royalty payments based on commercialization goals for these drug candidates.

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Delays or failures in validating, developing and obtaining regulatory approval for the NRAS-mutant melanoma companion diagnostic test could harm the prospects for approval and commercialization of binimetinib for NRAS-mutant melanoma.

Novartis is developing an NRAS melanoma companion diagnostic test for use with our product candidate binimetinb for NRAS-mutant melanoma. Companion diagnostics typically are subject to regulation by the FDA and comparable foreign regulatory authorities as medical devices and require separate regulatory approval prior to commercialization. Novartis may encounter difficulties in developing and obtaining approval for the NRAS melanoma companion diagnostic test, including, but not limited to, issues related to selectivity/specificity, analytical validation, reproducibility, or clinical validation. Any delay or failure by Novartis to develop or obtain regulatory approval of the companion diagnostic test could delay or prevent approval of our product candidate binimetinib. Even if Novartis obtains approval of the companion diagnostic test and transfers the test to a vendor of our designation, that vendor may encounter production difficulties that could constrain the supply of the companion diagnostic. The vendor and/or we also may have difficulties gaining acceptance of the use of the companion diagnostic in the clinical community. If the companion diagnostic fails to gain market acceptance, it could have an adverse effect on our ability to derive revenues from sales of our product candidate binimetinib, if approved, for use in NRAS-mutant melanoma. In addition, the vendor we designate could decide to discontinue selling or manufacturing the companion diagnostic or our relationship with such vendor may otherwise terminate. We may be delayed in identifying another vendor, or we may not be able to enter into arrangements with another vendor to maintain supply of the companion diagnostic, which could adversely affect our commercialization of binimetinib for NRAS-mutant melanoma, if it is approved for that use.

Even if our drug candidates obtain regulatory approval, we and our partners will be subject to ongoing government regulation, including federal and state fraud and abuse laws, such as anti-kickback and false claims laws.

Even if regulatory authorities approve any of our drug candidates, the manufacture, labeling, storage, recordkeeping, reporting, distribution, advertising, promotion, marketing, sale, import and of these drugs will be subject to strict and ongoing regulation. If we, our partners, our product candidates or the manufacturing facilities for our product candidates fail to comply with applicable regulatory requirements, a regulatory agency may suspend any ongoing clinical trials; issue warning letters or untitled letters; suspend or withdraw regulatory approval; refuse to approve pending applications or supplements to applications; suspend or impose restrictions on operations; seize or detain products, prohibit the export or import of products, or require us to initiate a product recall; or seek other monetary or injunctive remedies or impose civil or criminal penalties.

Compliance with ongoing regulation consumes substantial financial and management resources and may expose us and our partners 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 an appropriate benefit-risk profile 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. Alternatively, we may be required by the FDA to develop and implement a REMS to ensure the safe use of our products.

REMS may include costly risk management measures such as enhanced 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. Any of these events could delay or prevent us from generating revenue, or limit the revenue, from the commercialization of these drugs and cause us to incur significant additional costs.

In addition, the marketing of these drugs by us or our partners may be heavily scrutinized by the FDA, the Department of Justice, the Department of Health and Human Services' Office of Inspector General, state attorneys general, members of Congress and the public. Our promotional activities will be regulated by federal and state laws pertaining to health care “fraud and abuse,” such as:

- the federal Anti-Kickback Statute, which prohibits, among other things, knowingly and willfully soliciting, receiving, offering or paying remuneration, directly or indirectly, in cash or in kind, to induce or reward

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either the referral of an individual for, or the purchase, order or recommendation of, items or services for which payment may be made, in whole or in part, under federal healthcare programs, such as the Medicare and Medicaid programs;

- the federal civil False Claims Act, which prohibits, among other things, individuals or entities from knowingly presenting, or causing to be presented, false or fraudulent claims for payment of government funds or knowingly making, using or causing to be made or used, a false record or statement to get a false claim paid. There are also criminal penalties, including imprisonment and criminal fines, for making or presenting a false or fictitious or fraudulent claim to the federal government;
- the federal Health Insurance Portability and Accountability Act of 1996 (HIPAA), which created federal criminal laws that prohibit, among other actions, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program including private third-party payors;
- the federal Physician Payment Sunshine Act, which requires manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program to report annually (with certain exceptions) to the Centers for Medicare & Medicaid Services, or CMS, information related to payments or other ''transfers of value'' made to physicians and teaching hospitals, and requires applicable manufacturers and group purchasing organizations to report annually to CMS ownership and investment interests held by physicians and their immediate family members and payments or other ''transfers of value'' to such physician owners;
- the federal Foreign Corrupt Practices Act and similar anti-bribery laws in other jurisdictions, which generally prohibit companies and their intermediaries from making improper payments to government officials and/or other persons for the purpose of obtaining or retaining business; and
- analogous state and foreign law equivalents of each of the above federal laws, such as anti-kickback and false claims laws which may apply to items or services reimbursed by any third-party payor, including commercial insurers; state laws that require pharmaceutical manufacturers to comply with the industry's voluntary compliance guidelines and the applicable compliance guidance promulgated by the federal government or otherwise restrict payments that may be made to healthcare providers and other potential referral sources; and state laws that require pharmaceutical manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts.

Additional information about these laws is provided above under the heading "Interactions with Healthcare Providers."

Violations of these laws can result in costly litigation, and significant criminal, civil and administrative sanctions, including fines and/or imprisonment, monetary penalties, damages, exclusion from participation in federal health care programs, and burdensome reporting and compliance obligations.

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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Third-party manufacturers we rely on may encounter failures or difficulties in manufacturing or formulating clinical development and 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 rely on third parties to manufacture our drug candidates. In June 2015, we sold our chemical, manufacturing and controls activities and no longer have manufacturing facilities that can produce quantities of API and finished drug product for large-scale clinical trials. We therefore 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 foreign 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 an IND application or an approved NDA. 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 may be in short supply.

Accordingly, we must either develop such manufacturing facilities, which will require substantial additional funds, or rely 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.

Any performance failure on the part of a third-party manufacturer could delay clinical development, regulatory approval or, ultimately, sales of our or our partners' drug candidates. 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, 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 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 contractors and subcontractors. 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 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

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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 Drug Enforcement Administration, or 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 one of our manufacturers fails to maintain compliance, the contract manufacturer 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, among other potential consequences, and any of these events could result in delays, additional costs and potentially lost revenues.

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 partners conduct, that result in the future manufacture and sale of drugs by us or our partners 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 additional or maintain our current insurance policies at acceptable costs or at all.

Due to our reliance on CROs 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 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 third-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

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manufactured relating to the cross-border shipment of pharmaceutical ingredients. Although we have developed and instituted controls, we cannot assure you that we, our employees, our consultants or our contractors will operate at all times in full 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 consequences could result, including, but not limited to, the suspension or termination of clinical trials, failure to obtain approval of a product candidate, restrictions on our products or manufacturing processes, 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 DEA, 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, 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 partners. 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 partners' 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 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;

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- 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 partners.

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

Our research and development capabilities may not produce viable drug candidates.

We have entered into several research and development collaborations under which we provide drug discovery and development services to identify drug candidates for our partners. 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 partners' purposes, which may result in delayed or lost revenue, loss of partners or failure to expand our existing relationships. Our ability to create viable drug candidates for ourselves and our partners 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 partners.

