



Array BioPharma Reports Financial Results for the Fourth Quarter and Full Year of Fiscal 2018

August 14, 2018

- FDA approved BRAFTOVI™ (encorafenib) in combination with MEKTOVI® (binimetinib) for advanced BRAF-mutant melanoma --
- BRAFTOVI + MEKTOVI received positive CHMP opinion for advanced BRAF-mutant melanoma --
- NCCN guidelines recommend BRAFTOVI + MEKTOVI as a Category 1 treatment option for patients with advanced BRAF-mutant melanoma --
- FDA granted Breakthrough Therapy Designation for BRAFTOVI in combination with MEKTOVI and cetuximab for BRAF-mutant metastatic colorectal cancer --
- Cash, Cash Equivalents and Marketable Securities as of June 30, 2018 were \$413 million --

BOULDER, Colo., Aug. 14, 2018 /PRNewswire/ -- Array BioPharma Inc. (Nasdaq: ARRY) today reported results for its fourth quarter and full year of fiscal 2018 and provided an update on the progress of its key commercial products and clinical development programs.

"We were thrilled to launch BRAFTOVI™ + MEKTOVI® for patients with *BRAF*-mutant melanoma in the U.S. after receiving FDA approval for the combination in June. Since then, we have seen a very positive reception from melanoma healthcare providers. With the announcement of a median overall survival of 33.6 months from the Phase 3 COLUMBUS trial at ASCO, and an attractive tolerability profile, our commercial team is well-positioned for success," said Ron Squarer, Chief Executive Officer. "We were also very pleased to announce an observed overall survival of 62% at one year in patients with *BRAF*-mutant metastatic colorectal cancer in updated safety lead-in results from the Phase 3 BEACON CRC trial. At the time of analysis, the overall survival data were fully mature through 12.6 months and the median overall survival had not yet been reached. FDA Breakthrough Therapy Designation was based on the BEACON CRC safety lead-in data, which further demonstrates the opportunity for encorafenib and binimetinib to benefit patients with limited treatment options."

COMMERCIAL

BRAFTOVI + MEKTOVI Approval and Launch

On June 27, 2018, the U.S. Food and Drug Administration (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.

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

National Comprehensive Cancer Network (NCCN) Recommendation

On July 13, 2018, the 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.

Positive CHMP Opinion for Advanced BRAF-mutant Melanoma

On July 27, 2018, the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) adopted a positive opinion recommending approval of BRAFTOVI + MEKTOVI for unresectable or metastatic *BRAF*^{V600}-mutant melanoma. This opinion is based on data from the COLUMBUS trial and the 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, will be applicable to all 28 EU member states, as well as Liechtenstein, Iceland and Norway.

COLUMBUS PHASE 3 TRIAL

Updated COLUMBUS Trial Results including Overall Survival Announced at ASCO

Array announced updated results from the COLUMBUS trial in *BRAF*-mutant advanced melanoma as part of an oral presentation at the American Society of Clinical Oncology (ASCO) annual meeting on June 4, 2018, and that these results have been selected for the "Best of ASCO" program.

- The median OS 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. [1-2]
- 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%). The incidence of selected any grade AEs of special interest, defined based on toxicities commonly associated with commercially available BRAF+MEK-inhibitor treatments for patients receiving the combination of encorafenib and binimetinib included: rash (22%), serous retinopathy (20%), pyrexia (18%) and photosensitivity (5%). Full safety results of COLUMBUS Part 1 were published in [The Lancet Oncology](#).

BEACON CRC PHASE 3 TRIAL

Breakthrough Therapy Designation

On August 7, 2018, Array announced that the FDA granted Breakthrough Therapy Designation to BRAF^{V600E}, in combination with MEKTOVI and cetuximab for the treatment of patients with BRAF^{V600E}-mutant metastatic colorectal cancer (mCRC) as detected by an FDA-approved test, after failure of one to two prior lines of therapy for metastatic disease. BRAF^{V600E}-mutant mCRC patients have a mortality risk more than double that of mCRC patients without the mutation, and currently there are no therapies specifically approved for this high unmet need population. [3-8] 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.

Regulatory Update

Based on consultation with the FDA and EMA, Array plans 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, the Company plans 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 a 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 20th World Congress on Gastrointestinal Cancer (ESMO World GI), excitement among global investigators continues to increase. As a result of the recent FDA approval for BRAF^{V600E} + MEKTOVI in BRAF-mutant melanoma, Array has 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 Array expects 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, Array does not believe this decision will have a material impact on its plan to complete enrollment of the trial around the end of 2018.

