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): September 12, 2017 (September 12, 2017)

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 8.01 Other Events.

On September 12, 2017, Array issued a press release announcing Food and Drug Administration acceptance for review of binimetinib and encorafenib New Drug Applications for patients with advanced BRAF-mutant melanoma.

A copy of the press release is attached to this Form 8-K as Exhibit 99.1 and incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press release announcing Food and Drug Administration acceptance for review of binimetinib and encorafenib New Drug Applications for patients with advanced BRAF-mutant melanoma.

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: September 12, 2017

Array BioPharma Inc.

By: /s/ Jason Haddock
Jason Haddock
Chief Financial Officer

EXHIBIT INDEX

Exhibit No.	Description
99.1	Press release announcing Food and Drug Administration acceptance for review of binimetinib and encorafenib New Drug Applications for patients with advanced BRAF-mutant melanoma.

Array BioPharma Announces FDA Acceptance For Review Of Binimetinib And Encorafenib New Drug Applications For Patients With Advanced BRAF-mutant Melanoma

BOULDER, Colo., Sept. 12, 2017 /PRNewswire/ -- Array BioPharma (Nasdaq: ARRY) today announced that the U.S. Food and Drug Administration (FDA) has accepted for review its New Drug Applications (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 their preliminary review of the applications they have not identified any potential review issues, and that they are not currently planning to hold an advisory committee meeting to discuss these NDAs. Array completed its NDA submissions at the end of June 2017 based on findings from the pivotal Phase 3 COLUMBUS trial.

"We look forward to working with the FDA and EMA as they review our New Drug Applications for binimetinib and encorafenib," said Ron Squarer, Chief Executive Officer. "The robust PFS 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."

COLUMBUS Results
As presented at the 2016 Society for Melanoma Research Annual Congress, results from Part 1 of the COLUMBUS study showed that COMBO450 significantly extend PFS in patients with advanced *BRAF*-mutant melanoma, with a PFS of 14.9 months compared with 7.3 months observed with vemurafenib [hazard ratio (HR) 0.54, (95% CI 0.41-0.71, P<0.001)]. As part of the trial design, the primary analysis was based on a Blinded Independent Central Review (BICR) of patient scans, while results by local review at the investigative site were also analyzed. The table below outlines the median PFS (mPFS) results, as determined by both assessments, for COMBO450 versus vemurafenib, COMBO450 versus encorafenib, and encorafenib versus vemurafenib:

	mPFS BICR		mPFS Local Review	
	COMBO450	**Vemurafenib**	**COMBO450**	**Vemurafenib**
	14.9 months	7.3 months	14.8 months	7.3 months
COMBO450 vs. Vemurafenib	HR (95% CI): 0.54 (0.41-0.71); P<0.001		HR (95% CI): 0.49 (0.37-0.64); P<0.001	
	COMBO450	**Encorafenib**	**COMBO450**	**Encorafenib**
	14.9 months	9.6 months	14.8 months	9.2 months
COMBO450 vs. Encorafenib	HR (95% CI): 0.75 (0.56-1.00); P=0.051		HR (95% CI): 0.68 (0.52-0.90); P=0.006	
	Encorafenib	**Vemurafenib**	**Encorafenib**	**Vemurafenib**
	9.6 months	7.3 months	9.2 months	7.3 months
Encorafenib vs. Vemurafenib	HR (95% CI): 0.68 (0.52-0.90); P=0.007		HR (95% CI): 0.70 (0.54-0.91); P=0.008	

In this study, COMBO450 was generally well-tolerated, with a median duration of treatment of 51 weeks and median relative dose intensity for encorafenib and binimetinib of 100% and 99.6%, respectively. Grade 3/4 adverse events (AEs) that occurred in more than 5% of patients receiving COMBO450 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 MEK+BRAF-inhibitor treatments for patients receiving COMBO450 included: rash (23%), pyrexia (18%), retinal pigment epithelial detachment (13%) and photosensitivity (5%). Full safety results of COLUMBUS Part 1 were presented at the 2016 Society for Melanoma Research Annual Congress.

