ARRAY BIOPHARMA INC
Form 8-K
November 16, 2015

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): **November 16, 2015**

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:

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

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

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

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

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

Item 1.01 Entry into a Material Definitive Agreement.

On November 10, 2015, Array BioPharma entered into a Development and Commercialization Agreement (the **Agreement**) with Pierre Fabre Medicament SAS, a company duly organized and existing under the laws of France (**Pierre Fabre**) pursuant to which Array granted Pierre Fabre rights to commercialize two of Array s late-stage oncology products, binimetinib and encorafenib. The effectiveness of the Agreement is subject to European regulatory approvals and, if approved, will satisfy Array s commitment to secure a development and commercialization partner for the European market for both encorafenib and binimetinib acceptable to European Commission regulatory agencies made in connection with the Termination and Asset Transfer Agreement with Novartis Pharma AG and Novartis Pharmaceutical Ltd. and the Asset Transfer Agreement with Novartis Pharma AG that became effective in March 2015 (collectively, the **Novartis Agreements**).

Under the terms of the Agreement, Array will receive an upfront cash payment of $30 million when the Agreement becomes effective and will retain the right to develop and manufacture the products worldwide and full, exclusive commercialization rights for binimetinib and encorafenib in the United States, Canada, Japan, Korea and Israel. Pierre Fabre will have rights to develop the products worldwide and exclusive rights to commercialize both products in all other countries, including Europe. Array is also entitled to receive up to $425 million in milestone payments from Pierre Fabre if certain development and commercialization goals are achieved, and Array is eligible for tiered double-digit royalties on combined annual net sales of binimetinib and encorafenib in the Pierre Fabre territory, starting at 20%, and moving through multiple tiers, including a maximum of 35% on annual combined net sales of binimetinib and encorafenib which exceed 100 million.

All ongoing clinical trials involving binimetinib and encorafenib, including the NEMO, COLUMBUS and MILO trails and other ongoing Novartis sponsored and investigator sponsored clinical studies, will continue to be conducted pursuant to the terms of the Novartis Agreements. Further worldwide development activities will be governed by a Global Development Plan (GDP). Pierre Fabre and Array will jointly fund worldwide development costs under the GDP, with Array covering 60% and Pierre Fabre covering 40% of such costs. The initial GDP includes multiple trials, and Pierre Fabre and Array have agreed to commit at least 100 million in combined funds for these studies in colorectal cancer and melanoma.

Pierre Fabre is responsible for seeking regulatory and pricing and reimbursement approvals in the European Economic Area and its other licensed territories. Array and Pierre Fabre will also enter into a clinical and commercial supply agreement pursuant to which Array will supply or procure the supply of clinical and commercial supplies of drug substance and drug product for Pierre Fabre, the costs of which will be borne by Pierre Fabre. Array has also agreed to cooperate with Pierre Fabre to ensure the supply of companion diagnostics for use with binimetinib and encorafenib in certain indications.

Each party has also agreed not to distribute, sell or promote competing products in each party s respective markets during a period of exclusivity. Each party has also agreed to indemnify the other party from certain liabilities specified in the Agreement.

The Agreement will be effective upon the final regulatory approval by the European Commission of the Agreement and of Pierre Fabre as a suitable partner . If such approval is not obtained by March 31, 2016, or such other date the parties agree to, the Agreement will be null and void. Provided that it becomes effective, the Agreement will continue in effect for so long as Pierre Fabre continues to develop and commercialize products. The Agreement may be terminated by either party for breach of the Agreement by the other party, in the event of the insolvency or bankruptcy of the other party, by Pierre

Fabre on a region-by-region basis outside of the European Economic Area market with six months prior notice, or by Pierre Fabre on a product-by-product basis for certain safety reasons.

Array expects to file the Agreement as an exhibit to its Quarterly Report on Form 10-Q for the quarter ending December 31, 2015. The foregoing description is qualified in its entirety by reference to the text of the Agreement when filed.

Item 9.01 **Financial Statements and Exhibits.**

(d) Exhibits

Exhibit No.	**Description**
99.1	Press Release Announcing Development and Commercialization Agreement with Pierre Fabre

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: November 16, 2015

Array BioPharma Inc.

By: /s/ Mary P. Henahan
Mary Patricia Henahan
Chief Financial Officer