



Array BioPharma Reports Financial Results For The First Quarter Of Fiscal 2018

October 31, 2017

- Binimetinib and encorafenib New Drug Applications (NDAs) in BRAF-mutant melanoma accepted for review by U.S. Food and Drug Administration (FDA) and Marketing Authorization Applications (MAAs) validated for review by European Medicines Agency (EMA) -
- Promising data from BEACON CRC Phase 3 safety lead-in presented at 2017 European Society for Medical Oncology (ESMO) Congress -
- Cash, Cash Equivalents and Marketable Securities as of September 30, 2017 were \$464 million -

BOULDER, Colo., Oct. 31, 2017 /PRNewswire/ -- Array BioPharma Inc. (Nasdaq: ARRY), a biopharmaceutical company focused on the discovery, development and commercialization of targeted small molecule cancer therapies, today reported results for its first quarter of fiscal 2018 and provided an update on the progress of its key clinical development programs.



COLUMBUS PHASE 3 TRIAL: Binimetinib and encorafenib submissions under review at FDA and EMA

In September 2017, the FDA accepted for review Array's NDAs to support use of the combination of binimetinib 45 mg twice daily and encorafenib 450 mg once daily (COMBO450) for the treatment of patients with *BRAF*-mutant advanced, unresectable or metastatic melanoma. The FDA set a target action date under the Prescription Drug User Fee Act (PDUFA) of June 30, 2018 for both applications. In addition, the FDA informed Array that, based on its preliminary review of the applications, it has not identified any potential review issues, and that it is not currently planning to hold an advisory committee meeting to discuss these NDAs. Array completed its NDA submissions based on findings from the pivotal Phase 3 COLUMBUS trial.

"We look forward to supporting the FDA and EMA reviews of the submissions for binimetinib and encorafenib," said Ron Squarer, Chief Executive Officer. "The robust progression free survival benefit together with the attractive tolerability profile demonstrated in COLUMBUS suggest the combination represents a potentially important addition to the MEK/*BRAF* treatment landscape for patients with *BRAF*-mutant melanoma. We continue to build our team to support potential commercialization in 2018."

Metastatic melanoma is the most serious and life-threatening type of skin cancer and is associated with low survival rates[1-2]. 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[1, 3, 4].

Binimetinib and encorafenib are investigational medicines and are not currently approved in any country.

BEACON CRC PHASE 3 TRIAL: Promising results from safety lead-in presented at 2017 ESMO

Array continues to enroll BEACON CRC, a global Phase 3 trial of encorafenib and Erbitux® (cetuximab), an anti-EGFR antibody, with or without binimetinib, versus standard of care in patients with *BRAF*-mutant colorectal cancer (CRC) who have previously received first- or second-line systemic therapy. *BRAF*-mutant CRC represents a difficult-to-treat subtype of colorectal cancer that impacts 10 to 15% of CRC patients.

At the 2017 ESMO Congress held during the quarter, safety results and initial clinical activity were presented from the safety lead-in of the Phase 3 BEACON CRC study evaluating the triplet combination of binimetinib, encorafenib and Erbitux® (BINI 45 mg twice daily, ENCO 300 mg daily and CETUX per label). As of the data cutoff date of August 9, 2017, 30 patients were treated in the safety lead-in and received the triplet combination. Out of the 30 patients, 29 had a *BRAF*^{V600E} mutation. Microsatellite instability-high (MSI-H) was detected in only one patient. The triplet demonstrated good tolerability, supporting initiation of the randomized portion of the study. In addition, promising initial clinical activity was observed, with a confirmed overall response rate (ORR) of 41%, including a complete response, in patients with the *BRAF*^{V600E} mutation, a group of patients with historically poor outcomes. Responses were observed in 10 out of 17 patients (59%) who had received only one prior line of therapy. Out of 28 patients with both a *BRAF*^{V600E} mutation and a post-baseline assessment, 27 showed tumor regression.

In the safety lead-in, the triplet combination was generally well-tolerated. The most common grade 3 or 4 AEs observed in at least 10% of patients were nausea (10%), vomiting (10%), increased blood creatine kinase (10%) and urinary tract infection (10%). Three patients discontinued treatment due to AEs with only one considered related to treatment. At the time of the analysis, 76% of patients remain on study treatment after a median duration of treatment of 5.6 months (range 1.0 - 9.3 months).