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 partners could decline even further through consolidation among these companies. If the number of our potential partners 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 partners' ability to fund research and development.

Traditionally, many unprofitable biotechnology companies have funded their research and development expenditures through raising capital in the debt and equity markets. These markets have historically been volatile and declines in these markets may severely restrict their ability to raise new capital and to continue to expand or fund existing research and development efforts. If our current or future biotechnology partners are unable to raise sufficient capital to fund research and development expenditures, we may not be able to expand or maintain current revenue.

Health care reform, 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.

The Patient Protection and Affordable Care Act and the Health Care and Education Reconciliation Act of 2010, together the "Healthcare Reform Act", 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 are 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, rules regarding prescription drug benefits under the health insurance exchanges, and fraud and abuse

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enforcement. In addition, continued implementation of the Healthcare Reform Act may result in the expansion of new programs such as Medicare payment for performance initiatives, and may impact existing government healthcare programs, such as by improving the physician quality reporting system and feedback program.

Additional provisions of the Healthcare Reform Act may negatively affect any revenues from products we or our partners are able to commercialize in the future. For example, as part of the Healthcare Reform Act's provisions closing a coverage gap that currently exists in the Medicare Part D prescription drug program, manufacturers of branded prescription drugs are required to provide a 50% discount on drugs dispensed to beneficiaries within this coverage gap. The Healthcare Reform Act also expanded the 340B pricing program to include additional entity types, as described below in the risk factor under the heading "Pharmaceutical companies are subject to significant ongoing health care regulatory obligations and oversight, including reporting and payment obligations under the Medicaid Drug Rebate Program or other governmental pricing programs, which may result in significant additional expense and limit our or their ability to commercialize our products".

Many of the Healthcare Reform Act's most significant reforms did not take effect until 2014 or thereafter, and the resulting new programs and requirements will continue to evolve in the next few years. The Centers for Medicare & Medicaid Services, or CMS, the federal agency that administers the Medicaid program, currently is expected to issue a final regulation later in 2015 to implement changes made to the Medicaid Drug Rebate Program by the Healthcare Reform Act. Some states have chosen not to expand their Medicaid programs by raising the income limit to 133% of the federal poverty level. In part because not all states have expanded their Medicaid programs, it is unclear whether there will be more uninsured patients in 2015 than anticipated when Congress passed the Healthcare Reform Act. For each state that has opted not to expand its Medicaid program, there will be fewer insured patients overall. An increase in the proportion of uninsured patients who are prescribed products resulting from our proprietary or partnered programs could impact future sales of any products that are commercialized in the future and our business and results of operations.

Moreover, legislative changes to the Healthcare Reform Act remain possible. We expect that the Healthcare Reform Act, as currently enacted and as may be amended in the future, 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 partners 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, or may facilitate the introduction of generic competition with respect to products we are able to commercialize, and so may limit our commercial opportunity and reduce any associated revenue and profits.

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 partners, 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, beginning April 1, 2013, Medicare

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payments for all items and services, including drugs and biologicals, have been reduced by 2% under the sequestration (i.e., automatic spending reductions) required by the Budget Control Act of 2011, Pub. L. No. 112-25, or BCA, as amended by the American Taxpayer Relief Act of 2012, Pub. L. 112-240, or ATRA. The BCA requires sequestration for most federal programs, excluding Medicaid, Social Security, and certain other programs, because Congress failed to enact legislation by January 15, 2012, to reduce federal deficits by $1.2 trillion over ten years. The Bipartisan Budget Act of 2013, Pub. L. No. 113-67, extended the 2% reduction to 2023, and the Protecting Access to Medicare Act of 2014, Pub. L. 113-93, extended the 2% reduction, on average, to 2024. These sequestration cuts could adversely impact payment for products that we or our partners are able to commercialize, which could negatively impact our revenue.

We, or our partners, 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 payors' formularies, we or our partners may not be able to negotiate favorable reimbursement rates for our products. If we, or our partners, 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.

Payors also are increasingly considering new metrics as the basis for reimbursement rates, such as average sales price, or ASP, average manufacturer price, or AMP, and Actual Acquisition Cost. The existing data for reimbursement based on some of these metrics is relatively limited, although certain states have begun to survey acquisition cost data for the purpose of setting Medicaid reimbursement rates, and since November 2013, CMS has been publishing final National Average Drug Acquisition Cost, or NADAC, files, which reflect retail community pharmacy invoice costs, on a weekly basis. Therefore, it may be difficult to project the impact of these evolving reimbursement mechanics on the willingness of payors to cover candidate products that we or our partners are able to commercialize. As discussed above, to the extent that we or our partners participate in government pricing programs, recent legislative changes to the 340B drug pricing program, the Medicaid Drug Rebate Program, and the Medicare Part D prescription drug benefit also could impact our revenues. We anticipate that a significant portion of revenue from sales of drugs that we or our partners are able to commercialize may be obtained through government payors, including Medicaid, and any failure to qualify for reimbursement for those products under those programs would have a material adverse effect on our sales revenues and royalties.

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

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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 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.

Agreements we have with our employees, consultants and partners 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

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employed by other companies involved in one or more areas similar to the activities we conduct. In some situations, our confidentiality and proprietary information agreements may conflict with, or be subject to, the rights of third parties with whom our employees, consultants or advisors have prior employment or consulting relationships. Although we require our employees and consultants to maintain the confidentiality of all proprietary information of their previous employers, these individuals, or we, may be subject to allegations of trade secret misappropriation or other similar claims as a result of their prior affiliations. Finally, others may independently develop substantially equivalent proprietary information and techniques or otherwise gain access to our trade secrets. Our failure or inability to protect our proprietary information and techniques may inhibit or limit our ability to compete effectively, or exclude certain competitors from the market.

The drug research and development industry is highly competitive and we compete with some companies that offer a broader range of capabilities and have better access to resources than we do.

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

We face potential liability related to the privacy of health information we obtain from research institutions.

Most health care providers, including research institutions from which we or our partners obtain patient information, are subject to privacy and security regulations promulgated under HIPAA, as amended by HITECH. Our clinical research efforts are not directly regulated by HIPAA. However, depending on the facts and circumstances, we could face substantial criminal penalties if we knowingly receive individually identifiable health information from a health care provider or research institution that has disclosed information in violation of HIPAA. 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, other privacy, data security and genetic testing laws and regulations, including U.S. federal and state privacy and data security laws and regulations, may apply directly to our operations and/or those of our partners and may impose a number of obligations and restrictions, including restrictions on the use and disclosure of individuals' health information and other sensitive personal information. Moreover, patients about whom we or our partners 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. Finally, a security breach affecting sensitive personal information, including health information, could result in significant legal and financial exposure and reputational damages that could potentially have an adverse effect on our business.

Pharmaceutical companies are subject to significant ongoing health care regulatory obligations and oversight, including reporting and payment obligations under the Medicaid Drug Rebate Program or other governmental pricing programs, which may result in significant additional expense and limit our or their ability to commercialize our products.

