ARRAY BIOPHARMA INC
Form 8-K
January 23, 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): January 23, 2015 (January 19, 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:

__ 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))

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 January 23, 2015, Array BioPharma announced that it entered into an Asset Transfer Agreement, dated January 19, 2015 (the “Novartis Agreement”) with Novartis Pharma AG (“Novartis”). Under the Novartis Agreement, Array and Novartis agreed to the terms pursuant to which Array will obtain worldwide development and commercialization rights to encorafenib (LGX-818), a BRAF oncology product. At the same time, Array, Novartis and Novartis International Pharmaceutical Ltd. (“NIP”) amended the Termination and Asset Transfer Agreement dated November 26, 2014 (the “Binimetinib Agreement”), pursuant to which Array will regain worldwide development and commercialization rights to binimetinib, a MEK oncology product that Array had previously licensed to NIP, in order to reflect transfer of encorafenib rights to Array and not to a third party as originally contemplated.

Novartis’ divestiture of the encorafenib assets to Array pursuant to the Novartis Agreement is contingent upon, and shall automatically become effective as of (the “Effective Date”), the closing of the transactions announced by Novartis AG and GlaxoSmithKline PLC (GSK) on 22 April 2014. The transaction is also subject to the receipt of regulatory approvals.

Subject to the terms thereof, the Novartis Agreement requires that Novartis transfer or exclusively license to Array all assets, including intellectual property, regulatory filings, technology, inventory, the companion diagnostic partner agreement, and other contract rights, owned by Novartis or its affiliates that relate to encorafenib worldwide. Following the Effective Date and subject to certain commitments further described below, Array will have worldwide rights to develop, manufacture and commercialize encorafenib.

In addition to the Novartis Agreement, Array and Novartis will enter into certain ancillary agreements on the Effective Date relating to the transfer of the encorafenib assets, including: (1) a Transition Agreement pursuant to which Novartis and its affiliates will provide certain regulatory assistance, development technology transfer, and other transition services, financial support to Array, and manufacturing technology transfer services to Array and/or its contract manufacturing organizations; (2) certain clinical trial agreements to address the parties’ rights and obligations with respect to clinical trials involving encorafenib; (3) a Supply Agreement pursuant to which Novartis and its affiliates will manufacture and supply to Array encorafenib for use in clinical trials and commercial supply; (4) a Cross License Agreement relating to the use by the parties of certain intellectual property that is currently used both on the encorafenib program and on other Novartis programs to enable Novartis to use such intellectual property on programs other than encorafenib and to enable Array to use such intellectual property on the encorafenib program after the Effective Date; and (5) a Divestiture Commitment Agreement pursuant to which Array agrees to obtain an experienced partner for global development and commercialization in the European Economic Area of both binimetinib and encorafenib, as described more fully below. The parties will also form a transition team comprised of representatives of Array and Novartis to facilitate the transition of the encorafenib assets and the ongoing clinical trials.

All other clinical trials involving encorafenib, including the COLUMBUS trial, will continue to be conducted as currently contemplated until completion or transition to Array, with Novartis providing substantial financial support in the form of reimbursement to Array for out-of-pocket costs and for one-half of Array’s fully-burdened FTE costs based on an annual FTE rate in connection with completing the trials. At designated points for each trial, Novartis will transition responsibility and provide this continuing financial support to Array for completing the trials.

- COLUMBUS trial: Novartis will conduct and solely fund the Phase 3 BRAF melanoma clinical trial (COLUMBUS) through completion of last patient first visit, but no later than June 30, 2016. For all COLUMBUS activities required

following that date, Array would be responsible for conducting the trial and Novartis would provide the financial support to Array described above.

- Novartis will conduct and fund, and transfer at designated times, all other Novartis sponsored trials through no later than December 31, 2015. For all activities required following that date, Array will be responsible for conducting those trials and Novartis would provide financial support to Array as described above.
- At designated times following the Effective Date, Novartis will transfer to Array, and Array will oversee the conduct and completion of all ongoing and planned investigator sponsored clinical trials. Novartis will provide financial support to Array as described above.

Novartis will also supply encorafenib for clinical and commercial use for up to 30 months after closing, during which time Novartis will assist Array in the technology and manufacturing transfer of encorafenib. Novartis will also provide Array continued clinical supply of several Novartis pipeline compounds including, but not limited to, LEE011 (CDK 4/6 inhibitor) and BYL719 (-PI3K inhibitor), for use in currently ongoing combination studies, and possible future studies, including Phase 3 trials, with encorafenib.

Each party has also agreed to indemnify and hold the other party and its affiliates harmless from and against certain liabilities identified in the Novartis Agreement. Provided regulatory approval is obtained, the Novartis Agreement may be terminated only upon the mutual agreement of Novartis and Array or by either Novartis or Array if the GSK Transactions are terminated without the consummation thereof.

In order to address competition concerns raised by the European Commission, as part of the agreement, Array has committed to obtain an experienced partner for global development and European commercialization of both binimetinib and encorafenib acceptable to the European Commission. Array has granted a conditional license permitting the licensee to develop encorafenib and binimetinib worldwide and to exclusively commercialize both products in the European Economic Area. If Array is unable, in the prescribed time period, to negotiate a collaboration and license agreement with a partner and on terms acceptable to the European Commission, the conditional license will be assigned to a trustee approved by the European Commission, who will thereafter sell the license to a suitable third party for no minimum price.

In addition, Array agreed to undertake to obtain certain third party consents or waivers necessary for Array to consummate the transactions under the Novartis Agreement.

Array issued a press release on January 23, 2015 announcing the Novartis Agreement, a copy of which is attached to this Form 8-K as Exhibit 99.1.

As described above, under the Binimetinib Agreement Array will regain worldwide development and commercialization rights to binimetinib, contingent on and effective as of the closing of the Novartis/GSK transactions. Array, Novartis and NIP amended certain provisions of the Binimetinib Agreement relating to encorafenib in order to reflect transfer of encorafenib rights to Array and not to a third party as originally contemplated. If the Novartis Agreement terminates for any reason, the amendment to the Binimetinib Agreement (other than certain financial terms thereof) will terminate and be of no force and effect.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press Release Announcing Array to Acquire Rights to Encorafenib

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: January 23, 2015

Array BioPharma Inc.

By: /s/ R. Michael Carruthers
R. Michael Carruthers
Chief Financial Officer

EXHIBIT INDEX

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