"The *BRAF* mutation carries a very poor prognosis for patients with advanced colorectal cancer, and is particularly unresponsive after first-line therapy," said Dr. Victor Sandor, Chief Medical Officer. "In the safety lead-in, the triplet combination was well tolerated and showed impressive results with a confirmed overall response rate of 41%. Several patients also showed prolonged stable disease, with 76% of patients overall continuing on therapy after a median duration of exposure of 5.6 months. These results are unprecedented for this patient population based on existing standards of care."

BEACON CRC was initiated based on results from a Phase 2 study that included the combination of encorafenib and cetuximab in 50 patients with advanced *BRAF*-mutant CRC, and that was presented at the 2016 ASCO annual meeting. In this Phase 2 study, Overall Survival for patients treated with the doublet combination of encorafenib and cetuximab exceeded one year, which is more than double several separate historical standard of care published benchmarks for this population. [12-17] In addition, confirmed ORR from this study was 22%, whereas historical published benchmarks in this patient population using standard of care regimens range between 4-8%. [15-18]

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. Of these, nearly 750,000 were diagnosed in men, and 614,000 in women. Globally in 2012, approximately 694,000 deaths were attributed to colorectal cancer. In the U.S. alone, an estimated 135,430 patients will be diagnosed with cancer of the colon or rectum in 2017, and approximately 50,000 are estimated to die of their disease. [5] In the United States, BRAF mutations are estimated to occur in 10 to 15 percent of patients with colorectal cancer and represent a poor prognosis for these patients.[6-9] Based on recent estimates, the prevalence of MSI-H in tumors from patients with metastatic BRAF-mutant CRC ranged from 14% in a Phase 1b/2 trial (NCT01719380) (Array, data on file) to 18% from a recent Southwestern Oncology Group (SWOG) randomized phase 2 study.[10]

NEW CLINICAL TRIAL INITIATED IN MICROSATELLITE STABLE METASTATIC CRC (MSS CRC) WITH BRISTOL-MYERS SQUIBB; TRIAL WITH MERCK EXPECTED TO BEGIN IN SECOND HALF OF 2017

Array is collaborating separately with Bristol-Myers Squibb and Merck to study binimetinib plus anti-PD-1 therapy in patients with MSS CRC. The majority of metastatic colorectal cancers exhibit an MSS phenotype. [11]

The clinical trial in collaboration with Bristol-Myers Squibb, which was initiated in September 2017, will investigate the safety, tolerability and efficacy of binimetinib in combination with Bristol-Myers Squibb's Opdivo® (nivolumab) and Opdivo + Yervoy® (ipilimumab) regimen in patients with advanced MSS CRC and presence of a RAS mutation who have received one or two prior lines of therapy. The trial in collaboration with Merck, which is expected to begin during the second half of 2017, will investigate the safety, tolerability and efficacy of binimetinib with Merck's KEYTRUDA® (pembrolizumab) as part of multiple novel regimens. Array entered into these collaborations based on the growing body of preclinical and clinical evidence that the immune activity of an anti-PD-1 therapy can be enhanced when combined with a MEK inhibitor, such as binimetinib.

The Phase 1/2 studies are expected to establish recommended dose regimens and explore the preliminary anti-tumor activity of the combinations. Results from these studies will be used to determine optimal approaches to further clinical development of these combinations. Under the Merck agreement, Merck will act as the sponsor of this clinical trial, and Array will supply Merck with binimetinib for use in the trial. Under the Bristol-Myers Squibb agreement, Array and Bristol-Myers Squibb will jointly support the study with Array acting as the sponsor.

OTHER CLINICAL UPDATES: ARRY-382 and ARRY-797 programs

Array is advancing a Phase 1/2 dose escalation trial of ARRY-382 in combination with pembrolizumab (Keytruda®), a PD-1 antibody, in patients with advanced solid tumors, including melanoma and non-small cell lung cancer. ARRY-382 is a wholly-owned, highly selective and potent, small molecule inhibitor of CSF-1R kinase activity. A poster entitled "Phase 1b/2 dose-escalation study of ARRY-382, an oral inhibitor of colony-stimulating factor-1 receptor (CSF1R), in combination with pembrolizumab for treatment of patients with advanced solid tumors" will be presented at the Society for Immunotherapy of Cancer (SITC) Annual Meeting on November 10, 2017. The presentation will provide preliminary safety and pharmacokinetic data as well as initial efficacy data in patients with advanced solid tumors.

