ARRAY BIOPHARMA INC
Form 10-K
August 14, 2018

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, 2018
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 | 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. þ
Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See the definitions of “large accelerated filer,” “accelerated filer,” “smaller reporting company” and "emerging growth company" in Rule 12b-2 of the Exchange Act.

| | | | |
|---|---|---|---|
| Large Accelerated Filer þ | Accelerated Filer ¨ | Non-Accelerated Filer ¨ (do not check if smaller reporting company) | Smaller Reporting Company ¨<br>Emerging Growth Company ¨ |

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ¨

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 12/31/17, was $2,621,849,216, 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 9, 2018, the registrant had 211,665,676 shares of common stock outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the Proxy Statement for the Registrant's 2018 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., the Array BioPharma Inc. logo, BRAFTOVI™ and MEKTOVI® 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, together with its wholly owned subsidiary, Yarra Therapeutics, LLC.

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 2018 refers to the twelve-month period ended June 30, 2018.

FORWARD-LOOKING STATEMENTS

This Annual Report 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, among others, statements about the future development plans of encorafenib and binimetinib; expectations that events will occur that will create greater value for Array; and the potential for the results of current and future clinical trials to support regulatory approval or the marketing success of encorafenib and binimetinib. Because these statements reflect our current expectations concerning future events and involve significant risks and uncertainties, 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, the potential that the FDA, EMA or other regulatory agencies determine results from clinical trials are not sufficient to support registration or marketing approval of encorafenib and binimetinib; 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; risks associated with our dependence on third-party service providers to successfully conduct clinical trials and to manufacture drug substance and product within and outside the United States (the "U.S."); our ability to grow and successfully develop commercialization capabilities; our ability to achieve and maintain profitability and maintain sufficient cash resources; and our ability to attract and retain experienced scientists and management. Additional information concerning these and other risk factors can be found in this Annual Report on Form 10-K, 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. 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 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."

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ITEM 1. BUSINESS

Our Business

We are a fully-integrated, biopharmaceutical company focused on the discovery, development and commercialization of transformative and well-tolerated targeted small molecule drugs to treat patients afflicted with cancer and other high-burden diseases. We market in the United States BRAFTOVI™ (encorafenib) capsules in combination with MEKTOVI® (binimetinib) tablets for the treatment of patients with unresectable or metastatic melanoma with a $BRAF^{V600E}$ or $BRAF^{V600K}$ mutation. Our lead clinical programs, encorafenib and binimetinib, are being investigated in over 30 clinical trials across a number of solid tumor indications, including a Phase 3 trial in BRAF-mutant colorectal cancer (CRC). Our pipeline includes several additional programs being advanced by us or current license-holders, including selumetinib (partnered with AstraZeneca), larotrectinib (partnered with Loxo Oncology), ipatasertib (partnered with Genentech), tucatinib (partnered with Seattle Genetics) and ARRY-797 (being developed by Yarra Therapeutics, a wholly-owned subsidiary of Array), all of which are currently in registration trials. Ganovo® (danoprevir, partnered with Roche and licensed by Roche to Ascletis Pharmaceuticals Co., Ltd. in China) was recently approved in China for the treatment of viral hepatitis C.

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Our most significant commercial and clinical stage drugs include:

| Compound | Target/Disease State | Partner | Status |
|---|---|---|---|
| BRAFTOVI + MEKTOVI | BRAF and MEK inhibitors for advanced BRAF-mutant melanoma | Pierre Fabre Medicament SAS and Ono Pharmaceutical Co., Ltd. | Approved in US |
| Encorafenib | BRAF inhibitor for BRAF-mutant CRC | Pierre Fabre Medicament SAS and Ono Pharmaceutical Co., Ltd. | Phase 3 |
| Binimetinib | MEK inhibitor for BRAF-mutant CRC and other cancers | Pierre Fabre Medicament SAS and Ono Pharmaceutical Co., Ltd. | Phase 3 |
| Selumetinib (1) | MEK inhibitor for cancer and NF1 (2) | AstraZeneca, PLC | Phase 3 |
| Ganovo/Danoprevir (1) | Protease inhibitor for Hepatitis C virus | Roche Holding AG | Approved in China |
| Larotrectinib/LOXO-101 (1) | PanTrk inhibitor for cancer | Loxo Oncology, Inc. | Phase 2 / Registration Trial / New Drug Application ("NDA") |
| ARRY-797 | p38 inhibitor for Lamin A/C-related dilated cardiomyopathy | Wholly-owned by Array | Phase 3 |
| Ipatasertib/GDC-0068 (1) | AKT inhibitor for cancer | Genentech, Inc. | Phase 3 |
| Tucatinib/ONT-380 (1) | HER2 inhibitor for cancer | Seattle Genetics, Inc. | Phase 2 / Registration Trial |
| Varlitinib/ASLAN001 (1) | Pan-HER2 inhibitor for cancer | ASLAN Pharmaceuticals Pte Ltd. | Phase 2 / 3 |
| ARRY-382 | CSF1R inhibitor for cancer | Wholly-owned by Array | Phase 2 |
| Motolimod/VTX-2337 (1) | Toll-like receptor for cancer | Celgene Corp. / VentiRx Pharmaceuticals, Inc. | Phase 2 |
| Prexasertib/LY2606368 (1) | CHK-1 inhibitor for cancer | Eli Lilly and Company | Phase 2 |
| GDC-0575 (1) | CHK-1 inhibitor for cancer | Genentech, Inc. | Phase 1b |
| LOXO-292 (1) | Ret inhibitor for cancer | Loxo Oncology, Inc. | Phase 1 |
| LOXO-195 (1) | Trk inhibitor for cancer | Loxo Oncology, Inc. | Phase 1 |
| AK-1830 (1) | TrkA selective inhibitor for inflammation | Asahi Kasei Pharma Corporation | Phase 1 |

(1) Compound being advanced by the current license holder. We will be entitled to receive future potential milestone and/or potential royalty payments contingent upon successful development and commercialization.
(2) As we have previously disclosed, we have informed AstraZeneca of our position that the NF1 development program is outside of the permitted field for this license.

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BRAFTOVI and MEKTOVI

On June 27, 2018, the FDA approved BRAFTOVI capsules in combination with MEKTOVI tablets for the treatment of patients with unresectable or metastatic melanoma with a $BRAF^{V600E}$ or $BRAF^{V600K}$ mutation, as detected by an FDA-approved test. BRAFTOVI is not indicated for the treatment of patients with wild-type BRAF melanoma.

BRAFTOVI + MEKTOVI were available for sale beginning on July 2, 2018, and patients began receiving the combination therapy that same week.

We have exclusive rights to BRAFTOVI and MEKTOVI in the U.S. and Canada. Array has granted Ono Pharmaceutical exclusive rights to commercialize both products in Japan and South Korea, Medison exclusive rights to commercialize both products in Israel and Pierre Fabre exclusive rights to commercialize both products in all other countries, including those in Europe, Asia and Latin America.

BRAFTOVI and MEKTOVI are not approved outside of the U.S. The European Medicines Agency (EMA), the Swiss Medicines Agency (Swissmedic) and the Australian Therapeutic Goods Administration (TGA) are currently reviewing Marketing Authorization Applications submitted by Pierre Fabre. On July 27, 2018, the Committee for Medicinal Products for Human Use (CHMP) of the EMA adopted a positive opinion recommending approval of BRAFTOVI in combination with MEKTOVI for the treatment of adult patients with unresectable or metastatic melanoma with a $BRAF^{V600}$ mutation. This recommendation will now be reviewed by the European Commission (EC), which has the authority to approve medicines for the European Union (EU). The final EC decision, expected by the end of September 2018, will be applicable to all 28 EU member states, as well as Liechtenstein, Iceland and Norway. Japan’s Pharmaceuticals and Medical Devices Agency has accepted the Manufacturing and Marketing Approval applications submitted by Ono Pharmaceutical Co, Ltd.

The U.S. and international regulatory submissions were based on findings from the pivotal Phase 3 COLUMBUS trial.

On July 16, 2018, Array submitted supplementary New Drug Applications (sNDA) to seek inclusion of overall survival (OS) data from the Phase 3 COLUMBUS trial in the BRAFTOVI and MEKTOVI labels.

Also, on July 13, 2018, the National Comprehensive Cancer Network (NCCN) updated the Clinical Practice Guidelines in Oncology for Melanoma to include BRAFTOVI in combination with MEKTOVI as a Category 1 first-line and second-line treatment option for patients with $BRAF^{V600E}$ or $BRAF^{V600K}$-mutant metastatic or unresectable melanoma. A Category 1 recommendation indicates that, based upon high-level evidence, there is uniform NCCN consensus that the intervention is appropriate.

Encorafenib and Binimetinib

On March 2, 2015 (the "Effective Date"), we regained development and commercialization rights to binimetinib under the Termination and Asset Transfer Agreement with Novartis Pharma AG and Novartis Pharmaceutical Ltd. and to encorafenib under the Asset Transfer Agreement with Novartis Pharma AG (which we collectively refer to as the “Novartis Agreements”). Along with global ownership of both assets, the Novartis Agreements transferred to Array a low single digit royalty obligation payable based on net sales of encorafenib and we received an upfront payment of $85.0 million from Novartis. We believe these programs present significant opportunity to us in the area of oncology.

Novartis continues to fund ongoing trials with encorafenib and binimetinib that were active or planned as of the close of the Novartis Agreements in 2015. As of June 30, 2018, the level of spend associated with these studies continues to decrease as the studies progress through their later life cycle. As patients have continued to receive treatment under

certain trials for longer than initially anticipated, we may hit certain reimbursement limits for select trials, including the COLUMBUS Phase 3 trial. Reimbursement revenue from Novartis was approximately $81.0 million for the 12 months ended June 30, 2018.

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PIERRE FABRE AGREEMENT

We entered into a Development and Commercialization Agreement ("the PF Agreement") with Pierre Fabre in 2015 pursuant to which we granted Pierre Fabre rights to commercialize encorafenib and binimetinib in all countries except for the United States, Canada, Japan, Korea and Israel. The PF Agreement satisfied our commitment to secure a development and commercialization partner for the European market for both encorafenib and binimetinib acceptable to European Commission regulatory agencies made in connection with the Novartis Agreements.

The PF Agreement closed in December 2015. All clinical trials involving encorafenib and binimetinib that were ongoing or planned at the Effective Date, including the COLUMBUS trial and other then active Novartis sponsored and investigator sponsored clinical studies, continue to be conducted pursuant to the terms of the Novartis Agreements. Additional worldwide development activities of encorafenib and binimetinib will be governed by a Global Development Plan (GDP) with Pierre Fabre. Pierre Fabre and Array jointly fund worldwide development costs under the GDP, with Array covering 60% and Pierre Fabre covering 40% of such costs. The initial GDP includes multiple trials, including the BEACON CRC trial, we and Pierre Fabre have agreed to commit at least €100 million in combined funds for these studies in colorectal cancer (CRC) and melanoma.