If we or any partners fail to comply with applicable federal, state, or local regulatory requirements, we could be subject to a range of regulatory actions that could affect our or any partners' ability to commercialize our products and

could harm or prevent sales of any affected products that we are able to commercialize, or could substantially increase the costs and expenses of commercializing and marketing our products. Any threatened or actual government enforcement action could also generate adverse publicity and require that we devote substantial resources that could otherwise be used in other aspects of our business.

Once we have an approved drug, we intend to participate in the Medicaid Drug Rebate Program, which will require us to pay a rebate to each state Medicaid program for our covered outpatient drugs that are dispensed to

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Medicaid beneficiaries and paid for by a state Medicaid program as a condition of having federal funds being made available to the states for our drugs under Medicaid and Medicare Part B. Those rebates are based on pricing data that would be reported by us on a monthly and quarterly basis to CMS. If we participate in the Medicaid Drug Rebate Program, we must also participate in the Public Health Service's 340B drug pricing discount program. The 340B pricing program requires participating manufacturers to agree to charge statutorily-defined covered entities no more than the 340B "ceiling price" for the manufacturer's covered outpatient drugs, which can represent a significant discount and is based on the pricing data reporting to the Medicaid Drug Rebate Program.

The Healthcare Reform Act expanded the Public Health Service's 340B drug pricing program to include additional entity types: certain free-standing cancer hospitals, critical access hospitals, rural referral centers and sole community hospitals, each as defined by the Healthcare Reform Act. The Healthcare Reform Act exempts drugs designated under section 526 of the FDC Act as "orphan drugs" from the ceiling price requirements for these newly-eligible entities. On July 21, 2014, HRSA issued an "interpretive" rule that interprets the orphan drug exception narrowly and exempts orphan drugs from the ceiling price requirements for the newly-eligible entities only when the orphan drug is used for its orphan indication. Under the interpretive rule, the newly-eligible entities are entitled to purchase orphan drugs at the ceiling price when the orphan drug is not used for its orphan indication. A pending legal challenge to the validity of this interpretive rule has made the application of the statutory orphan drug exception uncertain. The uncertainty regarding how the statutory orphan drug exception will be applied will increase the complexity of compliance, will make compliance more time-consuming, and could negatively impact our results of operations.

The Healthcare Reform Act also obligates HRSA to create regulations and processes to improve the integrity of the 340B program and to update the agreement that manufacturers must sign to participate in the 340B program. HRSA has issued a proposed regulation and is currently expected to issue additional proposed regulations and guidance in 2015 that will address many aspects of the 340B program. Any final regulations and guidance could affect our obligations under the 340B program in ways we cannot anticipate. In addition, legislation may be introduced that, if passed, would further expand the 340B program to additional covered entities or otherwise expand the 340B program.

Federal law also requires that for a drug manufacturer's products to be eligible for payment with federal funds under the Medicaid and Medicare Part B programs and to be purchased by certain federal agencies and grantees, the manufacturer must participate in the Department of Veterans Affairs Federal Supply Schedule, or FSS, pricing program, established by Section 603 of the Veterans Health Care Act of 1992. Manufacturers that participate in the FSS pricing program must submit non-federal average manufacturer price data. In addition, if our products become available in the retail pharmacy setting when they are commercialized, we would be required to provide rebates to the Department of Defense for prescriptions dispensed to Tricare beneficiaries from Tricare retail network pharmacies under the Tricare Retail Refund Program. These programs obligate the manufacturer to pay rebates and offer its drugs at certain prices to certain federal purchasers. To the extent we choose to participate in these government healthcare programs, these and other requirements may affect our ability to profitably sell any product candidate for which we obtain marketing approval.

If we fail to comply with our reporting and payment obligations under the Medicaid program or other governmental pricing programs, we could be subject to additional reimbursement requirements, penalties, sanctions and fines which could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

Pricing and rebate calculations vary among products and programs. The calculations are complex and will often be subject to interpretation by us, governmental or regulatory agencies and the courts. If we become aware that our reporting of pricing data for a prior quarter was incorrect, we will be obligated to resubmit the corrected data. For the Medicaid Drug Rebate Program, corrected data must be submitted for a period not to exceed twelve quarters from the quarter in which the data originally were due. Such restatements and recalculations increase our costs for complying with the laws and regulations governing the Medicaid Drug Rebate Program and other governmental pricing

programs.

We may be liable for errors associated with our submission of pricing data. If we are found to have knowingly submitted false pricing data to the Medicaid program or the FSS pricing program, we may be liable for civil

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monetary penalties in the amount of up to $100,000 per item of false information. Our failure to submit pricing data to the Medicaid program or the FSS pricing program on a timely basis could result in a civil monetary penalty of $10,000 per day for each day the information is late. Such failure also could be grounds for CMS to terminate our Medicaid drug rebate agreement, which is the agreement under which we would participate in the Medicaid Drug Rebate Program. In the event that CMS terminates our rebate agreement, federal payments may not be available under Medicaid or Medicare Part B for our covered outpatient drugs. We cannot assure you that our submissions will not be found to be incomplete or incorrect.

Risks Related to Our Stock and Our 2020 Notes

Our quarterly operating results could fluctuate significantly, which could cause our stock price and the value of the 2020 Notes to decline.

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

Due to the possibility of fluctuations in our revenue and expenses, we believe that quarter-to-quarter comparisons of our operating results are not a good indication of our future performance. Our operating results in some quarters may not meet the expectations of stock market analysts and investors. If we do not meet analysts' and/or investors' expectations, our stock price and the value of our 2020 Notes could decline.

Because our stock price may be volatile, our stock price and the value of our 2020 Notes could experience substantial declines.

The market price of our common stock has historically experienced and may continue to experience volatility. The high and low sales prices for our common stock were $8.59 and $2.98, respectively, during fiscal 2015; $7.10 and $3.39, respectively, during fiscal 2014; and $6.56 and $3.25, respectively, during fiscal 2013. 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 partners 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 partners, 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 and the value of our 2020 Notes. 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 Loan and Security Agreement with Comerica Bank. 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.

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Conversion of the notes may dilute the ownership interest of our shareholders, including holders of 2020 Notes who convert their notes.

At our election, we may settle 2020 Notes tendered for conversion entirely or partly in shares of our common stock. As a result, the conversion of some or all of the 2020 Notes may dilute the ownership interests of existing shareholders. Any sales in the public market of the common stock issuable upon such conversion could adversely affect prevailing market prices of our common stock and, in turn, the price of the 2020 Notes. In addition, the existence of the notes may encourage short selling by market participants because the conversion of the 2020 Notes could depress the price of our common stock.

The accounting method for convertible debt securities that may be settled in cash, such as the 2020 Notes, could have a material effect on our reported financial results.

The 2020 Notes are accounted for in accordance with Financial Accounting Standards Board, or FASB, Accounting Standards Codification, or ASC, 470-20, Debt – Debt with Conversion and Other Options. Under ASC 470-20, an entity must separately account for the liability and equity components of the convertible debt instruments (such as the 2020 Notes) that may be settled entirely or partially in cash upon conversion in a manner that reflects the issuer's economic interest cost. The effect of ASC 470-20 on the accounting for the 2020 Notes is that the equity component is required to be included in the additional paid-in capital section of stockholders' equity on our balance sheet and the value of the equity component would be treated as original issue discount for purposes of accounting for the debt component of the notes. As a result, we will be required to record a greater amount of non-cash interest expense in current periods presented as a result of the amortization of the discounted carrying value of the 2020 Notes to their face amount over the term of the 2020 Notes. We will report lower net income in our financial results because ASC 470-20 will require interest to include both the current period's amortization of the debt discount and the instrument's coupon interest, which could adversely affect our reported or future financial results, the market price of our common stock and the trading price of the 2020 Notes.