COLUMBUS Part 2 was designed specifically to assess the contribution of binimetinib to the combination of binimetinib and encorafenib by reducing the dose of encorafenib to 300mg in the combination arm to allow for a comparison of equal doses across arms. In COLUMBUS Part 2, the primary analysis compared PFS in patients treated with binimetinib 45mg twice daily plus encorafenib 300mg daily (COMBO300) to patients treated with encorafenib 300mg daily as a single agent. Top-line results showed the mPFS for patients treated with COMBO300 was 12.9 months compared to 9.2 months for patients treated with single agent encorafenib, with HR of 0.77 [95% CI 0.61-0.97, p=0.029]. COMBO300 was generally well-tolerated and reported dose intensity and AEs were consistent with COMBO450 results in COLUMBUS Part 1. Results of COLUMBUS Part 2 were presented at the 2017 European Society for Medical Oncology Congress.

About the Phase 3 COLUMBUS Study
The COLUMBUS trial, (NCT01909453), is a two-part, international, randomized, open label Phase 3 study evaluating the efficacy and safety of the combination of binimetinib plus encorafenib to vemurafenib and encorafenib monotherapy in 921 patients with locally advanced, unresectable or metastatic melanoma with *BRAF V600* mutation. Prior immunotherapy treatment was allowed. Over 200 sites across North America, Europe, South America, Africa, Asia and Australia participated in the study. Patients were randomized into two parts:

- In Part 1, 577 patients were randomized 1:1:1 to receive 45mg binimetinib plus 450mg encorafenib (COMBO450), 300mg encorafenib alone, or 960mg vemurafenib alone. The dose of encorafenib in the combination arm is 50% higher than the single agent maximum tolerated dose of 300mg. A higher dose of encorafenib was possible due to improved tolerability when combined with binimetinib. The primary endpoint for the COLUMBUS trial was a PFS comparison of COMBO450 versus vemurafenib. PFS is determined based on tumor assessment (RECIST version 1.1 criteria) by a Blinded Independent Central Review (BICR). Secondary endpoints include a comparison of the PFS of encorafenib monotherapy to that of COMBO450 and a comparison of overall survival (OS) for COMBO450 to that of vemurafenib alone.
- In Part 2, 344 patients were randomized 3:1 to receive 45mg binimetinib plus 300mg encorafenib or 300mg encorafenib alone. Part 2 is designed to provide additional data to help evaluate the contribution of binimetinib to the combination of binimetinib and encorafenib. As the comparison of COMBO450 to encorafenib in Part 1 did not achieve statistical significance, analyses of other endpoints including the statistical analysis conducted in Part 2 is descriptive.

About Melanoma
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].

About Binimetinib and Encorafenib
MEK and BRAF 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, such as melanoma, colorectal and thyroid cancers. Binimetinib is a late-stage small molecule MEK inhibitor and encorafenib is a late-stage small molecule BRAF inhibitor, both of which target key enzymes in this pathway. Binimetinib and encorafenib are being studied in clinical trials in advanced cancer patients, including the Phase 3 BEACON CRC trial with encorafenib in combination with cetuximab with or without binimetinib in patients with *BRAF V600E*-mutant colorectal cancer.

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

Array BioPharma retains exclusive rights to binimetinib and encorafenib in key markets including the U.S., Canada and Israel. 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.

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. Eight 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).

References
[1] Melanoma Skin Cancer. American Cancer Society. Available at: https://www.cancer.org/cancer/melanoma-skin-cancer.html (link is external). Accessed June 2017.
[2] A Snapshot of Melanoma. National Cancer Institute. Available at: https://seer.cancer.gov/statfacts/html/melan.html (link is external). Accessed June 2017.
[3] Globocan 2012: Estimated Cancer Incidence, Mortality and Prevalence Worldwide in 2012. http://globocan.iarc.fr/Pages/fact_sheets_population.aspx (link is external). Accessed June 2017.
[4] Klein O, et al. (2013) BRAF inhibitor activity in V600R metastatic melanoma. Eur J Cancer. 49(5):1073-1079.

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 binimetinib and encorafenib, and the timing of the announcement of further results of clinical trials for binimetinib and encorafenib; expectations regarding the timing of regulatory filings for binimetinib and encorafenib and regarding approval of binimetinib and encorafenib for BRAF-mutant melanoma; expectations that events will occur that will result in greater value for Array; and the potential for the results of current and further clinical trials to support regulatory approval or the marketing success of binimetinib and encorafenib. 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 that results from clinical trials are not sufficient to support registration or marketing approval of binimetinib and encorafenib; 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; and our ability to attract and retain experienced scientists and management. We are providing this information as of September 12, 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.

CONTACT: Tricia Haugeto
(303) 386-1193
thaugeto@arraybiopharma.com

ARRAY BIOPHARMA