Pierre Fabre is responsible for seeking regulatory and pricing and reimbursement approvals in the European Economic Area and its other licensed territories. We have also entered into a Clinical Supply Agreement and a Commercial Supply Agreement with Pierre Fabre pursuant to which we will supply or procure the supply of clinical and commercial supplies of drug substance and drug product for Pierre Fabre, the costs of which will be borne by Pierre Fabre. We have also agreed to cooperate with Pierre Fabre to ensure the supply of companion diagnostics for use with encorafenib and binimetinib in indications as needed.

Each party has agreed not to distribute, sell or promote competing products in each party’s respective markets during a period of exclusivity. Each party has also agreed to indemnify the other party from certain liabilities specified in the Agreement.

In connection with the PF Agreement, we received $30.0 million as a non-refundable up-front payment during the year ended June 30, 2016. The PF Agreement contains substantive potential milestone payments of up to $25.0 million for achievement of two regulatory milestones relating to European Commission marketing approvals for two specified indications and of up to $390.0 million for achievement of seven commercialization milestones if certain net sales amounts are achieved for any licensed indications. We are also entitled to double-digit royalties based on net sales under the agreement.

ONO AGREEMENT

Effective May 31, 2017, we entered into a License, Development and Commercialization Agreement (the “Ono Agreement”) with Ono, a company duly organized and existing under the laws of Japan, pursuant to which we granted Ono exclusive rights to commercialize encorafenib and binimetinib in Japan and the Republic of Korea (the “Ono Territory”), along with the right to develop these products in the Ono Territory. We retain all rights outside the Ono Territory as well as the right to conduct development and manufacturing activities in the Ono Territory, except for rights we have granted to Pierre Fabre under the PF Agreement.

Under the terms of the Ono Agreement, we received a non-refundable upfront cash payment of ¥3.5 billion, or $31.2 million. We are entitled to receive potential milestone payments of up to ¥900.0 million for the achievement of two remaining development milestones, ¥5.0 billion for the achievement of eight regulatory milestones and ¥10.5 billion for the achievement of five commercialization milestones if certain annual net sales targets are achieved. A portion of these milestones is related to the advancement the Phase 3 BEACON CRC trial in the Ono Territory. We are further

eligible for tiered double-digit royalties on annual net sales of encorafenib and binimetinib in the Ono Territory, starting at 22% for annual net sales under ¥10.0 billion and increasing to 25% for annual net sales in excess of ¥10.0 billion subject to certain adjustments. As of June 30, 2018, ¥1.0 billion was the equivalent of approximately $9.0 million.

All ongoing clinical trials involving encorafenib and binimetinib, including the BEACON CRC and COLUMBUS trials, continued as planned as of the effective date of the Ono Agreement, and Ono is entitled to the data derived from such studies. As part of the Ono Agreement, Ono obtained the right to participate in any future global development of encorafenib and binimetinib by contributing 12% of the future costs of such development. Ono is responsible for seeking regulatory and marketing approvals for products in the Ono Territory and for any development of encorafenib and binimetinib specifically necessary to obtain such approvals. We will furnish clinical supplies of drug substance to

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Ono for use in Ono's development efforts, and Ono may elect to have us provide commercial supplies of drug product to Ono pursuant to a commercial supply agreement to be entered into by us and Ono, in each case the costs of which will be borne by Ono. We have also agreed to discuss and agree with Ono on a strategy to ensure the supply of companion diagnostics to Ono for use with encorafenib and binimetinib in certain indications in the Ono Territory. Each party has agreed not to distribute, sell or promote competing MEK or RAF products in the Ono Territory during the term of the Ono Agreement.

The Ono Agreement will continue in effect on a product-by-product, country-by-country basis for a period that expires ten years after the later of expiration of patent protection or marketing exclusivity for the applicable product. The Ono Agreement may be terminated by either party for breach of the Agreement by the other party, in the event of the insolvency or bankruptcy of the other party, by Ono with 180 days' prior notice after the fifth year after first commercial sale of either binimetinib or encorafenib in the Ono Territory, or by Ono on a product-by-product basis for certain safety reasons.

COLUMBUS PHASE 3 TRIAL

The COLUMBUS trial is a two-part, international, randomized, open label Phase 3 trial evaluating the efficacy and safety of encorafenib in combination with binimetinib compared to vemurafenib and encorafenib monotherapy in 921 patients with locally advanced, unresectable or metastatic melanoma with $BRAF^{V600}$ mutation. All secondary efficacy analyses, including overall survival, are descriptive in nature. Over 200 sites across North America, Europe, South America, Africa, Asia and Australia participated in the trial.

COLUMBUS Median Overall Survival Results

On June 4, 2018, we announced updated results from the Phase 3 COLUMBUS trial in BRAF-mutant advanced melanoma as part of an oral presentation at the American Society of Clinical Oncology (ASCO) annual meeting. The median overall survival (mOS) was 33.6 months for patients treated with the combination of encorafenib and binimetinib compared to 16.9 months for patients treated with vemurafenib as a monotherapy. The combination reduced the risk of death compared to treatment with vemurafenib alone hazard ratio (HR) of 0.61, [95% CI 0.47, 0.79, $p < 0.0001$]. The data showed limited use of post-trial immunotherapy, which is consistent with other published pivotal trials of BRAF and MEK-inhibitors in BRAF-mutant advanced melanoma.

As previously reported, the combination of encorafenib and binimetinib was generally well-tolerated. Grade 3/4 adverse events (AEs) that occurred in more than 5% of patients receiving the combination were increased gamma-glutamyltransferase (GGT) (9%), increased blood creatine phosphokinase (CK) (7%) and hypertension (6%). Full safety results of COLUMBUS Part 1 were published in The Lancet Oncology.

BEACON CRC PHASE 3 TRIAL

BEACON CRC is a randomized, open-label, global trial evaluating the efficacy and safety of BRAFTOVI, MEKTOVI and cetuximab in patients with BRAF-mutant metastatic CRC whose disease has progressed after one or two prior regimens. BEACON CRC is the first and only Phase 3 trial designed to test a BRAF/MEK combo targeted therapy in BRAF-mutant advanced CRC. Thirty patients were treated in the safety lead-in and received the triplet combination (BRAFTOVI 300 mg daily, MEKTOVI 45 mg twice daily and cetuximab, an anti-EGFR antibody, per label). Of the 30 patients, 29 had a $BRAF^{V600E}$ mutation. MSI-H, resulting from defective DNA mismatch repair, was detected in only one patient. As previously announced, the triplet combination demonstrated good tolerability, supporting initiation of the randomized portion of the trial.

The randomized portion of the BEACON CRC trial is designed to assess the efficacy of BRAFTOVI in combination with cetuximab with or without MEKTOVI compared to cetuximab and irinotecan-based therapy. Approximately 615 patients are expected to be randomized 1:1:1 to receive triplet combination, doublet combination (BRAFTOVI and cetuximab) or the control arm (irinotecan-based therapy and cetuximab). The primary endpoint of the trial is overall survival of the triplet combination compared to the control arm. Secondary endpoints address efficacy of the doublet combination compared to the control arm, and the triplet combination compared to the doublet therapy. Other secondary endpoints include PFS, ORR, duration of response, safety and tolerability. Health related quality of life data will also be assessed. The trial is being conducted at over 200 investigational sites in North America, South America, Europe and the Asia Pacific region.

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We are the global sponsor of the trial. Pursuant to the PF Agreement, Pierre Fabre has elected to co-fund 40% of the cost of the BEACON CRC trial. Merck KGaA, Darmstadt, Germany, is the owner of cetuximab outside the United States and Canada and will supply cetuximab to all trial sites outside the United States and Canada as part of the collaboration. If successful, results would support regulatory submissions for all three parties as well as Ono.

On August 7, 2018, the FDA granted Breakthrough Therapy Designation to BRAFTOVI in combination with MEKTOVI and cetuximab for the treatment of patients with $BRAF^{V600E}$-mutant metastatic CRC as detected by an FDA-approved test, after failure of one to two prior lines of therapy for metastatic disease. FDA Breakthrough Therapy Designation is an FDA process designed to expedite the development and review of drugs that are intended to treat a serious condition where preliminary clinical evidence indicates that they may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints.

Based on consultation with the FDA and EMA, we plan to amend the BEACON CRC protocol to allow for an interim analysis of trial endpoints. Should a planned analysis based primarily on confirmed overall response rate (ORR) and durability of response be supportive, we plan to use it to seek accelerated approval in the U.S. The interim analysis may also support regulatory submissions in other regions. The Company anticipates topline results from this analysis in the first half of 2019. This timing allows for the subset of patients required for the interim analysis of ORR to achieve an objective response and for the durability of responses to be appropriately evaluated.

The BEACON CRC trial continues to enroll well. Based on the updated data presented at the $20^{th}$ World Congress on Gastrointestinal Cancer (ESMO World GI), excitement among global investigators continues to increase. As a result of recent FDA approval for BRAFTOVI + MEKTOVI in BRAF-mutant melanoma, we have made the decision to conclude U.S.-specific patient enrollment in the BEACON CRC trial. This action was based on the recommendation of the trial Steering Committee and we expect this will help to avoid introducing unwanted informative censoring into the trial, as U.S. patients and investigators now have the potential to access encorafenib and binimetinib via commercial supply. As the number of active global sites has continued to increase since the beginning of the year, we do not believe this decision will have a material impact on our plan to complete enrollment of the trial around the end of 2018.

We announced updated safety and efficacy results, including OS, from the safety lead-in of the BEACON CRC trial evaluating the triplet combination of encorafenib, binimetinib and cetuximab, in 29 patients with $BRAF^{V600E}$-mutant metastatic CRC during an oral presentation at ESMO World GI on June 23, 2018. At the time of analysis, the OS data were fully mature through 12.6 months and the median OS had not yet been reached. The observed one-year OS rate for this cohort was 62%. The mPFS for patients treated with the triplet was 8 months [95% CI 5.6-9.3] and is similar between patients receiving one prior line of therapy and patients receiving two prior lines of therapy. The triple combination was generally well-tolerated with no unexpected toxicities. The most common grade 3 or 4 adverse events seen in at least 10% of patients were fatigue (13%), anemia (10%), increased blood creatine kinase (10%) and increased aspartate aminotransferase (10%).

IMMUNO-ONCOLOGY COLLABORATIONS WITH BRISTOL-MYERS SQUIBB, MERCK AND PFIZER

We are also developing binimetinib in combination with PD-1/PD-L1 checkpoint inhibitors and previously announced separate, strategic collaborations with Bristol-Myers Squibb, Merck and Pfizer. Each collaboration is pursuing a different rationally designed clinical approach.

BRISTOL-MYERS SQUIBB COLLABORATION

The clinical trial continues to advance and is designed to investigate the safety, tolerability and efficacy of binimetinib in combination with nivolumab (anti-PD-1 therapy), with and without ipilimumab (CTLA-4 antibody), in patients with advanced metastatic microsatellite stable (MSS) CRC and the presence of a RAS mutation who have received one or two prior regimens. The trial is jointly supported by us and Bristol-Myers Squibb and sponsored by us.