Updated BEACON CRC Safety Lead-In Data including Overall Survival Results Announced at ESMO World GI

Array 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 mCRC 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 median Progression Free Survival (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 CK (10%) and increased aspartate aminotransferase (10%).

IMMUNO-ONCOLOGY COLLABORATIONS: TRIALS ADVANCING WITH BRISTOL-MYERS SQUIBB AND MERCK; TRIAL WITH PFIZER EXPECTED TO START THIRD QUARTER OF 2018

Array is 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

- 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 Array and Bristol-Myers Squibb and sponsored by Array.

Merck

- 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 Array providing binimetinib supply.

Pfizer

- 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 quarter of 2018.
- Initially, the focus will be in non-small cell lung cancer and pancreatic cancer, with additional indications being explored at a later stage.
- The trial will be sponsored and funded by Pfizer, with Array providing binimetinib supply.

CORPORATE UPDATE

On August 10, 2018, Array announced that Carrie S. Cox joined the Company's Board of Directors as Chairman, effective immediately. Ms. Cox served as Executive Vice President and President of both Schering-Plough and Pharmacia's Global Pharmaceutical Businesses and has been named to FORTUNE Magazine's list of the "50 Most Powerful Women in Business" six times. As an experienced corporate director with a wealth of commercial expertise and a distinguished career in the biopharmaceutical industry, Ms. Cox's leadership will help drive the success of the Company's recent launch of BRAFTOVI + MEKTOVI and advance Array's innovative treatments for patients in critical need. Kyle Lefkoff, General Partner of Boulder Ventures Ltd., and former Array Chairman, will continue to serve as a director.

FINANCIAL HIGHLIGHTS

Fourth Quarter of Fiscal 2018 Compared to Third Quarter of Fiscal 2018 (Sequential Quarters Comparison)

- **Revenue** for the fourth quarter of fiscal 2018 was \$35.4 million, compared to \$66.4 million for the prior quarter. The decrease was primarily due to a one-time upfront license fee from ASLAN Pharmaceuticals received during the prior quarter as well as lower Novartis reimburseable activities.
- **Cost of partnered programs** for the fourth quarter of fiscal 2018 was \$16.2 million, compared to \$17.7 million for the prior quarter. The decrease was primarily due to timing of clinical trial expense.
- **Research and development expense for proprietary programs** was \$48.1 million, compared to \$53.6 million in the prior quarter. The decrease was driven by activity on the Novartis transitioned trials.
- **Selling, General and Administrative** for the fourth quarter of fiscal 2018 was \$19.3 million, compared to \$15.6 million for the prior quarter, primarily driven by increased commercial expenses.
- **Loss from operations** for the quarter was \$48.1 million, compared to a loss from operations of \$20.6 million in the previous quarter. The increase in net loss was primarily due to lower partner revenue during the current quarter.
- **Net loss** for the fourth quarter was \$52.4 million, or (\$0.25) per share, compared to \$22.9 million, or (\$0.11) per share, in the prior quarter.
- **Cash, cash equivalents and marketable securities** as of June 30, 2018 were \$413 million.

Fourth Quarter of Fiscal 2018 Compared to Fourth Quarter of Fiscal 2017 (Prior Year Comparison)

- **Revenue** for the fourth quarter of fiscal 2018 increased by \$1.7 million compared to the same quarter of fiscal 2017. The increase was primarily due to increased reimbursement of BEACON CRC trial expenses as well as new and expanded collaborations and milestones earned.
- **Cost of partnered programs** increased \$6.1 million compared to the fourth quarter of fiscal 2017. The increase was primarily due to higher costs incurred for the BEACON CRC trial, and more resources engaged on collaborations.
- **Research and development expense for proprietary programs** increased \$9.0 million, compared to the fourth quarter of fiscal 2017. The increase was driven by research and clinical activity on our proprietary programs.
- **Selling, General and Administrative** increased \$8.3 million compared to fourth quarter of fiscal 2017, primarily driven by increased commercial expenses.
- **Net loss** for the fourth quarter of fiscal 2018 was \$52.4 million, or (\$0.25) per share, compared to \$29.6 million, or (\$0.17) per share, for the same quarter in fiscal 2017. The increase in net loss was primarily due to increased research and development expense and costs to establish our commercial infrastructure in preparation for the BRAFTOVI + MEKTOVI launch.