In addition, under certain circumstances, convertible debt instruments (such as the 2020 Notes) that may be settled entirely or partly in cash are currently accounted for utilizing the treasury stock method, the effect of which is that the shares issuable upon conversion of the notes are not included in the calculation of diluted earnings per share except to the extent that the conversion value of the notes exceeds their principal amount. Under the treasury stock method, for diluted earnings per share purposes, the transaction is accounted for as if the number of shares of common stock that would be necessary to settle such excess, if we elected to settle such excess in shares, are issued. We cannot be sure that the accounting standards in the future will continue to permit the use of the treasury stock method. If we are unable to use the treasury stock method in accounting for the shares issuable upon conversion of the 2020 Notes, then our diluted earnings per share would be adversely affected.

Certain provisions in the 2020 Notes and the related indenture as well as Delaware law and our organizational documents could delay or prevent an otherwise beneficial takeover or takeover attempt of us, which may not be in the best interests of our stockholders.

Certain provisions in the 2020 Notes and the indenture, as well as certain provisions of Delaware law and our organizational documents could make it more difficult or more expensive for a third party to acquire us. For example, if an acquisition event constitutes a fundamental change, holders of the 2020 Notes will have the right to require us to purchase their notes in cash. In addition, if an acquisition event constitutes a make-whole fundamental change, we may be required to increase the conversion rate for holders who convert their 2020 Notes in connection with such make-whole fundamental change.

Delaware law prohibits, subject to certain exceptions, a Delaware corporation from engaging in any business combination with any interested stockholder for a period of three years following the date that the stockholder became an interested stockholder. Additionally, our certificate of incorporation and bylaws contain provisions that could similarly delay, defer or discourage a change in control of us or management. These provisions could also discourage a proxy contest and make it more difficult for stockholders to elect directors and take other corporate actions. Such provisions provide for the following, among other things: (i) the ability of our Board of Directors to issue shares of common stock and preferred stock without stockholder approval; (ii) the ability of our Board of Directors to establish the rights and preferences of authorized and unissued preferred stock; (iii) a Board of Directors divided into three classes of directors serving staggered three year terms; (iv) permitting only the

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Chairman of the Board of Directors, the Chief Executive Officer, the president or the Board of Directors to call a special meeting of stockholders; and (v) requiring advance notice of stockholder proposals and related information. In any of these cases, and in other cases, our obligations under the 2020 Notes and the indenture, as well as provisions of Delaware law and our organizational documents and other agreements could increase the cost of acquiring us or otherwise discourage a third party from acquiring us or removing incumbent management.

At our election, we may settle 2020 Notes tendered for conversion entirely or partly in shares of our common stock. As a result, the conversion of some or all of the 2020 Notes may dilute the ownership interests of existing shareholders. Any sales in the public market of the common stock issuable upon such conversion could adversely affect prevailing market prices of our common stock and, in turn, the price of the 2020 Notes. In addition, the existence of the 2020 Notes may encourage short selling by market participants because the conversion of the 2020 Notes could depress the price of our common stock.

ITEM 1B. UNRESOLVED STAFF COMMENTS

None.

ITEM 2. PROPERTIES

We are headquartered in Boulder, Colorado, where we currently lease 150 thousand square feet of office and laboratory space. Our Boulder lease was amended during the current fiscal year and now expires on March 31, 2025 and includes an option to extend the lease for up to two terms of five years each. Effective December 31, 2015, we will be reducing our leased square footage to 122 thousand square feet for the remainder of the lease term. We also lease 7 thousand square feet of office space in Morrisville, North Carolina under a lease that expires in October 2017, as well as a very small amount of office space in Boston, Massachusetts under a lease that expires in November 2015.

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. MINE SAFETY DISCLOSURES

None.

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PART II

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

Market Information, Holders of Record and Dividends

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 high and low sales prices for our common stock as reported by the NASDAQ Global Market.

Fiscal Year Ended June 30, 2015	High	Low
First Quarter	$4.81	$3.51
Second Quarter	$5.04	$2.98
Third Quarter	$8.59	$4.19
Fourth Quarter	$8.04	$6.16

Fiscal Year Ended June 30, 2014	High	Low
First Quarter	$7.10	$4.54
Second Quarter	$6.66	$4.54
Third Quarter	$5.64	$4.32
Fourth Quarter	$4.94	$3.39

As of August 20, 2015, there were approximately 53 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.

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 and Security Agreement with Comerica Bank and the terms of the 3.00% Convertible Senior Notes Due 2020 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.

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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, and the NASDAQ Biotechnology Index for the five-year period ended June 30, 2015. The graph assumes that $100 was invested on June 30, 2010 in the common stock of Array, the NASDAQ Composite 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.

	6/30/2010	6/30/2011	6/30/2012	6/30/2013	6/30/2014	6/30/2015
Array BioPharma Inc.	100.00	73.44	113.77	148.85	149.51	236.39
NASDAQ Composite	100.00	132.73	142.01	167.01	219.06	250.68
NASDAQ Biotechnology	100.00	138.84	169.87	228.43	339.18	489.13

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ITEM 6. SELECTED FINANCIAL DATA

The following selected financial data is derived from our audited financial statements. These historical results do not necessarily indicate future results. You should read the selected financial data along with our financial statements and related notes, as well as "Item 7. 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:

	Year Ended June 30,				
	2015	2014	2013	2012	2011
Revenue					
License and milestone revenue	$20,367	$25,111	$56,726	$71,249	$53,426
Collaboration and other revenue	31,542	16,967	12,854	13,886	18,475
Total revenue	51,909	42,078	69,580	85,135	71,901
Operating expenses					
Cost of partnered programs	44,392	45,965	30,078	24,261	28,916
Research and development for proprietary programs	54,442	49,824	59,420	56,719	63,498
General and administrative	31,433	21,907	19,624	15,202	16,261
Total operating expenses	130,267	117,696	109,122	96,182	108,675
Gain on the Binimetinib and Encorafenib Agreements, net	80,010	—	—	—	—
Gain on sale of CMC, net	1,641	—	—	—	—
Income (loss) from operations	3,293	(75,618)	(39,542)	(11,047)	(36,774)
Other income (expense)					
Realized gain from marketable securities, net	16,255	—	—	—	1,891
Loss on prepayment of long-term debt, net	—	—	(11,197)	(942)	(6,340)
Interest income	68	77	55	32	406
Interest expense	(10,247)	(9,716)	(11,258)	(11,624)	(15,507)
Total other income (expense), net	6,076	(9,639)	(22,400)	(12,534)	(19,550)
Net income (loss)	$9,369	$(85,257)	$(61,942)	$(23,581)	$(56,324)
Weighted average shares outstanding – basic	136,679	123,403	107,794	70,619	55,447
Weighted average shares outstanding – diluted	141,692	123,403	107,794	70,619	55,447
Net earnings (loss) per share – basic	$0.07	$(0.69)	$(0.57)	$(0.33)	$(1.02)
Net earnings (loss) per share – diluted	$0.07	$(0.69)	$(0.57)	$(0.33)	$(1.02)