MERCK COLLABORATION

The clinical trial continues to advance and is designed to investigate the safety, tolerability and efficacy of binimetinib in combination with pembrolizumab (anti-PD-1 therapy), with and without FOLFOX or FOLFIRI (chemotherapy), in first or second-line patients with CRC whose tumors are not microsatellite instability-high (MSI-H). The trial is sponsored and funded by Merck, with us providing binimetinib supply.

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PFIZER COLLABORATION

The clinical trial is designed to investigate the safety, tolerability and efficacy of several novel anti-cancer combinations, including binimetinib, avelumab (anti-PD-L1 therapy), and talazoparib (PARP inhibitor) across various tumor types and is expected to begin during the third calendar quarter of 2018. Initially, the focus will be in non-small cell lung cancer (NSCLC) and pancreatic cancer, with additional indications being explored at a later stage. The trial will be sponsored and funded by Pfizer, with us providing binimetinib supply.

ARRY-382

ARRY-382 is a wholly-owned, highly selective and potent, small molecule inhibitor of CSF1R kinase activity. We are advancing a Phase 2 trial of ARRY-382 in combination with pembrolizumab, an anti-PD-1 therapy, in patients with advanced solid tumors. The trial includes three cohorts: patients with pancreatic cancer with one prior line of therapy and no prior treatment with immune checkpoint inhibitors, patients with ovarian cancer who are platinum refractory and no prior treatment with immune checkpoint inhibitors, and patients with solid tumors who have progressed on prior PD1/PD-L1 inhibitors.

ARRY-797

ARRY-797 is an oral, selective p38 MAPK inhibitor that is currently advancing in a Phase 3 trial in patients with LMNA-related DCM a rare, degenerative cardiovascular disease caused by mutations in the LMNA gene and characterized by poor prognosis.

Preclinical Drug Discovery Programs

We also have a portfolio of proprietary and partnered preclinical drug discovery programs, including collaborations with Loxo Oncology, Mirati Therapeutics, Inc., and other companies.

In October 2014, we initiated an agreement with Mirati Therapeutics, Inc. whereby we conducted a feasibility program for Mirati related to an identified target in exchange for an up-front payment of $1.6 million. In September 2015, Mirati exercised an option to extend the feasibility program for six months, for which we received a $0.8 million option extension fee. During April 2016, Mirati elected to exercise an option to take an exclusive, worldwide license to an active compound under the agreement for which Array received $2.5 million and will receive additional fees as reimbursement for research and development services. In June 2017, we and Mirati entered into a second agreement related to a different target in exchange for an up-front payment of $2.0 million that was received in June 2017. During April 2018, Mirati elected to exercise an option to take an exclusive, worldwide license to an active compound under the second agreement for which we received $2.0 million and will receive additional fees as reimbursement for research and development services. The Mirati Agreements contain substantive potential milestone payments of up to $692.5 million if certain developmental, commercial and net sales amounts are achieved in the United States, the European Union and Japan.

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 advancing compounds discovered by Array include:

- Asahi Kasei Pharma – In March 2016, we entered into a strategic collaboration with Asahi Kasei Pharma Corporation ("AKP") to develop and commercialize select Tropomyosin receptor kinase A (TRKA) inhibitors, including Array-invented AK-1830 for pain, inflammation and other non-cancer indications. AKP is currently advancing AK-1830 in a Phase 1 clinical trial in patients with inflammatory disease in Japan.

- ASLAN – We entered into a Collaboration and License Agreement with ASLAN in July 2011 to develop our pan-HER inhibitor, varlitinib. ASLAN is currently advancing varlitinib in registration trials in patients with biliary tract cancer and gastric cancer. In January 2018, we granted ASLAN an exclusive license to develop, manufacture and commercialize varlitinib. The License Agreement replaced the 2011 agreement.
- Seattle Genetics – We entered into a Development and Commercialization Agreement with Cascadian Therapeutics in May 2013, to collaborate on the development and commercialization of tucatinib, an orally active, reversible and selective small-molecule HER2 inhibitor, for the treatment of cancer. In December 2014, we granted Cascadian Therapeutics an exclusive license to develop, manufacture and commercialize

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tucatinib. The License Agreement replaced the 2013 agreement. In March 2018, Seattle Genetics acquired Cascadian Therapeutics and is continuing development of tucatinib in registration trials in patients with metastatic breast cancer, including patients with brain metastases.

- 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 drug is ipatasertib, an AKT inhibitor for cancer, which is currently in Phase 3. 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.
- 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 larotrectinib, which is currently in a Phase 2/registration clinical trial. In May 2018, Loxo announced that it had filed an NDA with the FDA for larotrectinib and had been granted priority review. The FDA has set a target action date of November 26, 2018, under the Prescription Drug User Fee Act (PDUFA). Loxo is also advancing Array-invented LOXO-195, a Trk inhibitor, and LOXO-292, a Ret inhibitor, in Phase 1 / 2 clinical trials.

Business History

We have received a total of $1.2 billion in research funding and up-front and milestone payments from partners from inception through June 30, 2018. Our existing partnered programs provide Array the potential to receive up to a total of over $2.7 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 17 partnered clinical and discovery programs. Potential milestone payments we may receive in the future are further described in Note 4 – Collaboration and Other Agreements to our consolidated financial statements included elsewhere in this Annual Report on Form 10-K.

Our Strategy

We are a fully-integrated, biopharmaceutical company focused on the discovery, development and commercialization of transformative and well-tolerated targeted small molecule drugs to treat patients afflicted with cancer and other high-burden diseases.

Our strategy includes the following elements:

- Inventing best-in-class small molecule drugs for patient populations which have significant unmet medical need;
- Conducting clinical trials which maximize the overall value of our programs for patients and Array;
- Building and maintaining an oncology focused sales, marketing and medical organization to commercialize our products in the U.S.; and
- Selectively partnering with early-stage research programs outside oncology.

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. Under certain of 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

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

Partnered Development Programs

Below are summaries of the most advanced 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. Asahi Kasei Pharma — AK-1830 TRKA Program

In March 2016, we entered into a strategic collaboration with AKP to develop and commercialize select preclinical Tropomyosin receptor kinase A (TrkA) inhibitors, including Array-invented AK-1830, for pain, inflammation and other non-cancer indications. AKP is currently advancing a Phase 1 clinical trial of AK-1830 in patients with inflammatory disease in Japan. We have received $13.0 million up-front and milestone payments to date and may receive up to $62.5 million in additional development and commercialization milestone payments, including up to double-digit royalties on future sales. We will retain full commercialization rights for all compounds in all indications in territories outside of Asia and within Asia retain full rights to cancer indications for all compounds excluding those being developed by AKP.

2. ASLAN — Varlitinib Pan-HER Program

In July 2011, we entered into a Collaboration and License Agreement with ASLAN to develop Array's pan-HER inhibitor, varlitinib. ASLAN is currently advancing registration trials of varlitinib in patients with biliary tract cancer or gastric cancer in Asia. In January 2018, we entered into a second License Agreement with ASLAN pursuant to which we granted ASLAN full global rights to develop, manufacture and commercialize varlitinib. The License Agreement replaces and supersedes the Collaboration and License Agreement. Array received a $23.0 million upfront payment under the 2018 License Agreement and may receive up to $105.0 million in additional development, regulatory and commercialization milestone payments, including double-digit royalties on future sales.

3. 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 for oncology indications. AstraZeneca continues to advance selumetinib in SPRINT, the Phase 2 registration trial, in patients with neurofibromatosis type 1. On July 26, 2018, AstraZeneca and MSD reported that the Phase 3 ASTRA trial of selumetinib in differentiated thyroid cancer (DTC) did not meet its primary endpoint. Trial results demonstrated that treatment with a short course of selumetinib and single dose adjuvant radioactive iodine therapy (RAI) did not meet its primary endpoint of improvement in complete remission (CR) rate compared to placebo. AstraZeneca estimates top-line results from the SPRINT trial during the second half of 2018.

On July 28, 2017, AstraZeneca and Merck announced that they entered into an agreement to share the development and commercialization costs for selumetinib monotherapy and non-PD-L1/PD-1 combination therapy opportunities. We remain eligible to receive from AstraZeneca milestones and royalties on all future selumetinib sales and now expect to receive a portion of certain consideration paid by Merck to AstraZeneca under this agreement. We have informed AstraZeneca that we are disputing the consideration that AstraZeneca has paid us related to both upfront and potential future milestones under AstraZeneca's agreement with Merck. Furthermore, prior to the announcement of the AstraZeneca/Merck agreement, we informed AstraZeneca of our position that the Neurofibromatosis type 1 (NF1) development program is outside the permitted field of its license. We commenced legal proceedings against AstraZeneca on December 7, 2017 naming AstraZeneca as the defendant in New York State Court in Manhattan

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regarding this dispute. On February 1, 2018, we filed a second action against AstraZeneca AB in New York state court. We are seeking damages and a declaratory judgment in both actions.

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 $30.0 million specific for selumetinib and royalties on product sales.

4. Seattle Genetics — Tucatinib/ONT-380/ARRY-380 — HER2 Inhibitor Program

In May 2013, we entered into a Development and Commercialization Agreement with Cascadian Therapeutics (formerly Oncothyreon Inc.) to collaborate on the development and commercialization of tucatinib, an orally active, reversible and selective small-molecule HER2 inhibitor, for the treatment of cancer, including breast cancer, currently in Phase 2 / registration studies. Under the terms of the agreement, Cascadian Therapeutics paid us a one-time up-front fee of $10.0 million.

In December 2014, we granted Cascadian Therapeutics an exclusive license to develop, manufacture and commercialize tucatinib pursuant to a License Agreement that replaced the 2013 agreement. As part of the License Agreement, Cascadian Therapeutics paid Array $20.0 million as an up-front fee. We are also entitled to receive up to a double-digit royalty based on net sales of tucatinib. In March 2018, Seattle Genetics acquired Cascadian Therapeutics and is responsible for the tucatinib program.

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 Seattle Genetics on 180 days' notice to us. We and Seattle Genetics have also agreed to indemnify the other party in specified circumstances.

5. Genentech — Ipatasertib

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 $26.5

million in up-front and milestone payments, and we have the potential to earn an additional $20.0 million for all programs if Genentech continues development and achieves the remaining clinical milestones set forth in the agreement.

Genentech is advancing one collaborative drug, ipatasertib, an AKT inhibitor, in Phase 3 trials in prostate or breast cancers.

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6. Genentech — GDC-0575 — Checkpoint kinase 1, or CHK-1, Inhibitor Program

In August 2011, we entered into a License Agreement with Genentech for the development of each company's small-molecule CHK-1 program in oncology. The programs included Genentech's compound GDC-0425 (RG7602) and our compound GDC-0575 (previously known as ARRY-575), both of which are in Phase 1. Under the terms of the agreement, Genentech is responsible for all clinical development and commercialization activities. We received an up-front payment of $28.0 million and are eligible to receive clinical and commercial milestone payments up to $380.0 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 us. If Genentech terminates the agreement due to a material breach by us, the license Array granted to Genentech becomes irrevocable and the royalty to us will be reduced to a specified percentage. If the agreement is terminated by Genentech for convenience or by us due to a material breach by Genentech, the license we 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 our 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.