Full Year of Fiscal 2018 Compared to Full Year of Fiscal 2017 (Prior Year Comparison)

- **Revenue** was \$173.8 million for the fiscal year ended June 30, 2018, compared to \$150.9 million in fiscal 2017. This increase was primarily driven by higher license and milestone revenue earned in 2018 from Asahi Kasei Pharmaceutical, ASLAN Pharmaceuticals, Loxo Oncology, Mirati and Ono Pharmaceutical Co., Ltd.
- **Net loss** for the fiscal year ended June 30, 2018, was \$147.3 million, or (\$0.74) per share, compared to a net loss of \$116.8 million, or (\$0.72) per share, in fiscal 2017. The increase in net loss was primarily due to increased research and development expense to advance our proprietary programs and costs to establish our commercial infrastructure in preparation of the BRAFTOVI + MEKTOVI launch.
- **Net cash used in operating activities** for the fiscal year ended June 30, 2018, was \$119.8 million, compared to \$39.4 million in fiscal 2017. The increase in cash used in 2018 was driven by increased research and development expense and costs to establish our commercial infrastructure in preparation for the BRAFTOVI + MEKTOVI launch.

CONFERENCE CALL INFORMATION

Array will hold a conference call on Tuesday, August 14, 2018, at 9:00 a.m. Eastern Time to discuss these results and provide an update on the progress of its key commercial products and clinical development programs. Ron Squarer, Chief Executive Officer, will lead the call.

Date: Tuesday, August 14, 2018
Time: 9:00 a.m. Eastern Time
Toll-Free: (844) 464-3927
Toll: (765) 507-2598
Pass Code: 1766079

Webcast, including Replay and Conference Call Slides:

About **BRAF**-mutant Metastatic Melanoma

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. [10,11] 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. [10,12-14]

About **BRAF**TOVI + MEKTOVI

BRAFTOVI is an oral small molecule **BRAF** kinase inhibitor and MEKTOVI is an oral small molecule MEK inhibitor which target key enzymes in the MAPK signaling pathway (RAS-RAF-MEK-ERK). Inappropriate activation of proteins in this pathway has been shown to occur in many cancers including melanoma, colorectal cancer, non-small cell lung cancer, thyroid and others. In the U.S., **BRAF**TOVI + MEKTOVI are approved for the treatment of unresectable or metastatic melanoma with a **BRAF**^{V600E} or **BRAF**^{V600K} mutation, as detected by an FDA-approved test. **BRAF**TOVI is not indicated for treatment of patients with wild-type **BRAF** melanoma.

Array has exclusive rights to **BRAF**TOVI 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 Europe, Asia and Latin America.

BRAFTOVI + MEKTOVI are not approved outside of the U.S. The European Medicines Agency (EMA), as well as the Swiss Medicines Agency (Swissmedic) and the Australian Therapeutic Goods Administration (TGA), are currently reviewing the Marketing Authorization Applications submitted by Pierre Fabre, and Japan's Pharmaceuticals and Medical Devices Agency has accepted the Manufacturing and Marketing Approval applications submitted by Ono Pharmaceutical Co, Ltd.

Indications and Usage

BRAFTOVI™ (encorafenib) and MEKTOV® (binimetinib) are kinase inhibitors indicated for use in combination 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.

Limitations of Use: **BRAF**TOVI is not indicated for the treatment of patients with wild-type **BRAF** melanoma.

BRAFTOVI + MEKTOVI Important Safety Information

*The information below applies to the safety of the combination of **BRAF**TOVI and MEKTOVI unless otherwise noted.*

Warnings and Precautions New Primary Malignancies: New primary malignancies, cutaneous and non-cutaneous malignancies can occur. In the COLUMBUS trial, cutaneous squamous cell carcinoma, including keratoacanthoma, occurred in 2.6% and basal cell carcinoma occurred in 1.6% of patients. Perform dermatologic evaluations prior to initiating treatment, every 2 months during treatment, and for up to 6 months following discontinuation of treatment. Discontinue **BRAF**TOVI for RAS mutation-positive non-cutaneous malignancies.

Tumor Promotion in **BRAF Wild-Type Tumors:** Confirm evidence of **BRAF**^{V600E} or **BRAF**^{V600K} mutation prior to initiating **BRAF**TOVI.

Cardiomyopathy: In the COLUMBUS trial, cardiomyopathy occurred in 7% and Grade 3 left ventricular dysfunction occurred in 1.6% of patients. Cardiomyopathy resolved in 87% of patients. Assess left ventricular ejection fraction by echocardiogram or MUGA scan prior to initiating treatment, 1 month after initiating treatment, and then every 2 to 3 months during treatment. The safety has not been established in patients with a baseline ejection fraction that is either below 50% or below the institutional lower limit of normal.