	June 30,				
	2015	2014	2013	2012	2011
Cash, cash equivalents, marketable securities and accounts receivable	$185,129	$117,067	$118,301	$90,725	$66,939
Working capital	148,623	68,943	70,732	16,935	506
Total assets	198,207	136,625	133,335	107,129	88,136
Long-term debt, net	107,280	101,524	96,368	91,312	90,302
Total stockholders' equity (deficit)	42,653	(25,721)	(21,909)	(85,806)	(130,858)

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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, continuation, timing and success of drug discovery and development activities conducted by Array and by our partners, our ability to obtain additional capital to fund our operations, changes in our research and development spending, realizing new revenue streams and obtaining future out-licensing or 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 "Item 1A. Risk Factors" under Part I of this Annual Report on Form 10-K, and in other reports we file with the SEC. All forward-looking statements are made as of the date of this report 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 our accompanying audited financial statements and related notes to those statements included elsewhere in this Annual Report on Form 10-K.

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 2015 refers to the fiscal year ended June 30, 2015.

Overview

Array is a biopharmaceutical company focused on the discovery, development and commercialization of targeted small molecule drugs to treat patients afflicted with cancer. Six registration studies are currently advancing. These programs include three cancer drugs, binimetinib (MEK 162 / wholly-owed), encorafenib (LGX818 / wholly-owned) and selumetinib (partnered with AstraZeneca).

Our most advanced wholly-owned clinical stage drugs include:

	Proprietary Program	Indication	Clinical Status
1.	Binimetinib	MEK inhibitor for cancer	Phase 3
2.	Encorafenib	BRAF inhibitor for cancer	Phase 3
3.	Filanesib	KSP inhibitor for MM	Phase 2
4.	ARRY-797	p38 inhibitor for LMNA-DCM	Phase 2

In March 2015, Array announced the completion of the transactions contemplated by asset transfer agreements Array had entered into with Novartis under which Array regained rights to binimetinib and acquired rights to encorafenib. Along with global ownership of both assets, Array received an upfront payment of $85 million from Novartis. Also

during the third quarter, we entered into a third party agreement to complete the Novartis transactions for a net consideration payment to the third party of $25 million. We believe these programs present significant opportunities for Array in the area of oncology.

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Three pivotal trials of binimetinib and/or encorafenib, COLUMBUS (encorafenib in combination with binimetinib in BRAF-mutant melanoma patients), NEMO (binimetinib in NRAS-mutant melanoma patients), and MILO (binimetinib in low-grade serous ovarian cancer patients), continue to advance. Beyond the three Phase 3 trials, there are over 30 active binimetinib and/or encorafenib trials.

In April 2015, the NEMO and COLUMBUS (Part 1) Phase 3 studies completed patient enrollment. With NEMO enrollment complete, Array reaffirms a projected regulatory filing of binimetinib in NRAS melanoma during the first half of 2016. With COLUMBUS (Part 1) enrollment complete, Array reaffirms a projected regulatory filing of binimetinib in combination with encorafenib in BRAF melanoma in 2016. Patient enrollment continues in Part 2 of COLUMBUS.

The MILO Phase 3 study design was modified to incorporate a cross-over provision, allowing patients on the trial to have access to binimetinib. Array estimates the availability of top-line data from MILO in 2016 and a projected regulatory filing of binimetinib in LGSOC in 2017.

Novartis is responsible for continued conduct and funding of the COLUMBUS and NEMO trials. All other ongoing clinical trials involving binimetinib and encorafenib, including the MILO trial, continue to advance, with Novartis providing substantial financial support in the form of reimbursement to Array for all associated out-of-pocket costs and for one half of Array's fully-burdened FTE costs based on an annual FTE rate. At designated points for each trial, Novartis will transition responsibility and provide this continuing financial support to Array for completing the trials.

Array continues to progress select other wholly-owned programs including two Phase 2 trials of filanesib in MM, and a Phase 2 trial of ARRY-797 in a rare cardiovascular disease. In addition, we have 10 ongoing partner-funded clinical programs, including an Array-invented MEK inhibitor, selumetinib with AstraZeneca. Three registration clinical trials continue to evaluate selumetinib: SELECT-1, ASTRA and NF1.

	Drug Candidate	Indication	Partner	Clinical Status
1.	Selumetinib	MEK inhibitor for cancer	AstraZeneca, PLC	Phase 3
2.	ASC08 / Danoprevir	Protease inhibitor for Hepatitis C virus	Roche Holding AG	Phase 2
3.	ASLAN001/ARRY-543	Pan-HER inhibitor for gastric or breast cancer	ASLAN Pharmaceuticals Pte Ltd.	Phase 2
4.	Ipatasertib/GDC-0068	AKT inhibitor for cancer	Genentech, Inc.	Phase 2
5.	Motolimod/VTX-2337	Toll-like receptor for cancer	VentiRx Pharmaceuticals, Inc.	Phase 2
6.	LY2606368	Chk-1 inhibitor for cancer	Eli Lilly and Company	Phase 2
7.	GDC-0575	Chk-1 inhibitor for cancer	Genentech, Inc.	Phase 1b
8	ONT-380/ARRY-380	HER2 inhibitor for breast cancer	Oncothyreon Inc.	Phase 1b
9	GDC-0994	ERK inhibitor for cancer	Genentech, Inc.	Phase 1
10.	LOXO-101	PanTrk inhibitor for cancer	Loxo Oncology, Inc.	Phase 1

We also have a portfolio of proprietary and partnered preclinical drug discovery programs, including inhibitors that target Trk receptors for the treatment of oncology and other indications. Our most significant discovery collaborations are with Loxo (oncology program) and Biogen (auto-immune disorder program). We may out-license other select promising candidates through research collaborations in the future.

We have received a total of $678.2 million in research funding and in up-front and milestone payments from partners from inception through June 30, 2015, including $174 million in initial payments from strategic agreements with Amgen, Celgene, Genentech, Novartis and Oncothyreon that we entered into over the last five and a half years, and

we received an up-front cash payment of $85 million in March 2015 under our agreement with Novartis for the re-acquisition of binimetinib. Our existing partnered programs entitle Array to receive a total of over $2 billion in additional milestone payments if we or our partners achieve the drug discovery, development

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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 licensing or commercialization from 12 partnered clinical and discovery programs.

Recent Developments

Binimetinib and Encorafenib Agreements

The transactions contemplated by the asset transfer agreements Array entered into with Novartis International Pharmaceutical Ltd., or Novartis, and Novartis Pharma AG, or Novartis Pharma, for the re-acquisition of rights to binimetinib and acquisition of rights to encorafenib, which we refer to as the Binimetinib and Encorafenib Agreements, closed in March 2015. As a result of the closing, we received an $85 million cash payment, received $5 million for the reimbursement of certain transaction costs, extinguished net co-development liabilities of $21.6 million and recorded deferred revenue of $6.6 million in the third quarter of fiscal 2015. Also during the third quarter, we entered into a third party agreement to complete the Novartis transactions for a net consideration payment to the third party of $25 million.