In 2014, Genentech selected GDC-0575 over GDC-0425 to advance into further clinical trials. Genentech completed a Phase 1 multiple ascending dose trial to evaluate GDC-0575 alone and in combination with Gemzar® (gemcitabine) in approximately 100 patients with refractory solid tumors or lymphoma.

7. InterMune (program now owned by Roche/Ascletis) — Ganovo 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 Ganovo / danoprevir. In October 2010, Roche expanded its portfolio of investigational medicines for HCV through the purchase of Ganovo from InterMune for $175 million. InterMune thereafter ceased all further development efforts under the collaboration. In April 2014, Roche sublicensed rights to develop and commercialize Ganovo in China to Ascletis Pharmaceuticals. At this time, Roche and Ascletis are conducting all clinical development for Ganovo. Under the terms of our collaboration agreement with Roche, Roche has an obligation to make milestone payments to us based on the selection and progress of Ganovo, as well as royalties on commercial sales of Ganovo. To date, we have received $4.2 million in milestone payments and have the potential to earn an additional $5.0 million if all clinical and commercialization milestones for Ganovo are achieved under the agreement. Ganovo received marketing approval by the China Food and Drug Administration in June 2018. Ascletis has announced that it plans to commence commercial sales in the third quarter of 2018.

8. Lilly — Prexasertib/LY2606368 — CHK-1 Inhibitor Program

In 1999 and 2000, we entered into collaboration agreements involving small-molecule CHK-1 inhibitors with ICOS Corporation. LY2603618 and prexasertib resulted from the collaboration between us and ICOS. Eli Lilly and Company acquired ICOS in 2007. We received $0.4 million in clinical milestone payments due to program advancements. We are entitled to receive additional milestone payments totaling $2.5 million based on Lilly's achievement of clinical and regulatory milestones with the program. Prexasertib is being studied in multiple Phase 1 or 2 trials for cancer.

9. Loxo — Larotrectinib — PanTrk Inhibitor Program

In July 2013, we entered into a Drug Discovery Collaboration Agreement with Loxo which was subsequently amended in November 2013, April 2014, October 2014, March 2015 and February 2016. It granted Loxo exclusive rights to develop and commercialize certain Array-invented compounds including larotrectinib, which is currently in Phase 2/registration clinical trials. In May 2018, Loxo announced that it had filed an NDA with the FDA for larotrectinib and had been granted priority review. The FDA has set a target action date of November 26, 2018, under the PDUFA. LOXO-195, a next-generation TRK inhibitor, and LOXO-292, a RET inhibitor, are also advancing in Phase 1.

Under the terms of the amended agreement, Loxo is funding further discovery and preclinical programs to be conducted by Array, including a FGFR program. The most recent amended agreement extended the term through September

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2017, with Loxo retaining an option to extend the term for up to one additional year. During June 2017, Loxo exercised its option to extend the term through September 2018. Loxo is responsible for all additional preclinical and clinical development and commercialization.

We receive advance payments for the preclinical research and other services that we are providing during the term of the discovery program. To date, we have earned $13.0 million in milestone and other upfront payments and have the potential to earn up to approximately (i) $437.0 million with respect to products related to TRK, including larotrectinib and its backup compounds, and (ii) $209.0 million with respect to product candidates directed to targets other than TRK, if Loxo achieves additional clinical, regulatory and sales milestones plus royalties on sales of any resulting drugs.

The Loxo agreement, as amended, 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, we 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 us. If Loxo terminates the agreement for convenience, all licenses granted to Loxo will terminate and we will have all rights to further develop and commercialize the licensed programs. The period of exclusivity to be observed by us 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.

10. VentiRx (now owned by Celgene) — 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. In February 2017, VentiRx was acquired by Celgene. The program contains a number of compounds targeting TLRs to activate innate immunity, including motolimod/VTX-2337, which is currently in Phase 2. 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 Celgene achieves the remaining clinical and commercial milestones 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 $102 billion in 2017 to $191 billion in 2022.

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 to be used as targeted combination regimens or in combination with immunotherapy agents including PD1 inhibitors.

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According to estimates contained in the American Cancer Society, Cancer Facts and Figures 2018, in the U.S. there will be an estimated 1.7 million new cases of cancer in 2018 and just over 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 2018 by major cancer types of interest to us:

| Type of Cancer | Estimated 2018 New Cases | Deaths |
|---|---|---|
| Lung | 234,030 | 154,050 |
| Breast | 268,670 | 41,400 |
| Colon & rectum (combined) | 140,250 | 50,630 |
| Melanoma | 91,270 | 9,320 |
| Pancreas | 55,440 | 44,330 |
| Ovarian | 22,240 | 14,070 |
| Stomach | 26,240 | 10,800 |
| Myeloma | 30,770 | 12,770 |
| Gallbladder and Other Biliary | 12,190 | 3,790 |
| | 881,100 | 341,160 |

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 bevacizumab, crizotinib, trastuzumab, rituximab and vemurafenib.

In addition to targeted therapies, immunotherapy agents that target PD1 have gained approval across multiple tumor types including melanoma, NSCLC, Merkel cell carcinoma, urothelial carcinoma, squamous cell carcinoma of the head and neck, and classical Hodgkin Lymphoma. Recently, Merck’s pembrolizumab and BMS’ nivolumab (as a single agent or in combination with ipilimumab have been approved for patients with microsatellite instable (MSI) colorectal cancer. In melanoma, pembrolizumab and BMS’ nivolumab have become major players with significant market share. One area of particular interest for us is developing combination therapies of proprietary targeted therapies and PD1 inhibitors in order to address a broader range of patients.

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

Market growth of melanoma drug therapies is expected to be strong, with sales across the worldwide markets forecasted to grow at a CAGR of 14% from $3.7 billion in 2016 to $8.1 billion in 2022. 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.

Melanoma develops when unrepaired DNA damage to skin cells triggers mutations that may lead them to multiply and form malignant tumors. Metastatic melanoma is the most serious and life-threatening type of skin cancer and is associated with low survival rates. There are a variety of gene mutations that can lead to metastatic melanoma. The most common genetic mutation in metastatic melanoma is BRAF. There are about 200,000 new cases of melanoma diagnosed worldwide each year, approximately half of which have BRAF mutations, a key target in the treatment of metastatic melanoma.

The optimal treatment for melanoma varies with the stage of the disease. In patients with early disease, surgical excision can be followed by adjuvant therapy with interferon alpha, ipilimumab, Nivolumab, or dabrafenib + trametinib.

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Array's BRAFTOVI and MEKTOVI, Novartis' trametinib and dabrafenib and Roche's vemurafenib and cobimetinib are currently approved for the treatment of melanoma patients with BRAF mutations.

Colorectal Cancer (Binimetinib - MEK inhibitor and Encorafenib - BRAF inhibitor)

Worldwide, colorectal cancer is the third most common type of cancer in men and the second most common in women, with approximately 1.4 million new diagnoses in 2012. Globally in 2012, approximately 694,000 deaths were attributed to colorectal cancer. In the U.S. alone, an estimated 140,250 patients will be diagnosed with cancer of the colon or rectum in 2018, and approximately 50,000 are estimated to die of their disease. In the U.S., BRAF mutations are estimated to occur in 10% to 15% of patients with colorectal cancer and represent a poor prognosis for these patients. The risk of mortality in CRC patients with the $BRAF^{V600E}$ mutation is more than two times higher than for those with wild-type BRAF. Several irinotecan and cetuximab-containing regimens, similar to the BEACON CRC control arm, have established clinical activity benchmarks in $BRAF^{V600E}$-mutant mCRC patients, whose disease has progressed after one or two prior lines of therapy. The benchmarks include ORR of 4% to 8%, mPFS of 1.8 to 2.5 months and mOS of 4 to 6 months. Overall, with the addition of new treatment options to address existing and emerging biomarkers, the total CRC market is forecast to grow from $7.0 billion in 2014 to $7.6 billion in 2023.

Treatment for patients diagnosed with localized disease centers around surgery, with or without adjuvant or neoadjuvant chemotherapy regimens. Advanced or metastatic colorectal cancer is managed through the use of chemotherapy or monoclonal antibodies targeted against the EGFR or VEGF signaling pathways. The EGFR surface protein is overexpressed in approximately 40-80% of CRC tumors, and the EGFR-targeted therapies cetuximab (cetuximab) and panitumumab are FDA-approved for use in CRC patients. However, EGFR overexpression is not predictive of treatment efficacy, and only approximately 10-20% of CRC patients respond to EGFR-directed therapies. Targeting VEGF through the use of bevacizumab or ramucirumab is also an available treatment modality. However, despite use of these targeted agents against EGFR and VEGF, there remains high unmet need for additional therapies that target additional mutations in CRC patients.

We, in partnership with Pierre Fabre and Merck KGaA, have initiated the Phase 3 BEACON CRC trial to evaluate encorafenib and binimetinib in combination with cetuximab in patients with BRAF-mutated metastatic CRC who have progressed on first-line systemic therapy. Patients are to be randomized to receive the triplet therapy, doublet therapy of encorafenib and cetuximab, or a cetuximab and chemotherapy control arm. OS of the triplet therapy compared with the control arm will be evaluated as the primary endpoint; PFS, ORR, DOR, safety and tolerability are secondary endpoints.

Recently, CRC tumors have come to also be defined by the level of microsatellite stability or instability displayed, and pembrolizumab was approved by the FDA in May 2017 for the treatment of patients (including those with CRC) whose tumors display high levels of microsatellite instability. Recently, pembrolizumab and nivolumab (as a single agent or in combination with ipilimumab) have been approved for the treatment of this population. In addition, BMS has also submitted an application with FDA for the approval of nivolumab for the treatment of CRC patients with MSI-H tumors. However, despite the encouraging activity of PD1 inhibitors in MSI-H CRC, these tumors only account for approximately 5% of CRC in the U.S. To address the larger population of CRC patients with microsatellite stable tumors, we have initiated two collaborations with Merck and BMS to combine binimetinib with pembrolizumab or nivolumab in CRC patients with MSS tumors.

NF1 or Plexiform Neurofibromas (Selumetinib and Binimetinib - MEK inhibitors)

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 from the Phase 2 SPRINT trial of pediatric patients with NF1 was presented at the 2018 ASCO Annual Meeting. In the study, 72% (16 of 24) of patients treated with selumetinib achieved a partial response.

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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.

We are currently developing ARRY-797, a selective, oral inhibitor of the p38 MAPK pathway, which is currently in Phase 3 in patients with LMNA-DCM.

Research and Development for Proprietary Drug Discovery

Our primary research efforts during fiscal 2018 were focused on development of our 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 characteristics, including efficacy, tolerability or dosing to provide safer, more effective drugs. During fiscal years 2018, 2017 and 2016, we spent $185.8 million, $178.2 million and $160.7 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.

