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 8, 2017 (September 8, 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 8, 2017, Array issued a press release announcing data from the Phase 3 BEACON CRC Safety Lead-In study in BRAF-Mutant Colorectal Cancer that was presented as an electronic poster at the European Society for Medical Oncology Congress.

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 results from the Phase 3 BEACON CRC Safety Lead-In study in BRAF-Mutant Colorectal Cancer that were presented at the European Society for Medical Oncology Congress.

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 8, 2017

Array BioPharma Inc.

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

EXHIBIT INDEX

Exhibit No.	Description
99.1	Press release announcing results from the Phase 3 BEACON CRC Safety Lead-In study in BRAF-Mutant Colorectal Cancer that were presented at the European Society for Medical Oncology Congress.

Phase 3 BEACON CRC Safety Lead-In Results in BRAF-Mutant Colorectal Cancer Presented at European Society for Medical Oncology Congress

- 41% confirmed ORR for patients on combination of binimetinib, encorafenib and cetuximab –

- Median duration of treatment was 5.6 months at time of analysis and 76% of patients remain on study treatment –

- Generally well-tolerated with attractive safety profile –

- Array to host investor reception and webcast during ESMO on September 9 –

BOULDER, Colo., Sept. 8, 2017 /PRNewswire/ -- Array BioPharma (Nasdaq: ARRY) and Pierre Fabre today announced safety results and initial clinical activity from the safety lead-in of the Phase 3 BEACON CRC study evaluating binimetinib, a MEK inhibitor, encorafenib, a BRAF inhibitor and Erbitux® (cetuximab), an anti-EGFR antibody, in patients with *BRAF*-mutant colorectal cancer (CRC) whose disease has progressed after one or two prior regimens in the metastatic setting. *BRAF*-mutant CRC represents a difficult-to-treat subtype of colorectal cancer that impacts 10 to 15% of CRC patients. These data were presented as an e-poster on September 8 at the 2017 European Society for Medical Oncology Congress in Madrid, Spain (Abstract No. #517P).

As of August 9, 2017, 30 patients were treated in the safety lead-in and received the triplet combination of binimetinib, encorafenib and cetuximab (BINI 45 mg twice daily, ENCO 300 mg daily and CETUX per label). Out of the 30 patients, 29 had a $BRAF^{V600E}$ mutation. Microsatellite instability-high (MSI-H) (resulting from defective DNA mismatch repair) 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. The observed ORR was 59% in the 17 patients with the $BRAF^{V600E}$ mutation with only one prior therapy. Out of 28 patients with both a $BRAF^{V600E}$ mutation and a post-baseline assessment, 27 showed tumor regression.

"The *BRAF* mutation carries a very poor prognosis for patients with advanced colorectal cancer, and is particularly unresponsive after first-line therapy," said Scott Kopetz, M.D., Ph.D., FACP, Associate Professor, Department of Gastrointestinal Medical Oncology, Division of Cancer Medicine, The University of Texas MD Anderson Cancer Center. "In the safety lead-in, the triplet combination 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."

In the safety lead-in, the triplet combination was generally well-tolerated. The most common grade 3 or 4 adverse events (AEs) seen 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).

With these encouraging results, Array continues to enroll the randomized portion of the BEACON CRC study, assessing the efficacy of encorafenib in combination with cetuximab with or without binimetinib compared to cetuximab and irinotecan-based therapy.

"There has been a long-standing need to find improved treatment options for patients with *BRAF*-mutant colorectal cancer, and we are encouraged that data from the safety lead-in show binimetinib, encorafenib and cetuximab may have this potential," said Axel Grothey, M.D., Professor of Oncology, Mayo Clinic College of Medicine and Science. "We hope these promising findings, with the impressive response rates, including a complete response, and early signs of durability, will bring us one step closer to addressing this high unmet medical need."

ARRAY INVESTOR RECEPTION AND WEBCAST: Array will host an investor reception during ESMO 2017 where key opinion leaders in the colorectal cancer field, including Dr. Scott Kopetz, M.D. Anderson and Dr. Axel Grothey, Mayo Clinic, who will give presentations covering the *BRAF*-mutant colorectal cancer landscape and data from the BEACON CRC safety lead-in. The presentations will be webcast (live and replay), for those who wish to participate remotely.