The Binimetinib and Encorafenib Agreements executed with Novartis Pharma and Novartis involved multiple elements. We therefore identified each item given and received and determined how each item should be recognized and classified. The sum of the above transactions was accounted for in a manner consistent with a settlement of a material liability or gain contingency.

We deferred $6.6 million of the consideration received from Novartis Pharma to reflect the estimated fair value of certain future obligations we are to perform under the Binimetinib and Encorafenib Agreements, including completion of certain trials that are partially funded by Novartis Pharma. The amount deferred was determined using the estimated fair value of the services to be provided by our full-time employees that we do not anticipate will be covered in the funding reimbursements we will receive from Novartis Pharma under the Binimetinib and Encorafenib Agreements. The estimated fair value was based on amounts we have billed to other third parties in other transactions for similar services. We anticipate recording revenue over the deferral period, which is based upon our estimated time to complete our performance with respect to the applicable clinical trials. The balance of deferred revenue was $5.4 million at June 30, 2015.

As of March 2, 2015, prior to the closing of the Binimetinib and Encorafenib Agreements, we had an accounts receivable balance from Novartis of $6.7 million and a $28.3 million co-development liability balance that we owed to Novartis. On March 2, 2015, the termination of the License Agreement with Novartis relating to binimetinib and the effectiveness of the Binimetinib and Encorafenib Agreements resulted in the right to offset the accounts receivable and co-development liability balances. Because we and Novartis owed each other determinable amounts and we have the right to set off the amount payable with the amount receivable from Novartis, we set off these amounts resulting in a net co-development liability of $21.6 million that was extinguished in full upon termination of the License Agreement, which in turn increased our net gain.

See Note 3 - Binimetinib and Encorafenib Agreements, to the accompanying audited financial statements included elsewhere in this Annual Report on Form 10-K for more information.

Business Development and Partner 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 partners may terminate their agreements with us

with 60 to 180 days' prior notice. Specifics regarding termination provisions under our material collaboration or license agreements can be found in Note 5 – Collaboration and License Agreements to the accompanying audited financial statements included elsewhere in this Annual Report on Form 10-K.

Additional information related to the concentration of revenue among our partners is reported in Note 1 – Overview, Basis of Presentation and Summary of Significant Accounting Policies – Concentration of Business Risks to the accompanying audited financial statements included elsewhere in this Annual Report on Form 10-K.

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All of our collaboration and license 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 conformity with U.S. generally accepted accounting principles, or U.S. GAAP, and which requires us to make estimates and assumptions that affect the reported amounts of assets, liabilities, revenue and expenses, and related disclosure of contingent assets and liabilities. We base our estimates on historical experience and on various other assumptions that we believe are reasonable under the circumstances. These estimates are the basis for our judgments about the carrying values of assets and liabilities, which in turn may impact our reported revenue and expenses. Our actual results could differ significantly from these estimates under different assumptions or conditions.

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, or 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 the estimates to determine if adjustments are necessary or appropriate based on information we receive.

Revenue Recognition

We recognize revenue for the performance of services or the shipment of products when each of the following four criteria is met: (i) persuasive evidence of an arrangement exists; (ii) products are delivered or as services are rendered; (iii) the sales price is fixed or determinable; and (iv) collectability is reasonably assured.

We follow ASC 605-25, Revenue Recognition – Multiple-Element Arrangements and ASC 808, Collaborative Arrangements, if applicable, to determine the recognition of revenue under our collaborative research, development and commercialization agreements. The terms of these agreements generally contain multiple elements, or deliverables, which may include (i) grants of licenses, or options to obtain licenses, to our intellectual property, (ii) research and development services, (iii) drug product manufacturing, and/or (iv) participation on joint research and/or joint development committees. The payments we may receive under these arrangements typically include one or more of the following: non-refundable, up-front license fees; option exercise fees; funding of research and/or development efforts; amounts due upon the achievement of specified objectives; and/or royalties on future product sales.

ASC 605-25 provides guidance relating to the separability of deliverables included in an arrangement into different units of accounting and the allocation of arrangement consideration to the units of accounting. The evaluation of multiple-element arrangements requires management to make judgments about (i) the identification of deliverables, (ii) whether such deliverables are separable from the other aspects of the contractual relationship, (iii) the estimated selling price of each deliverable, and (iv) the expected period of performance for each deliverable.

To determine the units of accounting under a multiple-element arrangement, management evaluates certain separation criteria, including whether the deliverables have stand-alone value, based on the relevant facts and circumstances for

each arrangement. Management then estimates the selling price for each unit of accounting and allocates the arrangement consideration to each unit utilizing the relative selling price method. The allocated consideration for each unit of accounting is recognized over the related obligation period in accordance with the applicable revenue recognition criteria.

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If there are deliverables in an arrangement that are not separable from other aspects of the contractual relationship, they are treated as a combined unit of accounting, with the allocated revenue for the combined unit recognized in a manner consistent with the revenue recognition applicable to the final deliverable in the combined unit. Payments received prior to satisfying the relevant revenue recognition criteria are recorded as deferred revenue in the accompanying balance sheets and recognized as revenue when the related revenue recognition criteria are met.

We typically receive non-refundable, up-front payments when licensing our intellectual property, which often occurs in conjunction with a research and development agreement. When management believes that the license to our intellectual property has stand-alone value, we generally recognize revenue attributed to the license upon delivery provided that there are no future performance requirements for use of the license. When management believes that the license to our intellectual property does not have stand-alone value, we typically recognize revenue attributed to the license on a straight-line basis over the contractual or estimated performance period. 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.

Most of our agreements provide for non-refundable milestone payments. We recognize revenue that is contingent upon the achievement of a substantive milestone in its entirety in the period in which the milestone is achieved. A milestone is considered substantive when the consideration payable to us for such milestone (i) is consistent with our performance necessary to achieve the milestone or the increase in value to the collaboration resulting from our performance, (ii) relates solely to our past performance and (iii) is reasonable relative to all of the other deliverables and payments within the arrangement. In making this assessment, we consider all facts and circumstances relevant to the arrangement, including factors such as the scientific, regulatory, commercial and other risks that must be overcome to achieve the milestone, the level of effort and investment required to achieve the milestone and whether any portion of the milestone consideration is related to future performance or deliverables.

For payments payable on achievement of milestones that do not meet all of the conditions to be considered substantive, we recognize a portion of the payment as revenue when the specific milestone is achieved, and the contingency is removed, based on the applicable percentage earned of the estimated research or development effort, or other performance obligations that have elapsed, to the total estimated research and/or development effort attributable to the milestone. In other cases, when a non-substantive milestone payment is attributed to our future research or development obligations, we recognize the revenue on a straight-line basis, or other appropriate method, over the estimated remaining research or development effort. Other contingent event-based payments for which payment is either contingent solely upon the passage of time or the result of our partner's or collaborator's performance are recognized when earned.

We periodically review the estimated performance periods under each of our agreements that provide for non-refundable up-front payments, license fees or milestone payments. We adjust the periods over which revenue should be recognized when appropriate to reflect changes in assumptions relating to the estimated performance periods. We could accelerate revenue recognition in the event of early termination of programs or if our expectations change. Alternatively, we could decelerate revenue recognition if programs are extended or delayed. While such changes to our estimates have no impact on our reported cash flows, the amount of revenue recorded in future periods could be materially impacted.