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| Phase | Objective | Estimated Duration |
|---|---|---|
| Discovery | Lead identification and target validation. | 1 to 2 years |
| Preclinical | Initial toxicology for preliminary identification of risks for humans; gather early pharmacokinetic data. | 2 to 4 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.

Preclinical 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 in academia who enhance our current capabilities and keep us current with new science and methodologies. 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 continues to create high quality clinical candidates for our proprietary and partnered programs that selectively engage their mechanistic target and prove or disprove the pharmacological hypothesis either by a relevant human biomarker or by direct efficacy assessments.

Clinical Development

Our current key capabilities within clinical development include clinical science, clinical operations, clinical pharmacology, drug safety and pharmacovigilance, 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 laws and 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.

The focus of our research and development effort is on continuing to explore opportunities for and develop data sets to guide use of our marketed products, BRAFTOVI and MEKTOVI, including the design and conduct of registration trials for new indications. Our early development 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 either demonstrate the potential of

the drug or to "fail early."

Manufacturing and Product Supply

We currently contract with third-party, contract manufacturing organizations (“CMOs”) for the manufacture of BRAFTOVI and MEKTOVI commercial and clinical supply. We do not own or operate manufacturing facilities, nor do we have plans in place to build or acquire our own clinical or commercial scale manufacturing capabilities. Although

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we rely on contract manufacturers, we have personnel with extensive manufacturing experience to oversee the relationships with our contract manufacturers. To date, our third-party manufacturers have met our manufacturing requirements. We expect our CMOs to provide sufficient quantities of BRAFTOVI and MEKTOVI to meet current and future market demand for both products. Should any of our other drug candidates obtain marketing approval, we anticipate establishing relationships with third-party manufacturers and other service providers in connection with commercial production of those products.

Marketing, Sales and Distribution

In anticipation of FDA approval of BRAFTOVI and MEKTOVI, we put in place an experienced commercial leadership team and infrastructure, which includes nearly 60 customer-facing employees. We have experienced, senior-level sales, marketing and market access employees based at headquarters leading our sales force and strategic account managers who are based in the field.

Array launched BRAFTOVI and MEKTOVI in the United States in July 2018 following FDA approval for the treatment of patients with unresectable or metastatic melanoma with a $BRAF^{V600E}$ or $BRAF^{V600K}$ mutation. We promote our products utilizing customary pharmaceutical practices with a focus on oncologists, advanced practice practitioners and pharmacists. We distribute BRAFTOVI and MEKTOVI through a limited set of specialty distributors and specialty pharmacies with expertise in oral oncology products, which in turn, resell our products to hospitals and oncology clinics, or directly to patients.

While Array retains the commercial rights to both products in Canada, we have established regional partnerships with three outside organizations to commercialize BRAFTOVI and MEKTOVI in other territories around the world. Ono Pharmaceutical now has exclusive rights to commercialize both products in Japan and South Korea, Medison holds exclusive rights to commercialize both products in Israel and Pierre Fabre owns exclusive rights to commercialize both products in all other countries, including those in Europe, Asia and Latin America.

BRAFTOVI and MEKTOVI are not approved outside of the United States. The EMA, Swissmedic, TGA, and the Pharmaceuticals and Medical Devices Agency in Japan are currently reviewing the Marketing Authorization Applications for BRAFTOVI and MEKTOVI.

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 export of such

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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 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.

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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 as 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.

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.

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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) encorafenib and binimetinib 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.

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

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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 tests being developed for our lead products are 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 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.

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 our lead products and its 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.

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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 obtain, use or disclose individually identifiable health information maintained by a HIPAA-covered entity in a manner that is not authorized or permitted by HIPAA In addition, we and our partners may be directly subject to certain data protection laws and regulations (i.e., laws and regulations that address privacy and data security).

In the U.S., numerous federal and state laws and regulations that govern the collection, use, disclosure, and protection of health-related and other personal information could apply to our operations or the operations of our partners, including state data breach notification laws, state health information privacy laws, state genetic privacy laws, and federal and state consumer protection laws (e.g., Section 5 of the FTC Act). 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) may apply to some or all of the clinical data obtained outside of the U.S. The EU Data Protection Directive, as implemented into national laws by the EU Member States, imposes strict obligations and restrictions on the ability to collect, analyze and transfer personal data, including health data from clinical trials and adverse event reporting. The EU Data Protection Directive prohibits the transfer of personal data to countries outside of the European Economic Area, or EEA, such as the U.S., which are not considered by the European Commission to provide an adequate level of data protection. Switzerland has adopted similar restrictions. Although there are legal mechanisms to allow for the transfer of personal data from the EEA and Switzerland to the U.S., a recent decision of the European Court of Justice that invalidated the safe harbor framework has increased uncertainty around compliance with EU privacy law requirements. As a result of the decision, it will no longer be possible to rely on safe harbor certification as a legal basis for the transfer of personal data from the EU to entities in the U.S. In addition, data protection authorities from the different EU Member States may interpret the EU Data Protection Directive and national laws differently, and guidance on implementation and compliance practices are often updated or otherwise revised, which adds to the complexity of processing personal data in the EU. In February 2016, the European Commission announced an agreement with the U.S. Department of Commerce, or DOC, to replace the invalidated Safe Harbor framework with a new EU-U.S. “Privacy Shield.” On July 12, 2016, the European Commission adopted a decision on the adequacy of the protection provided by the Privacy Shield. The Privacy Shield is intended to address the requirements set out by the European Court of Justice in its recent ruling invalidating safe harbor by imposing more stringent obligations on companies, providing stronger monitoring and enforcement by the DOC and FTC, and making commitments on the part of public authorities regarding access to information. U.S. companies are able to certify to the DOC their compliance with the privacy principles of the Privacy Shield since August 1, 2016. In December 2015, a proposal for an EU General Data Protection Regulation, intended to replace the current EU Data Protection Directive, was agreed between the European Parliament, the Council of the European Union and the European Commission. The EU General Data Protection Regulation, which was officially adopted in April 2016 and will be applicable in May 2018, will introduce new data protection requirements in the EU, as well as substantial fines for breaches of the data protection rules. The EU General Data Protection Regulation will increase our responsibility and liability in relation to any personal data that we process, and we may be required to put in place additional mechanisms to ensure compliance with the new EU data protection rules.

Failure to comply with U.S. and international data protection laws and regulations could result in government enforcement actions (which could include civil and/or criminal penalties), private litigation and/or adverse publicity and could negatively affect our operating results and business. 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.

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

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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.

Additional provisions of the Healthcare Reform Act 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. On February 1, 2016, the Centers for Medicare & Medicaid Services, or CMS, the federal agency that administers the Medicare and Medicaid programs, issued final regulations to implement the changes to the Medicaid Drug Rebate Program under the Health Reform Act. These regulations became effective on April 1, 2016.

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 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.

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.

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 issued a proposed regulation in 2015 regarding the calculation of the 340B ceiling price and the imposition of civil monetary penalties on manufacturers that knowingly and intentionally overcharge covered entities. HRSA has indicated it plans to issue the final regulation regarding these topics in 2016. HRSA in 2015 also released proposed omnibus guidance that addresses many aspects of the 340B program. HRSA has indicated it plans to release the omnibus guidance in final form in 2016. HRSA recently issued a proposed regulation regarding an administrative

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dispute resolution process for 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 list their covered (innovator) drugs on an FSS contract and charge no more than Federal Ceiling Price, or FCP, to the Department of Veterans Affairs, Department of Defense, Public Health Service, and Coast Guard when those agencies purchase from the FSS contract or a depot contract. FCP is calculated based on non-federal average manufacturer price data, which manufacturers must submit quarterly and annually. 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.

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.

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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 or specific intent to violate it. 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. Certain marketing practices may implicate the federal civil False Claims Act, including promotion of pharmaceutical products for unapproved uses, providing free product to customers with the expectation that the customer would bill federal programs for the product, or inflating prices report to private price publication services used to set drug reimbursement rates under federal healthcare programs. 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. 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, which increased to a range of $10,957 to $21,916 for violations after November 2, 2015, and assessed after August 1, 2016. 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. Pharmaceutical companies also are subject to other federal false claim laws, including laws that impose criminal penalties, including imprisonment and criminal fines, for making or presenting a false or fictitious or fraudulent claim to the federal government.

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, 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.

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Physician Payment Sunshine Act

The federal Physician Payment Sunshine Act 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.

Analogous State and Foreign Laws

The majority of states also have statutes or regulations similar to the federal laws described above, including state anti-kickback and false claims laws. These state laws apply to items and services reimbursed under Medicaid and other state programs, or, in several states, apply regardless of the payor. In addition, a number of states require pharmaceutical companies to report expenses relating to the marketing and promotion of pharmaceutical products and to report gifts and payments to individual physicians in the states. Other states restrict when pharmaceutical companies may provide meals to prescribers or engage in other marketing related activities, or require pharmaceutical companies to implement compliance programs or marketing codes of conduct. Outside the U.S., we are subject to similar regulations in those countries where we market and sell products.

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 programs and proprietary technologies.

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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.

We own or have license rights under issued patents covering encorafenib and related molecules, as well and their equivalent counterparts in dozens of countries. These patents include composition of matter, method of treatment and combination therapy claims, which will expire on various dates in 2031. We believe that patent term extension under the Hatch-Waxman Act could be available to extend our patent exclusivity for encorafenib to at least 2036 in the United States. In Europe, we believe that patent term extension under a supplementary protection certificate could be available for an additional five years to at least 2036. Additionally, other patent applications are directed to methods of using encorafenib, combination therapies and formulations, which, if issued, have expiration dates between 2032 and 2034, excluding any patent term adjustment.

We have issued patents covering ARRY-797 and related molecules and their equivalent counterparts in dozens of countries. These patents include composition of matter and method of treatment claims, which will expire on various dates in 2023. We believe that patent term extension under the Hatch-Waxman Act could be available to extend our patent exclusivity for ARRY-797 to at least 2028 in the United States. In Europe, we believe that patent term extension under a supplementary protection certificate could be available for an additional five years to at least 2028.

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.

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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.

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, 2018, we had 298 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.

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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

We are largely dependent on the commercial success of BRAFTOVI (ENCORAFENIB) + MEKTOVI (BINIMETINIB) in the U.S. for the foreseeable future. We cannot guarantee when, or if, we will attain profitability or positive cash flows.

The commercial success of BRAFTOVI + MEKTOVI depends on a number of factors, including the effectiveness of BRAFTOVI capsules in combination with MEKTOVI tablets as a treatment for patients with unresectable or metastatic melanoma with a $BRAF^{V600E}$ or $BRAF^{V600K}$ mutation; the size of the treatable patient population; the effectiveness of the sales, managed markets and marketing efforts by us; the adoption of BRAFTOVI + MEKTOVI by physicians, which depends on whether physicians view it as a safe and effective treatment for patients with unresectable or metastatic melanoma with a $BRAF^{V600E}$ or $BRAF^{V600K}$ mutation; our success in educating and activating patients with unresectable or metastatic melanoma with a $BRAF^{V600E}$ or $BRAF^{V600K}$ mutation to enable them to more effectively communicate their symptoms and treatment history to their physicians; our ability to both secure and maintain adequate reimbursement for, and optimize patient access to, BRAFTOVI + MEKTOVI by providing third party payers with a strong value proposition based on the existing burden of illness associated with unresectable or metastatic melanoma with a $BRAF^{V600E}$ or $BRAF^{V600K}$ mutation and the benefits of BRAFTOVI + MEKTOVI; the effectiveness of our partners' distribution networks; the occurrence of any side effects, adverse reactions or misuse, or any unfavorable publicity in these areas, associated with BRAFTOVI + MEKTOVI; and the development or commercialization of competing products or therapies for the treatment of unresectable or metastatic melanoma with a $BRAF^{V600E}$ or $BRAF^{V600K}$ mutation, or their associated symptoms.

