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 4, 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 4, 2018, Array BioPharma Inc. issued a press release announcing additional median overall survival results of encorafenib and binimetinib in patients with BRAF-mutant advanced melanoma that will be presented at the American Society of Clinical Oncology annual meeting. 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 4, 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 4, 2018

Array BioPharma Inc.

By: /s/ JASON HADDOCK

Jason Haddock

Chief Financial Officer

News Release

Array BioPharma Announces Additional Median Overall Survival Results of Encorafenib and Binimetinib in Patients with BRAF-mutant Advanced Melanoma

– Combination of encorafenib and binimetinib achieved 33.6 month median overall survival –
– Data shows limited use of post-trial immunotherapy across treatment groups –
– Phase 3 COLUMBUS results selected for "Best of ASCO" –
– Encore investor webcast presentation today at 11:15 a.m. Central Time –

Boulder, Colo., *(June 4, 2018)* – Array BioPharma Inc. (NASDAQ: ARRY) today announced updated results from the Phase 3 COLUMBUS trial in *BRAF*-mutant advanced melanoma. The results showed median overall survival (mOS) 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 observed efficacy of vemurafenib in the control arm is also consistent with historical data, providing an additional benchmark for validating the patient population and results observed in COLUMBUS. [1, 2] Further, the two-year OS with combination therapy was 58%. These results will be part of an oral presentation today at the American Society of Clinical Oncology (ASCO) annual meeting in Chicago, Illinois and have been selected for the "Best of ASCO" program.

Importantly, the presentation will include data showing 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, 3]

"The data presented today at ASCO demonstrate that the use of subsequent immunotherapies was consistent across treatment groups, indicating that these subsequent treatments are unlikely to have contributed to the observed differences in survival," said Keith T. Flaherty, M.D., Director of the Termeer Center for Targeted Therapy, Massachusetts General Hospital Cancer Center and Professor of Medicine, Harvard Medical School. "This further suggests encorafenib and binimetinib could be a promising new treatment option for patients with *BRAF*-mutant advanced melanoma."

Additionally, the updated median progression-free survival (mPFS) results for patients treated with the combination of encorafenib and binimetinib remained consistent with what was previously reported at 14.9 months versus 7.3 months for patients treated with vemurafenib [HR= 0.51, 95% CI 0.39-0.67; p<0.0001].

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 including retinal pigment epithelial detachment (20%), pyrexia (18%) and photosensitivity (5%). Full safety results of COLUMBUS Part 1 were published in *The Lancet Oncology*.

A PDF of the ASCO COLUMBUS presentation will be available on Array's website.

In the COLUMBUS trial, eligible patients were randomized 1:1:1 to receive the combination of encorafenib, 450 mg daily, plus binimetinib, 45 mg twice daily, encorafenib 300 mg daily as a monotherapy, or vemurafenib 960 mg twice daily as a monotherapy.

Data from Array's partnered programs with AstraZeneca, Genentech and Loxo Oncology were also presented on the Array-invented molecules selumetinib, ipatasertib and LOXO-292, respectively.

Array will host an encore webcast presentation of the COLUMBUS trial data.

Encore Webcast:
Presenter: Keith T. Flaherty, M.D.
Date: Monday, June 4, 2018
Time: 11:15 a.m. Central Time (12:15 p.m. Eastern Time)
Toll-Free: (844) 464-3927
Toll: (765) 507-2598
Pass Code: 9615719

Webcast, including replay and conference call slides: https://edge.media-server.com/m6/p/8juh6tcn

About Melanoma
Metastatic melanoma is the most serious and life-threatening type of skin cancer and is associated with low survival rates. [4, 5] 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. [4, 6, 7, 8]

About COLUMBUS
The COLUMBUS trial (NCT01909453) is a two-part, international, randomized, open label Phase 3 trial evaluating the efficacy and safety of the combination of encorafenib and binimetinib compared 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 trial. Patients were randomized into two parts:

- In Part 1, 577 patients were randomized 1:1:1 to receive the combination of encorafenib 450 mg daily and binimetinib 45 mg twice daily (COMBO450), encorafenib, 300 mg daily alone (ENCO 300), or vemurafenib, 960 mg twice daily alone. The dose of encorafenib in the combination arm is 50% higher than the single agent maximum tolerated dose of 300 mg. A higher dose of encorafenib was possible due to improved tolerability when combined with binimetinib. The primary endpoint for the COLUMBUS trial was an mPFS comparison of the COMBO450 arm versus vemurafenib. mPFS 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 mPFS of COMBO450 arm to that of ENCO300 and a comparison of overall survival (OS) in patients treated in the COMBO450 arm to that of vemurafenib alone. Results from Part 1 of the COLUMBUS trial, previously published in *The Lancet Oncology* May 2018, showed that COMBO450 more than doubled mPFS in patients with advanced *BRAF*-mutant melanoma, with a mPFS of 14.9 months compared with 7.3 months observed with vemurafenib [HR 0.54, (95% CI 0.41-0.71, p<0.0001)]. In the secondary mPFS comparison of COMBO450 to ENCO300, ENCO300 demonstrated a mPFS of 9.6 months [HR 0.75, (95% CI 0.56-1.00, p=0.051)].
- In Part 2, 344 patients were randomized 3:1 to receive encorafenib 300 mg daily plus binimetinib 45 mg twice daily (COMBO300) or ENCO300. Part 2 was designed to provide additional data to help evaluate the contribution of binimetinib to the combination of encorafenib and binimetinib.

As the secondary endpoint comparison of mPFS between the COMBO450 arm and ENCO300 arm in Part 1 did not achieve statistical significance, the protocol specified analysis of OS is descriptive.

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 COLUMBUS trial and the Phase 3 BEACON CRC trial.

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

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 and other conditions. Ten registration studies are currently advancing related to eight Array-owned or partnered drugs: encorafenib (LGX818), binimetinib (MEK162), ARRY-797, selumetinib (partnered with AstraZeneca), danoprevir (partnered with Roche), ipatasertib (partnered with Genentech), larotrectinib (partnered with Loxo Oncology) and tucatinib (partnered with Seattle Genetics). For more information on Array, please go to www.arraybiopharma.com.

References

[1] Ascierto PA, et al. Lancet Oncol. 2016;17:1248-1260.
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[6] Globocan 2012: Estimated Cancer Incidence, Mortality and Prevalence Worldwide in 2012. http://globocan.iarc.fr/Pages/fact_sheets_population.aspx. Accessed January 2018.
[7] Klein O, et al. *Eur J Cancer*, 2013.
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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 4, 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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