Venous Thromboembolism (VTE): In the COLUMBUS trial, VTE occurred in 6% of patients, including 3.1% of patients who developed pulmonary embolism.

Hemorrhage: In the COLUMBUS trial, hemorrhage occurred in 19% of patients and ≥Grade 3 hemorrhage occurred in 3.2% of patients. Fatal intracranial hemorrhage in the setting of new or progressive brain metastases occurred in 1.6% of patients.

Ocular Toxicities: In the COLUMBUS trial, serous retinopathy occurred in 20% of patients; 8% were retinal detachment and 6% were macular edema. Symptomatic serous retinopathy occurred in 8% of patients with no cases of blindness. In patients with **BRAF** mutation-positive melanoma across multiple clinical trials, 0.1% of patients experienced retinal vein occlusion (RVO). Permanently discontinue MEKTOVI in patients with documented RVO. In COLUMBUS, uveitis, including iritis and iridocyclitis, was reported in 4% of patients. Assess for visual symptoms at each visit. Perform ophthalmic evaluation at regular intervals and for any visual disturbances.

Interstitial Lung Disease (ILD): ILD, including pneumonitis, occurred in 0.3% of patients with **BRAF** mutation-positive melanoma across multiple clinical trials. Assess new or progressive unexplained pulmonary symptoms or findings for possible ILD.

Hepatotoxicity: In the COLUMBUS trial, the incidence of Grade 3 or 4 increases in liver function laboratory tests was 6% for alanine aminotransferase (ALT) and 2.6% for aspartate aminotransferase (AST). Monitor liver laboratory tests before and during treatment and as clinically indicated.

Rhabdomyolysis: In the COLUMBUS trial, elevation of laboratory values of serum creatine phosphokinase (CPK) occurred in 58% of patients. Rhabdomyolysis was reported in 0.1% of patients with **BRAF** mutation-positive melanoma across multiple clinical trials. Monitor CPK periodically and as clinically indicated.

QTc Prolongation: In the COLUMBUS trial, an increase in QTcF to >500 ms was measured in 0.5% (1/192) of patients. Monitor patients who already have or who are at significant risk of developing QTc prolongation. Correct hypokalemia and hypomagnesemia prior to and during **BRAF**TOVI administration. Withhold, reduce dose, or permanently discontinue for QTc >500 ms.

Embryo-Fetal Toxicity: **BRAF**TOVI or MEKTOVI can cause fetal harm when administered to pregnant women. Nonhormonal contraceptives should be used during treatment and for at least 30 days after the final dose for patients taking **BRAF**TOVI + MEKTOVI.

Adverse Reactions

The most common adverse reactions (≥20%, all Grades, in the COLUMBUS trial) were: fatigue, nausea, diarrhea, vomiting, abdominal pain, arthralgia, myopathy, hyperkeratosis, rash, headache, constipation, visual impairment, serous retinopathy.

In the COLUMBUS trial, the most common laboratory abnormalities (≥20%, all Grades) included: increased creatinine, increased CPK, increased gamma glutamyl transferase, anemia, increased ALT, hyperglycemia, increased AST, and increased alkaline phosphatase.

Drug interactions

Avoid concomitant use of strong or moderate CYP3A4 inhibitors or inducers and sensitive CYP3A4 substrates with BRAF^TTOVI. Modify BRAF^TTOVI dose if concomitant use of strong or moderate CYP3A4 inhibitors cannot be avoided.

Please see full Prescribing Information for BRAF^TTOVI and full Prescribing Information for MEKTOVI for additional information. You may report side effects to the FDA at (800) FDA-1088 or www.fda.gov/medwatch. You may also report side effects to Array at 1-844-Rx-Array (1-844-792-7729).

About COLUMBUS

The COLUMBUS trial (NCT01909453) is a two-part, international, randomized, open label Phase 3 trial evaluating the efficacy and safety of BRAF^TTOVI (encorafenib) in combination with MEKTOVI (binimetinib) compared to vemurafenib and encorafenib monotherapy in 921 patients with locally advanced, unresectable or metastatic melanoma with BRAF^{V600E} 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.