See Note 5 – Collaboration and License Agreements to the accompanying audited financial statements included elsewhere in this Annual Report on Form 10-K for further information.

Valuation of Equity Received

From time to time, we may enter into collaboration and license agreements under which we receive an equity interest as consideration for all or a portion of up-front, license or other fees under the terms of the agreement. In July 2013, Array entered into a collaboration agreement with Loxo Oncology, Inc. under which we received shares of non-voting preferred stock as consideration for licensing rights granted to Loxo. There was no public market for the shares, and we estimated the fair value of these shares to be $4.5 million based on a valuation analysis prepared with the assistance of a third-party valuation firm. The valuation of the preferred shares required the use

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of significant assumptions and estimates, including assumptions about the estimated volatility of the equity, the estimated time to a liquidity event, and the likelihood of Loxo obtaining additional future financing; none of which was readily available to us as Loxo is not a publicly-traded company. Equity securities received from non-publicly traded companies in which we do not exercise a significant or controlling interest are reported at cost in other long-term assets in the accompanying audited financial statements included elsewhere in this Annual Report on Form 10-K.

Restructuring Charges

In August 2013, we completed a reduction in force of approximately 50 employees, mainly in our drug discovery organization. After the 20% reduction, we had approximately 200 employees whose capabilities are more tightly aligned with our strategy to fund our discovery organization with strategic collaborations and focusing development and commercialization resources on our later stage clinical programs. See Note 12 - Restructuring Charges to the accompanying audited financial statements included elsewhere in this Annual Report on Form 10 K.

Results of Operations

License and Milestone Revenue

License and milestone revenue consists of up-front license fees and ongoing milestone payments from partners and collaborators.

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

	Year Ended June 30,			Change 2015 vs. 2014		Change 2014 vs. 2013	
	2015	2014	2013	$	%	$	%
License revenue	$20,367	$14,461	$41,440	$5,906	41 %	$(26,979)	(65)%
Milestone revenue	—	10,650	15,286	(10,650)	(100)%	(4,636)	(30)%
Total license and milestone revenue	$20,367	$25,111	$56,726	$(4,744)	(19)%	$(31,615)	(56)%

Fiscal 2015 compared to Fiscal 2014 – License revenue for fiscal 2015 increased due to the recognition of the $20 million up-front fee received from Oncothyreon under our new License Agreement in December 2014. Additionally, we completed the recognition of the remaining $367 thousand of Genentech license revenue during fiscal 2015. We had expected to amortize the Genentech deferred revenue from inception of the agreement until a specified milestone had been achieved, but due to the immaterial amount remaining, we elected to recognize the remainder although the milestone has not been achieved. We will be entitled to an additional milestone payment if and when the specified milestone is achieved.

License revenue for fiscal 2014 primarily included $8.0 million recognized under our Novartis collaboration and $4.5 million of non-cash revenue recognized under our collaboration with Loxo, representing the fair value of shares of preferred stock received under the collaboration, as discussed under Note 5 - Collaboration and License Agreements - Loxo Oncology, Inc. to our audited financial statements included elsewhere in this Annual Report on Form 10-K. The remaining fiscal 2014 license revenue of $1.9 million represents the amortization of deferred revenue recognized under our Genentech collaboration.

No milestone revenue was recognized during the current fiscal year, compared with $5 million earned from AstraZeneca, $4.0 million earned from Novartis, $1 million earned from Genentech, as well as several other smaller

milestones earned during fiscal 2014.

Fiscal 2014 compared to Fiscal 2013 – The primary contributor to the decline in license revenue from fiscal 2013 to fiscal 2014 was the recognition of all remaining revenue under our arrangements with Amgen and Celgene during fiscal 2013. Additionally, decreased up-front payments and decreased revenue recognized under our arrangements with Genentech and Novartis also contributed. We concluded the recognition of license revenue

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under our arrangements with Amgen and Celgene prior to the start of fiscal 2014 by recognizing $9.8 million and $7.3 million of license revenue in fiscal 2013 from Amgen and Celgene, respectively. We entered into a Drug Discovery and Collaboration Agreement with Loxo at the beginning of fiscal 2014 and recognized $4.5 million in non-cash license revenue. In comparison, we received and recognized a $10 million up-front payment from Oncothyreon for licenses during the fourth quarter of fiscal 2013. Please refer to Note 5 – Collaboration and License Agreements – Oncothyreon Inc. to the accompanying audited financial statements included elsewhere in this Annual Report on Form 10-K. Additionally, license revenue under our Chk-1 License Agreement with Genentech decreased by $2.3 million in fiscal 2014 because we extended the expected timing for milestone achievement under the Genentech collaboration by 10 months, resulting in adjustments to the amount of the remaining license revenue recognized each quarter. Finally, we concluded the recognition of license revenue under the Novartis License Agreement in April 2014, resulting in a $2.0 million decrease between the two fiscal years.

Milestone revenue decreased during fiscal 2014 due to the recognition of all remaining revenue for several collaborations in fiscal 2013 and a reduction in Novartis milestone revenue. Novartis milestone revenue decreased $3.7 million mainly due to the fiscal 2013 recognition of $4.0 million of the $5 million milestone earned in June 2013 for the commencement of the first Phase 3 trial and the April 2014 conclusion of revenue recognition for all previous Novartis milestone payments received. Revenue recognition for milestone payments also concluded in December 2012 and March 2013 for Amgen and Celgene, respectively, resulting in no milestone revenue during fiscal 2014 under those agreements, compared with $1.3 million for Amgen and $3.8 million for Celgene during fiscal 2013. During fiscal 2013 we earned $2.5 million of additional revenue for milestone events from VentiRx and Genentech, as compared with $6.6 million of additional milestones earned during fiscal 2014, which included $5 million from AstraZeneca for the start of a Phase 3 clinical study and $1 million from Genentech for a Phase 2 start.

Collaboration and Other Revenue

Collaboration and other revenue historically has primarily consisted of revenue for our performance of drug discovery and development activities in collaboration with partners, which includes development of proprietary drug candidates we out-license. During the current fiscal year, collaboration and other revenue also includes reimbursable expenses paid or payable by Novartis related to the Binimetinib and Encorafenib Agreements, as well as the revenue recognized due to the amortization of the deferred portion of the up-front payment that was received also related to these agreements with Novartis.

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

	Year Ended June 30,			Change 2015 vs. 2014		Change 2014 vs. 2013	
	2015	2014	2013	$	%	$	%
Collaboration and other revenue	$31,542	$16,967	$12,854	$14,575	86 %	$4,113	32 %

Fiscal 2015 compared to Fiscal 2014 – We recognized over $7.0 million in reimbursed research and development expenses and $1.2 million for the amortization of the deferred up-front payment from Novartis, as mentioned above, since the March 2, 2015 effective date of the Binimetinib and Encorafenib Agreements, accounting for over half of the increase in collaboration and other revenue in fiscal 2015. Additionally, our collaboration with Biogen, which was new in the last quarter of fiscal 2014, represents an increase of $4.3 million between the comparable periods and our expanded collaboration with Loxo accounts for another $3.3 million of the current period increase. Chemistry, manufacturing and control ("CMC") activities also contributed over $2.0 million to the current fiscal year increase. These were partially offset by $3.0 million in decreased collaboration revenue related to several smaller collaborations that concluded at various points during or prior to fiscal 2015.