Array plans to initiate a Phase 3 trial of ARRY-797, an oral, selective p38 MAPK inhibitor, in patients with LMNA A/C-related dilated cardiomyopathy as it evaluates options regarding the asset, including advancing it internally, partnering the program or creating a separate company to advance development and commercialization. LMNA A/C-related dilated cardiomyopathy is a rare, degenerative cardiovascular disease caused by mutations in the LMNA gene and characterized by poor prognosis.

FINANCIAL HIGHLIGHTS

Novartis Financial Commitment

Novartis continues to substantially fund all ongoing trials with binimetinib and encorafenib that were active or planned as of the close of the Novartis Agreements in 2015, including the COLUMBUS Phase 3 trial. Reimbursement revenue from Novartis was approximately \$94.1 million for the 12 months ended September 30, 2017, of which \$18.2 million was recorded in the quarter ended September 30, 2017. Total revenue and upfront payment collected from Novartis since the start of the 2015 agreement is \$326.3 million.

Raised \$258.8 million in public offering

Array completed an underwritten public offering of 24.1 million shares of its common stock at a price of \$10.75 per share on September 19, 2017. The total gross proceeds from the offering were \$258.8 million, before underwriting discounts, commissions and offering expenses.

First Quarter of Fiscal 2018 Compared to Fourth Quarter of Fiscal 2017 (Sequential Quarters Comparison)

- **Revenue** for the first quarter of fiscal 2018 was \$29.7 million, compared to \$33.8 million for the prior quarter due to slightly higher milestones received in the prior quarter.
- **Cost of partnered programs** for the first quarter of fiscal 2018 was \$11.8 million, compared to \$10.1 million for the prior quarter. The increase was primarily due to higher costs incurred for the BEACON CRC trial as it continues to advance.
- **Research and development expense** was \$41.4 million, compared to \$39.1 million in the prior quarter. The increase was driven by \$6.4 million in one-time charges for commercial drug supply of binimetinib and encorafenib from Novartis, which was partially offset by reduced expenses associated with the Novartis transitioned studies.
- **Loss from Operations** for the quarter was \$35.5 million, which includes \$6.2 million of stock-based compensation and depreciation expense. The higher than normal stock-based compensation expense was primarily due to an employee departure. This compares to a loss from operations of \$26.3 million in the previous quarter, which included \$3.7 million of stock-based compensation and depreciation expense. The increase in net loss was primarily due to non-recurring costs for commercial drug supply from Novartis, increased stock-based compensation expense and decrease in reimbursement revenue from Novartis.
- **Net loss** for the first quarter was \$38.0 million, or (\$0.22) per share, compared to \$29.6 million, or (\$0.17) per share, in the prior quarter.
- **Cash, Cash Equivalents and Marketable Securities** as of September 30, 2017 were \$464.3 million.

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

- **Revenue** for the first quarter of fiscal 2018 decreased \$9.5 million compared to the same quarter of fiscal 2017. The decrease was primarily due to decreased reimbursement revenue for the Novartis transitioned studies.
- **Cost of partnered programs** increased \$2.9 million compared to the first quarter of fiscal 2017. The increase was primarily due to higher costs incurred for the BEACON CRC trial.
- **Research and development expense** decreased \$5.1 million, compared to the first quarter of fiscal 2017. The decrease was due to expenses associated with the Novartis transitioned studies.
- **Net loss** for the first quarter of fiscal 2018 was \$38.0 million, or (\$0.22) per share, compared to \$28.6 million, or (\$0.20) per share, for the same quarter in fiscal 2017. The increase in net loss was primarily due to a decrease in reimbursement revenue from Novartis and non-recurring costs for commercial drug supply from Novartis.

CONFERENCE CALL INFORMATION

Array will hold a conference call on Tuesday, October 31, 2017 at 9:00 a.m. Eastern Time to discuss these results and provide an update on the progress of its key clinical development programs. Ron Squarer, Chief Executive Officer, will lead the call.