Our revenues from the commercialization of BRAFTOVI + MEKTOVI are subject to these factors, and therefore may be unpredictable from quarter-to-quarter. Ultimately, we may never generate sufficient revenues from BRAFTOVI + MEKTOVI to reach or maintain profitability or to sustain our anticipated levels of operations.

BRAFTOVI + MEKTOVI may cause undesirable side effects or have other properties that could limit its commercial potential.

The most common adverse reactions in the Phase 3 COLUMBUS trial for BRAFTOVI + MEKTOVI were fatigue, nausea, diarrhea, vomiting, abdominal pain, arthralgia, myopathy, hyperkeratosis, rash, headache, constipation, visual impairment, serous retinopathy. In the Phase 3 COLUMBUS trial, the most common laboratory abnormalities included increased creatinine, increased CPK, increased gamma glutamyl transferase, anemia, increased ALT, hyperglycemia, increased AST, and increased alkaline phosphatase. If we or others identify previously unknown side effects, if known side effects are more frequent or severe than in the past, if we or others detect unexpected safety signals for BRAFTOVI + MEKTOVI or any products perceived to be similar to BRAFTOVI + MEKTOVI, or if any of the foregoing are perceived to have occurred, then in any of these circumstances, sales of BRAFTOVI + MEKTOVI may be impaired; regulatory approvals for BRAFTOVI + MEKTOVI may be denied, restricted or withdrawn; we may decide to, or be required to, send product warning letters or field alerts to physicians, pharmacists and hospitals; reformulation of the product, additional nonclinical or clinical studies, changes in labeling or changes to

or reapprovals of manufacturing facilities may be required; we may be precluded from pursuing additional development opportunities to enhance the clinical profile of BRAFTOVI + MEKTOVI within its indicated populations, as well as be precluded from studying BRAFTOVI + MEKTOVI in additional indications, populations and formulations; our reputation in the marketplace may suffer; and government investigations or lawsuits, including class action suits, may be brought against us.

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Any of the above occurrences would harm or prevent sales of BRAFTOVI + MEKTOVI, increase our expenses and impair our ability to successfully commercialize BRAFTOVI + MEKTOVI. Furthermore, as we explore development opportunities to enhance the clinical profile of BRAFTOVI + MEKTOVI through additional clinical trials, the number of patients treated with BRAFTOVI + MEKTOVI within and outside of its current indications or patient populations may expand, which could result in the identification of previously unknown side effects, increased frequency or severity of known side effects, or detection of unexpected safety signals. As a result, regulatory authorities, healthcare practitioners, third party payers or patients may perceive or conclude that the use of BRAFTOVI + MEKTOVI is associated with serious adverse effects, undermining our commercialization efforts.

We require additional funding and may be unable to raise capital when needed, which may force us to delay, curtail or eliminate commercialization efforts of BRAFTOVI + MEKTOVI.

Our operations have consumed substantial amounts of cash since inception. During the years ended June 30, 2018 and 2017, net cash flow used in operations was approximately $119.8 million and $39.4 million, respectively. We expect to continue to spend substantial amounts on product development and commercialization activities, including the commercialization of our recently FDA-approved BRAFTOVI + MEKTOVI. Until such time, if ever, as we can generate a sufficient amount of product revenue and achieve profitability, we expect to seek to finance future cash needs through equity or debt financings or corporate collaboration and licensing arrangements. In addition, we may seek other alternatives to maximize the value of our intellectual property, to focus more on, and finance, our medical applications. If we are unable to raise additional capital, we will have to delay, curtail or eliminate the commercialization of BRAFTOVI + MEKTOVI, our efforts to obtain FDA approval of our other drug products and/or our product development and other commercialization efforts.

We are highly dependent on the commercial success of BRAFTOVI + MEKTOVI in the U.S.; we may not be able to meet expectations with respect to BRAFTOVI + MEKTOVI sales or attain profitability and positive cash-flow from operations.

On June 27, 2018, the FDA granted approval for BRAFTOVI + MEKTOVI for the treatment of patients with unresectable or metastatic melanoma with a $BRAF^{V600E}$ or $BRAF^{V600K}$ mutation. BRAFTOVI + MEKTOVI is commercially available. The commercial success of BRAFTOVI + MEKTOVI will depend on a number of factors, including, but not limited to the effectiveness of our sales, managed markets and marketing efforts; the effectiveness of our commercialization activities, including negotiating and entering into any additional commercial and supply contracts, scaling up manufacturing and hiring any additional personnel; FDA-mandated package insert requirements and the time it would take us to comply with any related FDA post-marketing requirements and commitments; demonstration and/or confirmation of clinical efficacy and safety and acceptance of the same by the medical community; the occurrence of any side effects, adverse reactions or misuse, or any unfavorable publicity in these areas; whether BRAFTOVI + MEKTOVI can consistently be manufactured in commercial quantities and at acceptable costs; the cost-effectiveness of the product; the adoption of BRAFTOVI + MEKTOVI by physicians, which depends on whether physicians view it as a safe and effective treatment for patients with unresectable or metastatic melanoma with a $BRAF^{V600E}$ or $BRAF^{V600K}$ mutation; adequate reimbursement by third parties, including government payors, managed care organizations and private health insurers; our ability to comply with the FDA requirements, and achieve the required clinical endpoints in the studies included in the BRAFTOVI + MEKTOVI approval letter; the need for, and success of, other confirmatory trials and post-marketing requirements; the development or commercialization of competing products or therapies for the treatment of patients with unresectable or metastatic melanoma with a $BRAF^{V600E}$ or $BRAF^{V600K}$ mutation, or its symptoms; marketing and distribution support for BRAFTOVI + MEKTOVI; our ability to remain compliant with laws and regulations that apply to us and our commercial activities; the actual market-size for BRAFTOVI + MEKTOVI, which may be different than expected; the sufficiency of our drug supply to meet commercial and clinical demands which could be negatively impacted if our projections on the potential number of amenable patients are inaccurate, we are subject to

unanticipated regulatory requirements that increase our drug supply needs, our current drug supply is destroyed or negatively impacted at our manufacturing sites, storage sites or in transit, or it takes longer than we project for the number of patients we anticipate to get on BRAFTOVI + MEKTOVI and any significant portion of our BRAFTOVI + MEKTOVI supply expires before we are able to sell it; our ability to obtain regulatory approvals to commercialize BRAFTOVI + MEKTOVI in markets outside of the U.S.; and the awareness of patients with unresectable or metastatic melanoma with a $BRAF^{V600E}$ or $BRAF^{V600K}$ mutation and whether the mutation is amenable to BRAFTOVI + MEKTOVI.

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Our prospects are highly dependent on the successful commercialization of BRAFTOVI + MEKTOVI. To the extent BRAFTOVI + MEKTOVI is not commercially successful, our business, financial condition and results of operations may be materially adversely affected.

BRAFTOVI + MEKTOVI is our only drug that has been approved for sale and it has only been approved for the treatment of patients with unresectable or metastatic melanoma with a $BRAF^{V600E}$ or $BRAF^{V600K}$ mutation in the United States. We are focusing a significant portion of our activities and resources on BRAFTOVI + MEKTOVI, and we believe our prospects are highly dependent on, and a significant portion of the value of our company relates to, our ability to successfully commercialize BRAFTOVI + MEKTOVI in the United States.

Successful commercialization of BRAFTOVI + MEKTOVI is subject to many risks. We have never, as an organization, commercialized a product, and there is no guarantee that we will be able to do so successfully with BRAFTOVI + MEKTOVI for its approved indication. There are numerous examples of failures to meet high expectations of market potential, including by pharmaceutical companies with more experience and resources than us.

Market acceptance of BRAFTOVI + MEKTOVI and any other product for which we receive approval, will depend on a number of factors, including the efficacy and safety as demonstrated in clinical trials; the timing of market introduction of the product as well as competitive products; the clinical indications for which the product is approved; acceptance by physicians, the medical community and patients of the product as a safe and effective treatment; the ability to distinguish safety and efficacy from existing, less expensive generic alternative therapies; the convenience of prescribing, administrating and initiating patients on the product; the potential and perceived advantages of the product over alternative treatments; the potential and perceived value of the product over alternative treatments; the cost of treatment in relation to alternative treatments, including any similar generic treatments; the availability of coverage and adequate reimbursement and pricing by third-party payers and government authorities; the prevalence and severity of adverse side effects; and the effectiveness of sales and marketing efforts.

The FDA granted marketing approval of BRAFTOVI + MEKTOVI for the treatment of patients with unresectable or metastatic melanoma with a $BRAF^{V600E}$ or $BRAF^{V600K}$ mutation, and we could face liability if a regulatory authority determines that we are promoting BRAFTOVI + MEKTOVI for any off-label uses.

A company may not promote “off-label” uses for its drug products. An off-label use is the use of a product for an indication that is not described in the product’s FDA-approved label in the United States or for uses in other jurisdictions that differ from those approved by the applicable regulatory agencies. Physicians, on the other hand, may prescribe products for off-label uses. Although the FDA and other regulatory agencies do not regulate a physician’s choice of drug treatment made in the physician’s independent medical judgment, they do restrict promotional communications from pharmaceutical companies or their sales force with respect to off-label uses of products for which marketing clearance has not been issued. A company that is found to have promoted off-label use of its product may be subject to significant liability, including civil and criminal sanctions.

We intend to comply with the requirements and restrictions of the FDA and other regulatory agencies with respect to our promotion of BRAFTOVI + MEKTOVI and any future products, but we cannot be sure that the FDA or other regulatory agencies will agree that we have not violated their restrictions. For example, as part of our promotion strategy for BRAFTOVI + MEKTOVI we communicate certain results from our Phase 3 COLUMBUS trial and other clinical data that are consistent with, but not directly included in, the product label. While we believe our communication of this data is in accordance with FDA guidance and applicable laws, we cannot be certain that the FDA or other regulatory agencies will agree with our use of this data or our sales force may use such data in a way that is inconsistent with our policies. As a result, we may be subject to criminal and civil liability. In addition, our management’s attention could be diverted to handle any such alleged violations. A significant number of pharmaceutical companies have been the target of inquiries and investigations by various U.S. federal and state

regulatory, investigative, prosecutorial and administrative entities in connection with the promotion of products for unapproved uses and other sales practices, including the Department of Justice and various U.S. Attorneys' Offices, the Office of Inspector General of the Department of Health and Human Services, the FDA, the Federal Trade Commission and various state Attorneys General offices. These investigations have alleged violations of various U.S. federal and state laws and regulations, including claims asserting antitrust violations, violations of the Federal Food, Drug, and Cosmetic Act, or the FDCA, the federal False Claims Act, the Prescription Drug Marketing Act, anti-kickback laws, and other alleged violations in connection with the promotion of products for unapproved uses, pricing and Medicare and/or Medicaid

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reimbursement. If the FDA or any other governmental agency initiates an enforcement action against us or if we are the subject of a qui tam suit and it is determined that we violated prohibitions relating to the promotion of products for unapproved uses, we could be subject to substantial civil or criminal fines or damage awards and other sanctions such as consent decrees and corporate integrity agreements pursuant to which our activities would be subject to ongoing scrutiny and monitoring to ensure compliance with applicable laws and regulations. Any such fines, awards or other sanctions would have an adverse effect on our revenue, business, financial prospects and reputation.