About Colorectal Cancer

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. [15] 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. [16] 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. [7,8,17,18] 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. [19] 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. These benchmarks include ORR of 4% to 8% ,mPFS of 1.8 to 2.5 months and median OS of 4 to 6 months. [3-9]

About BEACON CRC

BEACON CRC is a randomized, open-label, global trial evaluating the efficacy and safety of BRAF^TTOVI, MEKTOVI and cetuximab in patients with BRAF^{V600E}-mutant mCRC 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^{V600E}-mutant mCRC. Thirty patients were treated in the safety lead-in and received the triplet combination (BRAF^TTOVI 300 mg daily, MEKTOVI 45 mg twice daily and cetuximab per label). Of the 30 patients, 29 had a BRAF^{V600E} mutation. MSI-H, resulting from defective DNA mismatch repair, was detected in only 1 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 BRAF^TTOVI 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 (BRAF^TTOVI 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. The BEACON CRC trial is being conducted with support from Ono Pharmaceutical Co., Pierre Fabre and Merck KGaA, Darmstadt, Germany (support is for sites outside of North America).

About Array BioPharma

Array BioPharma Inc. is 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. Array markets in the United States BRAF^TTOVITM (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. Array's 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. Array's pipeline includes several additional programs being advanced by Array 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) was recently approved in China for the treatment of viral hepatitis C. For more information on Array, please visit www.arraybiopharma.com or follow @arraybiopharma on Twitter and LinkedIn.

References

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BRAFTOVI™ (encorafenib) Prescribing Information Array BioPharma Inc., June 2018

MEKTOVI® (binimetinib) Prescribing Information. Array BioPharma Inc., June 2018

Forward-Looking Statement

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, including, 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 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 our most recent annual report filed on Form 10-K, in our quarterly reports filed on Form 10-Q, and in other reports filed by Array with the Securities and Exchange Commission. We are providing this information as of August 14, 2018. 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.

BRAFTOVI™ is a trademark of Array BioPharma Inc.

MEKTOVI® is a registered trademark of Array BioPharma Inc. in the United States and various other countries.

Array BioPharma Inc.
Consolidated Statements of Operations
(Unaudited)
(in thousands, except per share amounts)

	Three Months Ended June 30,		Twelve Months Ended June 30,	
	2018	2017	2018	2017
Revenue				
Reimbursement revenue	\$ 15,620	\$ 21,843	\$ 80,958	\$ 107,197
Collaboration revenue	9,644	5,962	36,273	23,811
License and milestone revenue	10,173	5,973	56,537	19,844
Total revenue	35,437	33,778	173,768	150,852
Operating expenses				
Cost of partnered programs	16,187	10,092	59,374	35,395
Research and development for proprietary programs	48,127	39,098	185,821	178,199
Selling, general and administrative	19,272	10,926	58,500	39,336
Total operating expenses	83,586	60,116	303,695	252,930
Loss from operations	(48,149)	(26,338)	(129,927)	(102,078)
Other income (expense)				
Loss on extinguishment and conversion of Notes	—	—	(6,457)	—
Impairment loss related to cost method investment	—	—	—	(1,500)
Realized gain on investments and other	—	112	69	897
Change in fair value of notes payable	(2,187)	(500)	(2,387)	(2,600)
Interest income	1,395	286	4,470	796
Interest expense	(2,407)	(3,152)	(10,814)	(12,333)
Total other expense, net	(3,199)	(3,254)	(15,119)	(14,740)
Loss before income tax expense	(51,348)	(29,592)	(145,046)	(116,818)
Income tax expense	1,100	—	2,300	—

Net loss	<u>\$ (52,448)</u>	<u>\$ (29,592)</u>	<u>\$ (147,346)</u>	<u>\$ (116,818)</u>
Net loss per share - basic	<u>\$ (0.25)</u>	<u>\$ (0.17)</u>	<u>\$ (0.74)</u>	<u>\$ (0.72)</u>
Net loss per share - diluted	<u>\$ (0.25)</u>	<u>\$ (0.17)</u>	<u>\$ (0.74)</u>	<u>\$ (0.72)</u>
Weighted average shares outstanding - basic	<u>210,705</u>	<u>170,779</u>	<u>198,490</u>	<u>163,207</u>
Weighted average shares outstanding - diluted	<u>210,705</u>	<u>170,779</u>	<u>198,490</u>	<u>163,207</u>

Summary Consolidated Balance Sheet Data

(Unaudited)
(in thousands)

	<u>June 30, 2018</u>	<u>June 30, 2017</u>
Cash, cash equivalents and marketable securities	\$ 413,406	\$ 235,055
Working capital	\$ 355,612	\$ 200,626
Total assets	\$ 460,364	\$ 279,145
Long-term debt, net and note payable at fair value	\$ 111,775	\$ 133,905
Total stockholders' equity	\$ 219,743	\$ 11,727

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