Fiscal 2014 compared to Fiscal 2013 – Collaboration revenue increased during fiscal 2014 as revenue of $5.2 million and $3.5 million from new collaborations with Loxo and Oncothyreon, respectively, more than offset the decreases in revenue from other collaborations such as our 2003 agreement with Genentech following the

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conclusion of the research term in January 2013, our Clovis Oncology collaboration that terminated during the second quarter of fiscal 2014 and under our previous collaboration with DNA BioPharma, which concluded in February 2013. Additionally, collaboration revenue from our January 2013 Global Blood collaboration increased due to a full years' revenue recognition in fiscal 2014 versus only five months in fiscal 2013 and collaboration revenue under our new July 2013 agreement with Celgene was slightly higher during fiscal 2014 compared with the collaboration revenue recognized during the same period of the prior year under the 2007 Celgene agreement. Our obligations under the 2007 Celgene agreement were completed during the fourth quarter of fiscal 2013.

Cost of Partnered Programs

Cost of partnered programs represents research and development costs attributable to discovery and development including preclinical and clinical trials we may conduct for or with our partners. Research and development costs primarily consist of personnel related expenses, including salaries, benefits, costs to recruit and relocate new employees, travel, and other related expenses, stock-based compensation, payments made to third party contract research organizations for preclinical and clinical studies, investigative sites for clinical trials and consultants, the cost of acquiring and manufacturing clinical trial materials, costs associated with regulatory filings and patents, software and facilities, and laboratory costs and other supply costs.

Below is a summary of our cost of partnered programs (dollars in thousands):

	Year Ended June 30,			Change 2015 vs. 2014		Change 2014 vs. 2013	
	2015	2014	2013	$	%	$	%
Cost of partnered programs	$44,392	$45,965	$30,078	$(1,573)	(3)%	$15,887	53%

Fiscal 2015 compared to Fiscal 2014 – We concluded fiscal 2015 with a small decrease in cost of partnered programs. This decrease was due to the costs related to development of binimetinib and encorafenib being moved from cost of partnered programs to research and development expenses for propriety programs for the last four months of fiscal 2015 following the effective date of the Binimetinib and Encorafenib Agreements on March 2, 2015. The impact of this change was mostly offset by increased partnered program expenses due to our new Biogen collaboration and expanded Loxo collaboration. Additionally, the costs to continue to advance binimetinib through clinical trials under our previous License Agreement with Novartis though March 2, 2015 had also increased in comparison to the prior fiscal year.

Fiscal 2014 compared to Fiscal 2013 – Cost of partnered programs increased during fiscal 2014 due to increasing costs to advance binimetinib, our MEK inhibitor, through clinical trials under our co-development arrangement with Novartis, as well as our new collaborations with Loxo and Oncothyreon. Partially offsetting the increases were reduced costs under our 2003 agreement with Genentech following the conclusion of the research term.

Research and Development Expenses for Proprietary Programs

Our research and development expenses for proprietary programs include costs associated with our proprietary drug programs, which primarily consist of personnel related expenses, including salaries, benefits, costs to recruit and relocate new employees, travel, and other related expenses, stock-based compensation, payments made to third party contract research organizations for preclinical and clinical studies, investigative sites for clinical trials and consultants, the cost of acquiring and manufacturing clinical trial materials, costs associated with regulatory filings and patents, software and facilities, and laboratory costs and other supply costs. 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.

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

	Year Ended June 30,			Change 2015 vs. 2014		Change 2014 vs. 2013	
	2015	2014	2013	$	%	$	%
Salaries, benefits and share-based compensation	$14,697	$18,443	$24,080	$(3,746)	(20)%	$(5,637)	(23)%
Outsourced services and consulting	28,433	18,170	19,634	10,263	56 %	(1,464)	(7)%
Laboratory supplies	4,513	5,756	6,887	(1,243)	(22)%	(1,131)	(16)%
Facilities and depreciation	5,229	6,069	7,115	(840)	(14)%	(1,046)	(15)%
Other	1,570	1,386	1,704	184	13 %	(318)	(19)%
Total research and development expenses	$54,442	$49,824	$59,420	$4,618	9 %	$(9,596)	(16)%

Fiscal 2015 compared to Fiscal 2014 – The increase in research and development for proprietary programs during fiscal 2015 was due to an increase in outsourced services and consulting costs incurred to advance filanesib in two ongoing Phase 2 clinical studies, as well as having costs related to binimetinib and encorafenib included in research and development for proprietary programs for the last four months of the fiscal year rather than in cost of partnered programs. The increase in outsourced services was offset in part by a reduction in salaries and benefits related to an increased number of our scientists who were working on partnered programs during the current fiscal year. Additionally, fiscal 2014 included $2.2 million of salaries and benefit expenses related to our workforce reduction in August 2013. Decreased expenses for lab supplies and facilities also helped to offset the increased outsourced services expenses.

Fiscal 2014 compared to Fiscal 2013 – Research and development expenses for proprietary programs decreased during fiscal 2014 primarily due to lower spending on our preclinical programs and shifting funding to our partnered programs, including Loxo and Oncothyreon. In addition, we largely completed the ARRY-502 Phase 2 asthma study prior to the start of the current fiscal year. Partially offsetting these decreases were higher costs to advance filanesib including start-up costs for three clinical studies, FACTOR, AfFIRM and ARRAY-520-216. During fiscal 2014, we also incurred $2.2 million of additional expenses for termination benefits related to our reduction in workforce in August 2013 that are reflected in salaries, benefits and share-based compensation.

General and Administrative Expenses

General and administrative expenses consist mainly of compensation and associated fringe benefits not included in cost of partnered programs or research and development expenses for proprietary programs 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):

	Year Ended June 30,			Change 2015 vs. 2014		Change 2014 vs. 2013	
	2015	2014	2013	$	%	$	%
General and administrative expenses	$31,433	$21,907	$19,624	$9,526	43 %	$2,283	12 %

Fiscal 2015 compared to Fiscal 2014 – The increase in general and administrative expenses in fiscal 2015 are largely the result of legal, consulting and other expenses, including higher, non-cash share-based compensation costs, related to regaining the rights to binimetinib through the Binimetinib Agreement and acquiring the rights to encorafenib through the Encorafenib Agreement, see Note 3 - Binimetinib and Encorafenib Agreements to the audited financial statements included elsewhere in this Annual Report on Form 10-K.

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Fiscal 2014 compared to Fiscal 2013 – General and administrative expenses increased during fiscal 2014 compared to fiscal 2013. Increases in share-based compensation expenses of $818 thousand, patent expenses of $494 thousand and general business consulting and commercialization expenses of $349 thousand were the primary contributors, as well as $602 thousand of severance costs related to the reduction in our workforce.

Other Income (Expense), Net

Below is a summary of our other income (expense) (dollars in thousands):

	Year Ended June 30,			Change 2015 vs. 2014		Change 2014 vs. 2013	
	2015	2014	2013	$	%	$	%