Notwithstanding the regulatory restrictions on off-label promotion, the FDA and other regulatory authorities allow companies to engage in truthful, non-misleading and non-promotional scientific exchange concerning their products. We intend to engage in medical education activities and communicate with healthcare providers in compliance with all applicable laws, regulatory guidance and industry best practices. Although we have established a compliance program and continue to enhance it to ensure that all such activities are performed in a legal and compliant manner, BRAFTOVI + MEKTOVI is our first commercial product which could increase risk of non-compliance with our internal compliance policies and applicable rules and regulations, which could negatively impact 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 and to build our commercialization capabilities. Additional funds will be required to manufacture and market any products we own or retain rights to that are approved for commercial sale. Because the successful development of our products is uncertain, we are unable to precisely estimate the actual funds we will require to develop and potentially commercialize them.

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, 2018 will enable us to continue to fund operations in the normal course of business for at least the next 12 months from the date of filing this Annual Report on Form 10-K. 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. 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 late stage 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 2.625% Convertible Senior Notes due 2024. In addition, if we are unable to maintain certain levels of cash and marketable securities, our obligations under our loan agreement with Silicon Valley Bank may be accelerated.

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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, 2018, we had an accumulated deficit of $1.1 billion. 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 payments on achievement of development or commercialization milestones and for royalties on product sales. However, many of 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 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. Physicians or consumers may not find that our drug candidates' effectiveness, ease of use, side-effect profile, cost or other factors make them 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 ability 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;

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- 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
- 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.

We expect to continue to spend significantly on our proprietary drug candidates.

We are committing significant resources to create our own proprietary drug candidates and to build a commercial-stage biopharmaceutical company, in particular after regaining binimetinib and acquiring encorafenib in March 2015. We have built our clinical and discovery programs through spending $1.2 billion from our inception through June 30, 2018. In fiscal 2018, we spent $185.8 million in research and development for proprietary programs, compared to $178.2 million and $160.7 million for fiscal years 2017 and 2016, respectively. We expect to continue to spend significant funds on further development of encorafenib and binimetinib and our other proprietary programs. Additionally, we expect to spend significant funds building our commercialization capabilities. Most of our proprietary programs are in development and are unproven. Thus, despite significant spending on the development of our proprietary programs and building commercialization capabilities, drugs other than encorafenib and binimetinib may not be approved for marketing and sale or, even if approved, may not result in a commercially successful drug or provide the expected return on our investment. 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 and on our ability to raise additional funds through sales of our equity securities or issuance of debt.

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.

Our liquidity depends in part on our ability to enter into license agreements that include up-front milestone and/or royalty payments. We have 17 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
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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.

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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 2.625% Convertible Senior Notes due 2024. 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.

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 December 2017, we issued $126.1 million aggregate principal amount of 2.625% Convertible Senior Notes due 2024, or the 2024 Notes, to investors pursuant to an effective shelf registration statement filed with the SEC. Interest is payable on the 2024 Notes semi-annually and the 2024 Notes mature on December 1, 2024, unless redeemed or converted prior to that date. In addition, if an event considered a Fundamental Change under the 2024 Notes occurs, holders of the 2024 Notes may require us to purchase for cash all or any portion of their 2024 Notes at a purchase price equal to 100% of the principal amount of the 2024 Notes to be purchased plus accrued and unpaid interest, if any, to, but excluding, the Fundamental Change purchase date. As of June 30, 2018, all $126.1 million principal amount of the 2024 Notes remained outstanding. We also have a term loan with Silicon Valley Bank under which $15.0 million is outstanding as of June 30, 2018 and have issued Subordinated Convertible Promissory Notes to Redmile Capital Offshore Fund II, Ltd. and Redmile Biopharma Investments I, L.P. under which $10.0 million principal and $0.9 million accrued interest is outstanding as of June 30, 2018.

Our ability to make scheduled payments of interest and principal on our indebtedness, including the 2024 Notes, or to pay the redemption price for the 2024 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.

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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 limited experience advancing drug candidates that ultimately lead to a commercially viable drug. Other than BRAFTOVI and MEKTOVI, many of our other drug candidates are in the early stages of development. 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 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 as internal spending on our proprietary programs increases.

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 expect to continue to fund, solely or primarily at our expense, further development, clinical trials, manufacturing and marketing activities for promising proprietary candidates and that our spending on these activities will increase as the programs are developed further and near regulatory approval. However, these efforts 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.

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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. Novartis accounted for 47% and 72% of our total revenue, Loxo accounted for 8% and 11%, and Pierre Fabre accounted for 12% and 8% of our total revenue for fiscal years 2018 and 2017, respectively. ASLAN accounted for 13% of our total revenue for fiscal 2018 and none for fiscal 2017. We expect that revenue from a limited number of partners, including Novartis, Pierre Fabre, 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 2024 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 patient enrollment will commence or be complete, 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 us 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 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 298 full-time employees as of June 30, 2018, 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; Jason Haddock,

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our Chief Financial Officer; Dr. Victor Sandor, our Chief Medical Officer; Dr. Nicholas Saccomano, our Chief Scientific Officer; Andrew Robbins, our Chief Operating Officer; and Curtis Oltmans, our Executive Vice President and General Counsel. We have employment agreements with each of these employees that are terminable upon 30 days' prior notice.

Our liquidity and results of operations is dependent on the full and timely collection of the Company's receivables from Novartis.

As a result of the asset transfer agreements with Novartis, which included the reimbursement by Novartis of significant costs we incur for the development of encorafenib and binimetinib, we anticipate recording significant accounts receivable from Novartis on a monthly basis. If we are unable to collect our accounts receivable from Novartis in full and on a timely basis, there could be a negative impact on our liquidity and results of operations.

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

We have limited later-stage clinical development and commercialization experience.

One of our business strategies is to develop select drug candidates through later stage clinical trials before out-licensing them to a pharmaceutical or biotechnology partner for further clinical development and commercialization and to commercialize select drug candidates ourselves. We have limited experience conducting later-stage clinical trials and obtaining regulatory approvals and we may not be successful in some or all of these activities. 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. Developing commercialization capabilities is expensive and time-consuming and may be more expensive and time consuming than we anticipate, requiring us to divert resources from other intended purposes. Any failure to develop or difficulties or delays in developing or optimizing these capabilities could delay any product launch and adversely impact the successful commercialization of our product candidates. 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.

If we are unable to establish sales, marketing and distribution capabilities or enter into or maintain agreements with third parties to market and sell our product candidates, we may not be successful in commercializing our product candidates if and when they are approved.

We have no experience in the sales, marketing or distribution of pharmaceutical products in any country. To achieve commercial success for any product for which we obtain marketing approval, we will need to establish sales and marketing capabilities or make and maintain our existing arrangements with third parties to perform these services at a level sufficient to support our commercialization efforts.

To the extent that we would undertake sales and marketing of any of our products directly, there are risks involved with establishing our own sales, marketing and distribution capabilities. Factors that may inhibit our efforts to commercialize our products on our own include our inability to recruit, train and retain adequate numbers of effective sales and marketing personnel; the inability of sales personnel to obtain access to physicians or persuade adequate numbers of physicians to prescribe any future products; our inability to effectively manage geographically dispersed sales and marketing teams; the lack of complementary products to be offered by sales personnel, which may put us at a competitive disadvantage relative to companies with more extensive product lines; and unforeseen costs and expenses associated with creating an independent sales and marketing organization.

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

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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 encorafenib and/or binimetinib, selumetinib (partnered with AstraZeneca) danoprevir (partnered with Intermune/Roche Holding AG), ipatasertib (partnered with Genentech), and larotrectinib (partnered with Loxo Oncology) 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;
- 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.

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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 example, following our submission of NDAs for encorafenib and binimetinib in BRAF-mutant melanoma, we continued to work with the FDA as they reviewed the submissions. We may also experience other delays in obtaining regulatory review or 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.

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

Even after regulatory authorities approve any of our drug candidates, the manufacture, labeling, storage, record keeping, reporting, distribution, advertising, promotion, marketing, sale, import and export of these drugs continue to 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

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or detain products, prohibit the export or import of products, or require us to initiate a product recall; 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 requirements 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 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 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 or specific intent to violate it;
- 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 some of which 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

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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.”

The complexity of U.S. federal and state laws governing our business continues to increase, and additional governmental resources are being committed to enforce these laws and to prosecute companies and individuals who are believed to be violating them. 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. Even if we are not found to be in violation of these laws, responding to lawsuits, government investigations, and enforcement actions would be expensive and time-consuming, and could have a material adverse effect on our reputation, business, financial condition, operations, and growth prospects.

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.

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, following FDA approval for encorafenib and binimetinib, 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

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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 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.

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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 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.

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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 Boulder 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;
- 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.

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Risks Related to Our Industry

The concentration of the pharmaceutical and biotechnology industry and any further consolidation could reduce the number of our potential 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 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. On February 1, 2016, the Centers for Medicare & Medicaid Services, or CMS, the federal agency that administers the Medicare and Medicaid programs, issued final regulations to implement the changes to the Medicaid Drug Rebate Program under the Health Reform Act. These regulations became effective April 1, 2016. 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 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.

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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 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. Subsequent legislation extended the 2% reduction, on average, to 2025. 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.

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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. Certain states have begun to survey acquisition cost data for the purpose of setting Medicaid reimbursement rates. CMS surveys and publishes National Average Drug Acquisition Cost, or NADAC, files, which reflect retail community pharmacy invoice costs, on a weekly basis. 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 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.

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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 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.

If we fail to comply with data protection laws and regulations, we could be subject to government enforcement actions (which could include civil or criminal penalties), private litigation and/or adverse publicity, which could negatively

affect or operating results and business.