Date: Tuesday, October 31, 2017
Time: 9:00 a.m. Eastern Time
Toll-Free: (844) 464-3927
Toll: (765) 507-2598
Pass Code: 94698561

Webcast, including Replay and Conference Call Slides:

<https://edge.media-server.com/m6/p/hcxct4b>

About Array BioPharma

Array BioPharma Inc. is a biopharmaceutical company focused on the discovery, development and commercialization of targeted small molecule drugs to treat patients afflicted with cancer. Nine registration studies are currently advancing related to seven Array-owned or partnered drugs: binimetinib (MEK162), encorafenib (LGX818), selumetinib (partnered with AstraZeneca), danoprevir (partnered with Roche), ipatasertib (partnered with Genentech), larotrectinib (partnered with Loxo Oncology) and tucatinib (partnered with Cascadian Therapeutics).

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- [13] Saridaki et al., *PLoS One*. 2013
- [14] Loupakis et al., *Br J Cancer*. 2009
- [15] De Roock et al., *Lancet Oncol*, 2010
- [16] Peeters et al., *ASCO* 2014
- [17] Kopetz et al., *ASCO* 2017
- [18] Seymour et al., *Lancet Oncol*, 2013 (supplementary appendix)

Forward-Looking Statement

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, including statements about the timing of the announcement of the results of clinical trials for our proprietary and our partnered programs, the timing of the completion or initiation of further development of our wholly-owned and our partnered programs, including the timing of regulatory filings or approvals, expectations that events will occur that will result in greater value for Array, the potential for the results of ongoing preclinical and clinical trials to support regulatory approval or the marketing success of a drug candidate, our ability to partner our proprietary drug candidates for up-front fees, milestone and/or royalty payments, our future plans to progress and develop our proprietary programs, our future capital requirements and the plans of our collaborators to progress and develop programs we have licensed to them, and our plans to build a commercial-stage biopharmaceutical company. These statements involve significant risks and uncertainties, including those discussed 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. Because these statements reflect our current expectations concerning future events, our actual results could differ materially from those anticipated in these forward-looking statements as a result of many factors. These factors include, but are not limited to, our ability to continue to fund and successfully progress internal research and development efforts and to create effective, commercially-viable drugs; risks relating to the regulatory approval process for our

drug candidates, which may not result in approval for our drug candidates, cause delays in development or require that we expend more resources to obtain approval than expected; risks associated with our dependence on our collaborators for the clinical development and commercialization of our out-licensed drug candidates; the ability of our collaborators and of Array to meet objectives tied to milestones and royalties; our ability to 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 within and outside the United States; our ability to achieve and maintain profitability and maintain sufficient cash resources; the extent to which the pharmaceutical and biotechnology industries are willing to in-license drug candidates for their product pipelines and to collaborate with and fund third parties on their drug discovery activities; our ability to out-license our proprietary candidates on favorable terms; and our ability to attract and retain experienced scientists and management. We are providing this information as of October 31, 2017. 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.

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

	Three Months Ended	
	September 30,	
	2017	2016
Revenue		
Reimbursement revenue	\$ 18,192	\$ 31,321
Collaboration and other revenue	8,008	6,289
License and milestone revenue	3,546	1,661
Total revenue	29,746	39,271
Operating expenses		
Cost of partnered programs	11,759	8,845
Research and development for proprietary programs	41,445	46,563
General and administrative	12,048	7,862
Total operating expenses	65,252	63,270
Loss from operations	(35,506)	(23,999)
Other income (expense)		
Impairment loss related to cost method investment	—	(1,500)
Realized gains on investments and other	—	—
Change in fair value of notes payable	200	(200)
Interest income	525	70
Interest expense	(3,213)	(2,979)
Total other expense, net	(2,488)	(4,609)
Net loss	\$ (37,994)	\$ (28,608)
Net loss per share – basic	\$ (0.22)	\$ (0.20)
Net loss per share – diluted	\$ (0.22)	\$ (0.20)
Weighted average shares outstanding – basic	174,772	145,100
Weighted average shares outstanding – diluted	174,772	145,100

Summary Balance Sheet Data
(Unaudited)
(in thousands)

	September 30, 2017	June 30, 2017
Cash, cash equivalents and marketable securities	\$ 464,336	\$ 235,055
Working capital	\$ 402,899	\$ 200,626
Total assets	\$ 502,309	\$ 279,145
Long-term debt, net	\$ 123,266	\$ 121,305
Total stockholders' equity	\$ 226,621	\$ 11,727

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