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

Form 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d) of the
Securities Exchange Act of 1934
Date of Report (Date of earliest event reported): June 25, 2018

Array BioPharma Inc.

(Exact name of registrant as specified in its charter)

Delaware	**001-16633**	**84-1460811**
(State or other jurisdiction of incorporation)	*(Commission File Number)*	*(I.R.S. Employer Identification No.)*

3200 Walnut Street, Boulder, Colorado 80301
(Address of principal executive offices, including Zip Code)

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

(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

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. ☐

In this report, "Array BioPharma," "Array," "we," "us" and "our" refer to Array BioPharma Inc., unless the context otherwise provides.

Item 7.01 Regulation FD Disclosure.

On June 23, 2018, Array BioPharma Inc. issued a press release announcing additional results of encorafenib, binimetinib and cetuximab in patients with *BRAF*-mutant colorectal cancer that were presented at the ESMO 20th World Congress on Gastrointestinal Cancer. A copy of the press release is included as Exhibit 99.1 to this Form 8-K and incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press release dated June 23, 2018.

SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Date: June 25, 2018

Array BioPharma Inc.

By: /s/ JASON HADDOCK

Jason Haddock

Chief Financial Officer

News Release

Array BioPharma Announces a 62% Observed Overall Survival at One Year from the Phase 3 BEACON CRC Safety Lead-In of the Combination of Encorafenib, Binimetinib and Cetuximab in BRAF-Mutant CRC at the ESMO 20th World Congress on Gastrointestinal Cancer

– Median Overall Survival (mOS) was not reached; OS data are fully mature through 12.6 months–
– Encore investor webcast today at 10:30 am Eastern Time –

Boulder, Colo., (June 23, 2018) -- Array BioPharma Inc. (NASDAQ: ARRY) today announced updated safety and efficacy results, including OS, from the safety lead-in of the Phase 3 BEACON CRC trial evaluating the triplet combination of encorafenib, a BRAF inhibitor, binimetinib, a MEK inhibitor and cetuximab, an anti-EGFR antibody, in patients with $BRAF^{V600E}$-mutant metastatic colorectal cancer (CRC). The results showed that, at the time of analysis, the OS data were fully mature through 12.6 months and that the median OS had not yet been reached. The one-year overall survival rate for this cohort was 62%. These data were presented in an oral presentation on Saturday, June 23, at the ESMO 20th World Congress on Gastrointestinal Cancer in Barcelona, Spain.

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 confirmed overall response rate (ORR) was 48% and among the 17 patients who received only one prior line of therapy the ORR was 62%.

"The results of the BEACON CRC safety lead-in demonstrate substantial improvements in efficacy outcomes when compared to current approved standard of care benchmarks in patients with BRAF-mutant metastatic CRC. The median progression-free survival of 8 months is a meaningful improvement compared to the benchmark of about 2 months, and the overall survival of 62% at 12 months is very promising given that with current approved standards of care, half of patients will succumb to their disease within 4 to 6 months," said Axel Grothey, M.D., Division of Hematology/Oncology, Mayo Clinic. "These data underscore the potential of this triplet combination to benefit patients with $BRAF^{V600E}$-mutant metastatic CRC, who, despite their poor prognosis, currently have limited effective treatment options."

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%).

The presentation also referenced updated, mature Phase 2 results for the doublet of encorafenib and cetuximab that showed an mOS of 9.3 months, mPFS of 4.2 months and an ORR of 24%. The data cutoff for that analysis was January 2018 with the last patient enrolled in April of 2015; a detailed presentation of these data will occur at a future medical congress.

Enrollment in the randomized portion of the BEACON CRC trial is ongoing. Patients interested in participating in this trial may talk to their doctor to have their tumor tested for the BRAF mutation for eligibility to enroll in this new and important trial. Further details on the trial are available at clinicaltrials.gov (NCT02928224).

A PDF of the ESMO World Congress on Gastrointestinal Cancer presentation will be available on Array's website.

Array will host an encore webcast presentation of the BEACON CRC safety lead-in data.

Encore Investor Webcast:
Presenter: Axel Grothey, M.D., Division of Hematology/Oncology, Mayo Clinic
Date: Saturday, June 23
Time: 4:30 pm CET (10:30 am ET)
Toll-Free: (844) 464-3927
Toll: (765) 507-2598
Pass Code: 8588348

Webcast, including replay and conference call slides: https://edge.media-server.com/m6/p/bn2j2g45