Date:	Saturday, September 9, 2017
Time:	4:00-6:00 PM CEST (10:00 am – 12-noon EDT)
Location:	Neuvo Boston Hotel, Madrid, Spain
RSVP:	https://www.eiseverywhere.com/arrayesmo2017

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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. 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. [1] In the United States, *BRAF* mutations are estimated to occur in 10% to 15% of patients with colorectal cancer and represent a poor prognosis for these patients.[2-5] Based on recent prospective historical data, the prevalence of 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) and 18% a recent Southwestern Oncology Group (SWOG) randomized phase 2 study.[6]

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.

BEACON CRC was initiated based on results from a Phase 2 study which included the combination of encorafenib and cetuximab in 50 patients with advanced *BRAF*-mutant CRC. These results were presented at the 2016 ASCO annual meeting. In this arm, median overall survival for these patients exceeded one year, which is more than double several separate historical standard of care published benchmarks for this population. [7-12] The objective response rate (ORR) was 22%; historical published benchmarks in this patient population using standard of care regimens range between 4% to 8%. [10-13]

On July 5, 2017, Array announced that it submitted two NDAs to the FDA 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. Array completed its NDA submissions based on findings from the pivotal Phase 3 COLUMBUS trial. In addition, Array's European partner, Pierre Fabre, announced on August 28, 2017 that the European Medicines Agency (EMA) has validated the review of the Marketing Authorization Applications for binimetininb and encorafenib.

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. 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. 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).

About Pierre Fabre
With a portfolio representing a continuum of activities spanning from prescription drugs and consumer healthcare products to dermo-cosmetics, Pierre Fabre is the 2nd largest dermo-cosmetics laboratory in the world, the 2nd largest private French pharmaceutical group and the market leader in France for products sold over the counter in pharmacies. Its portfolio includes several global brands and franchises among which Eau Thermale Avène - the worldwide dermo-cosmetic market leader - Klorane, Ducray, René Furterer, A-Derma, Galénic, Elancyl, Naturactive, Pierre Fabre Health Care, Pierre Fabre Oral Care, Pierre Fabre Dermatologie and Pierre Fabre Oncologie.

In 2016, Pierre Fabre generated 2,282 million euros in revenues, of which 60% came from its international business and 59% from its dermo-cosmetics division. Pierre Fabre, which has always been headquartered in the South-West of France, counts more than 13,000 employees worldwide, owns subsidiaries and offices in 47 countries and enjoys distribution agreements in over 130 countries. In 2016, Pierre Fabre dedicated ca. 195 million euros to its R&D efforts, split between oncology, central nervous system, consumer healthcare, dermatology and dermo-cosmetics.

Pierre Fabre is 86%-owned by the Pierre Fabre Foundation, a government-recognized public-interest foundation, and secondarily by its own employees through an international employee stock ownership plan.

The independent French certification group AFNOR audited Pierre Fabre for its corporate social responsibility policy at the "exemplary" level, according to the ISO 26000 standard for CSR.

To find out more about Pierre Fabre, please go to www.pierre-fabre.com

References

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[4] Loupakis F, et al. (2009) KRAS codon 61, 146 and BRAF mutations predict resistance to cetuximab plus irinotecan in KRAS codon 12 and 13 wild-type metastatic colorectal cancer. British Journal of Cancer 101(4), 715 – 721
[5] Vecchione, et al. (2016) A Vulnerability of a Subset of Colon Cancers with Potential Clinical Utility. Cell 165, 317–330
[6] Kopetz et al. J Clin Oncol. 2017;35:520-20
[7] Ulivi et al., J Transl Med. 2012
[8] Saridaki et al., *PLoS One. 2013*
[9] Loupakis et al., Br J Cancer. 2009
[10] De Roock et al., Lancet Oncol, 2010
[11] Peeters et al., ASCO 2014
[12] Kopetz et al., ASCO 2017
[13] Seymour et al., *Lancet Oncol,* 2013 (supplementary appendix)

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. Specifically, there is no assurance that results from the BEACON CRC study will satisfy the requirements of regulatory authorities necessary to

file an application for marketing approval, or that if such application is accepted, that it will be approved. 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 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 and to manufacture drug substance and product within and outside the United States; 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 September 8, 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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