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 obtain, use or disclose individually identifiable health information maintained by a HIPAA-covered entity in a manner that is not authorized or permitted by HIPAA. In addition, we and our partners may be directly subject to certain data protection laws and regulations (i.e., laws and regulations that

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address privacy and data security). In the U.S., numerous federal and state laws and regulations that govern the collection, use, disclosure, and protection of health-related and other personal information could apply to our operations or the operations of our partners, including state data breach notification laws, state health information privacy laws, state genetic privacy laws, and federal and state consumer protection laws (e.g., Section 5 of the FTC Act). International data protection laws and regulations may also apply to some or all of the clinical data obtained outside of the U.S. For example, the EU Data Protection Directive, as implemented into national laws by the EU Member States, imposes strict obligations and restrictions on the ability to collect, analyze and transfer personal data, including health data from clinical trials and adverse event reporting. The EU Data Protection Directive prohibits the transfer of personal data to countries outside of the European Economic Area, or EEA, such as the U.S., which are not considered by the European Commission to provide an adequate level of data protection. Switzerland has adopted similar restrictions. Although there are legal mechanisms to allow for the transfer of personal data from the EEA and Switzerland to the U.S., a recent decision of the European Court of Justice that invalidated the safe harbor framework has increased uncertainty around compliance with EU privacy law requirements. As a result of the decision, it will no longer be possible to rely on safe harbor certification as a legal basis for the transfer of personal data from the EU to entities in the U.S. In addition, data protection authorities from the different EU Member States may interpret the EU Data Protection Directive and national laws differently, and guidance on implementation and compliance practices are often updated or otherwise revised, which adds to the complexity of processing personal data in the EU. In February 2016, the European Commission announced an agreement with the U.S. Department of Commerce, or DOC, to replace the invalidated Safe Harbor framework with a new EU-U.S. “Privacy Shield.” On July 12, 2016, the European Commission adopted a decision on the adequacy of the protection provided by the Privacy Shield. The Privacy Shield is intended to address the requirements set out by the European Court of Justice in its recent ruling by imposing more stringent obligations on companies, providing stronger monitoring and enforcement by the DOC and FTC, and making commitments on the part of public authorities regarding access to information. U.S. companies are able to certify to the DOC their compliance with the privacy principles of the Privacy Shield since August 1, 2016. In December 2015, a proposal for an EU General Data Protection Regulation, intended to replace the current EU Data Protection Directive, was agreed between the European Parliament, the Council of the European Union and the European Commission. The EU General Data Protection Regulation, which was officially adopted in April 2016 and become applicable in May 2018, introduced new data protection requirements in the EU, as well as substantial fines for breaches of the data protection rules. The EU General Data Protection Regulation has increased our responsibility and liability in relation to any personal data that we process, and we may be required to put in place additional mechanisms to ensure compliance with the new EU data protection rules.

Failure to comply with U.S. and international data protection laws and regulations could result in government enforcement actions (which could include civil and/or criminal penalties), private litigation and/or adverse publicity and could negatively affect our operating results and business. 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.

Significant disruptions of information technology systems or security breaches could adversely affect our business.

We are dependent upon information technology systems, infrastructure and data to operate our business. In the ordinary course of business, we collect, store and transmit confidential information (including but not limited to intellectual property, proprietary business information and personal information). It is critical that we do so in a secure manner to maintain the confidentiality and integrity of such confidential information. We also have outsourced elements of our operations to third parties, and as a result we manage a number of third party vendors who may or could have access to our confidential information. The size and complexity of our information technology systems, and those of third party vendors with whom we contract, and the large amounts of confidential information stored on

those systems, make such systems potentially vulnerable to service interruptions or to security breaches from inadvertent or intentional actions by our employees, third party vendors, and/or business partners, or from cyber-attacks by malicious third parties (including the deployment of harmful malware, denial-of-service attacks, social engineering and other means to affect service reliability and threaten the confidentiality, integrity and availability of information). Significant disruptions of our information technology systems or security breaches could adversely affect our business operations and/or result in the loss, misappropriation, and/or unauthorized access, use or disclosure of, or the prevention of access to, confidential information (including intellectual property, proprietary

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business information and personal information), and could result in financial, legal, business and reputational harm to us. Any such event that leads to unauthorized access, use or disclosure of personal information, including personal information regarding our patients or employees, could compel us to comply with federal and/or state breach notification laws and foreign law equivalents, subject us to mandatory corrective action, and otherwise subject us to liability under laws and regulations that protect the privacy and security of personal information, which 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.

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. 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.

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 issued a proposed regulation in 2015 regarding the calculation of the 340B ceiling price and the imposition of civil monetary penalties on manufacturers that knowingly and intentionally overcharge covered entities. HRSA has indicated it plans to issue the final regulation regarding these topics in 2016. HRSA in 2015 also released proposed omnibus guidance that addresses many aspects of the 340B program. HRSA has indicated it plans to release the omnibus guidance in final form in 2016. HRSA recently issued a proposed regulation regarding an administrative dispute resolution process for 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 list their covered (innovator) drugs on an FSS contract and charge no more than Federal Ceiling Price, or FCP, to the Department of Veterans Affairs, Department of Defense, Public Health Service, and Coast Guard when those agencies purchase from the FSS contract or a depot contract. FCP is calculated based on non-federal average manufacturer price data, which manufacturers must submit quarterly and annually. 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

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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 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 2024 Notes

Our quarterly operating results could fluctuate significantly, which could cause our stock price and the value of the 2024 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 2024 Notes could decline.

Because our stock price may be volatile, our stock price and the value of our 2024 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 $20.21 and $7.15, respectively, during fiscal 2018; $12.56 and $3.17, respectively, during fiscal 2017; and $7.11 and $2.50, respectively, during fiscal 2016. 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

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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 2024 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 Silicon Valley 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.

Conversion of the notes may dilute the ownership interest of our shareholders, including holders of 2024 Notes who convert their notes.

At our election, we may settle 2024 Notes tendered for conversion entirely or partly in shares of our common stock. As a result, the conversion of some or all of the 2024 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 2024 Notes. In addition, the existence of the notes may encourage short selling by market participants because the conversion of the 2024 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 2024 Notes, could have a material effect on our reported financial results.

The 2024 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 2024 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 2024 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 2024 Notes to their face amount over the term of the 2024 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 2024 Notes.

In addition, under certain circumstances, convertible debt instruments (such as the 2024 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 2024 Notes, then our diluted earnings per share would be adversely affected.

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Certain provisions in the 2024 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 2024 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 2024 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 2024 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 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 2024 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 2024 Notes tendered for conversion entirely or partly in shares of our common stock. As a result, the conversion of some or all of the 2024 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 2024 Notes. In addition, the existence of the 2024 Notes may encourage short selling by market participants because the conversion of the 2024 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 127 thousand square feet of office and laboratory space. Our Boulder lease expires on March 31, 2025 and includes an option to extend the lease for up to two terms of five years each. We also lease 7 thousand square feet of office space in Morrisville, North Carolina under a lease that expires in March 2023 and 8 thousand square feet of office space in Cambridge, Massachusetts under a lease that expires in April 2026.

## ITEM 3. LEGAL PROCEEDINGS

On November 20, 2017, we were notified that a complaint (the "Initial Complaint") was filed against us and our Chief Executive Officer, former interim Chief Financial Officer, and current Chief Financial Officer as officers of Array, in

the United States District Court for the District of Colorado by Wendell Rose, individually and on behalf of all others similarly situated (the "Rose Action"). A second complaint was filed on November 28, 2017 also in the United States District Court for the District of Colorado by Robert Nauman, individually and on behalf of all others similarly situated (the "Nauman Action"). The complaints in both actions contain substantially similar allegations of violations of the federal securities laws by us and the defendant executive officers in connection with certain disclosures made, or omitted, by us regarding our NRAS-mutant melanoma program and seek to establish a class of investors who purchased our common stock between December 16, 2015 and March 17, 2017, inclusive, affected by the allegations in the Complaints. The Complaints seek unspecified remedies under the Securities Act of 1934, as amended. On

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March 12, 2018, the Court granted Peter Voulgaris's motion seeking appointment as lead plaintiff and their respective law firm. The Court also consolidated the Rose Action and the Nauman Action into one proceeding. Array filed a Motion to Dismiss the complaint on June 11, 2018. We will continue to evaluate the allegations set forth in the Complaint and intend to vigorously defend against all such allegations.

On July 28, 2017, AstraZeneca and Merck announced that they entered into an agreement to share the development and commercialization costs for selumetinib monotherapy and non-PD-L1/PD-1 combination therapy opportunities. Array remains eligible to receive from AstraZeneca milestones and royalties on all future selumetinib sales and now expects to receive a portion of certain consideration paid by Merck to AstraZeneca under this agreement. Array has informed AstraZeneca, however, that it is disputing the consideration that AstraZeneca has paid Array related to both upfront and potential future milestones under AstraZeneca's agreement with Merck. Array commenced legal proceedings against AstraZeneca on December 7, 2017, naming AstraZeneca as the defendant in New York State Court in Manhattan regarding this dispute. On February 1, 2018, we filed a second action against AstraZeneca AB in New York State court. We are seeking damages and a declaratory judgment in both actions.

ITEM 4. MINE SAFETY DISCLOSURES

None.

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, 2018 | High | Low |
|---|---|---|
| First Quarter | $12.47 | $7.15 |
| Second Quarter | $13.17 | $9.98 |
| Third Quarter | $18.78 | $12.09 |
| Fourth Quarter | $20.21 | $12.80 |

| Fiscal Year Ended June 30, 2017 | High | Low |
|---|---|---|
| First Quarter | $6.75 | $3.17 |
| Second Quarter | $8.80 | $5.38 |
| Third Quarter | $12.56 | $8.56 |
| Fourth Quarter | $9.07 | $6.96 |

As of August 9, 2017, there were approximately 55 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 Silicon Valley Bank and the terms of the 2.625% Convertible Senior Notes Due 2024 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 below 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 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, 2018. The graph assumes that $100 was invested on June 30, 2013 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.

| | 6/30/2014 | 6/30/2015 | 6/30/2016 | 6/30/2017 | 6/30/2018 |
|---|---|---|---|---|---|
| Array BioPharma Inc. | 100.44 | 158.81 | 78.41 | 184.36 | 369.60 |
| NASDAQ Composite | 131.23 | 150.40 | 148.02 | 190.07 | 235.00 |
| NASDAQ Biotechnology | 148.48 | 214.13 | 149.83 | 181.40 | 193.94 |

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ITEM 6. SELECTED FINANCIAL DATA

The following selected financial data is derived from our audited consolidated financial statements. These historical results do not necessarily indicate future results. You should read the selected financial data along with our consolidated 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, | | | | |
|---|---|---|---|---|---|
| | 2018 | 2017 | 2016 | 2015 | 2014 |
| Revenue | | | | | |
| Reimbursement revenue | $80,958 | $107,197 | $107,330 | $7,020 | $ — |
| License and milestone revenue | 56,537 | 19,844 | 3,876 | 20,367 | 25,111 |
| Collaboration and other revenue | 36,273 | 23,811 | 26,673 | 24,522 | 16,967 |
| Total revenue | 173,768 | 150,852 | 137,879 | 51,909 | 42,078 |
| Operating expenses | | | | | |
| Cost of partnered programs | 59,374 | 35,395 | 23,166 | 44,392 | 45,965 |
| Research and development for proprietary programs | 185,821 | | | | |