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. [1] 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. [2] 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. [3-6] 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. [7] Several approved standard of care benchmarks for patients with BRAF-mutant CRC whose disease has progressed after one or two prior lines of therapy, range between 4% to 8% ORR, 1.8 and 2.5 months mPFS and 4 and 6 months mOS. [8-14] Recently published results (April 2018; June 2017) from BRAF-containing triplet regimens in this population resulted in an mOS of approximately 9 months. Specifically, the triplet combination of dabrafenib, a BRAF inhibitor, trametinib, a MEK inhibitor and panitumumab, a monoclonal EGFR antibody, demonstrated an mOS of 9.1 months (n=91) and the triplet combination of vemurafenib, a BRAF inhibitor, cetuximab and irinotecan, a chemotherapy, demonstrated an mOS of 9.6 months (n=49). [8,15] Based on recent prospective historical data, the prevalence of microsatellite instability-high (MSI-H) in tumors from patients with metastatic BRAF-mutant CRC ranged from 14% in a recent Phase 1b/2 trial (NCT01719380) (Array, data on file) to 18% in a recent Southwestern Oncology Group (SWOG) randomized phase 2 trial. [8]

About BEACON CRC
BEACON CRC is a randomized, open-label, global trial evaluating the efficacy and safety of encorafenib, binimetinib 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 (encorafenib 300 mg daily, binimetinib 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 encorafenib in combination with cetuximab with or without binimetinib compared to cetuximab and irinotecan-based therapy. Approximately 615 patients are expected to be randomized 1:1:1 to receive triplet combination, doublet combination (encorafenib 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. Patient enrollment is expected to be completed in 2018.

About Encorafenib and Binimetinib
BRAF and MEK are key protein kinases in the MAPK signaling pathway (RAS-RAF-MEK-ERK). Research has shown this pathway regulates several key cellular activities including proliferation, differentiation, survival and angiogenesis. Inappropriate activation of proteins in this pathway has been shown to occur in

many cancers, including melanoma and colorectal cancer. Encorafenib is a late-stage small molecule BRAF inhibitor and binimetinib is a late-stage small molecule MEK inhibitor, both of which target key enzymes in this pathway. Encorafenib and binimetinib are being studied in clinical trials in advanced cancer patients, including the Phase 3 BEACON CRC trial and the Phase 3 COLUMBUS trial.

The U.S. Food and Drug Administration (FDA) is currently reviewing the New Drug Applications (NDAs) to support use of the combination of encorafenib and binimetinib for the treatment of patients with $BRAF^{V600E}$ or $BRAF^{V600K}$-mutant, 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. The European Medicines Agency (EMA), as well as the Swiss Medicines Agency (Swissmedic) and the Australian Therapeutic Goods Administration (TGA), are reviewing the Marketing Authorization Applications (MAAs) submitted by Pierre Fabre and Japan's Pharmaceuticals and Medical Devices Agency (PMDA) has accepted the Manufacturing and Marketing Approval (MMA) applications submitted by Ono Pharmaceutical Co, Ltd.

Encorafenib and binimetinib are investigational medicines and are not currently approved in any country.

Array BioPharma has exclusive rights to encorafenib and binimetinib in the U.S. and Canada. Array has granted Ono Pharmaceutical exclusive rights to commercialize both products in Japan and South Korea and Pierre Fabre exclusive rights to commercialize both products in all other countries, including Europe, Asia and Latin America. The BEACON CRC trial is being conducted with support from Pierre Fabre and Merck KGaA, Darmstadt, Germany (support is for sites outside of North America).

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: encorafenib (LGX818), binimetinib (MEK162), ARRY-797, selumetinib (partnered with AstraZeneca), ipatasertib (partnered with Genentech), larotrectinib (partnered with Loxo Oncology) and tucatinib (partnered with Seattle Genetics). Ganovo® (danoprevir, partnered with Roche) was recently approved in China for the treatment of viral hepatitis C. For more information on Array, please go to www.arraybiopharma.com.

References

[1] Global Cancer Facts & Figures 3rd Edition. American Cancer Society. Available at: https://www.cancer.org/content/dam/cancer-org/research/cancer-facts-and-statistics/global-cancer-facts-and-figures/global-cancer-facts-and-figures-3rd-edition.pdf. Accessed January 2018.
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[4] Loupakis et al., Br J Cancer. 2009
[5] Sorbye H, et al. PLoS One. 2015
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[9] De Roock et al., Lancet Oncol, 2010
[10] Ulivi et al., J Transl Med. 2012
[11] Peeters et al., ASCO 2014
[12] Saridaki et al., PLoS One. 2013
[13] Loupakis et al., Br J Cancer. 2009
[14] Seymour et al., Lancet Oncol, 2013 (supplementary appendix)
[15] Corcoran et al., Cancer Discovery, 2018

Array BioPharma 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 future development plans of encorafenib and binimetinib; expectations regarding approval of encorafenib and binimetinib for BRAF-mutant melanoma

and timing of such approvals; expectations that events will occur that will result in 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. Specifically, there is no assurance that results from the BEACON CRC and COLUMBUS trials will satisfy the requirements of regulatory authorities necessary for approval. 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, the determination by the FDA, EMA or other regulatory agencies that 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. We are providing this information as of June 23, 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.

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