ARRAY BIOPHARMA INC
Form 8-K
December 03, 2014

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): **December 3, 2014 (November 26, 2014)**

Array BioPharma Inc.

(Exact name of registrant as specified in its charter)

Delaware

(State or other jurisdiction
of incorporation)

001-16633	**23-2908305**
(Commission File Number)	(I.R.S. Employer Identification No.)
3200 Walnut Street, Boulder, Colorado	**80301**
(Address of principal executive offices)	(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 December 3, 2014, Array BioPharma announced that it entered into a Termination and Asset Transfer Agreement dated November 26, 2014 (the **Novartis Agreement**) with Novartis Pharma AG (**Novartis**) and Novartis International Pharmaceutical Ltd. (**NIP**). Under the Novartis Agreement, Array, Novartis and NIP agreed to the terms pursuant to which Array will regain all development and commercialization rights to binimetinib, a MEK oncology program that Array had previously licensed to NIP under a License Agreement dated April 19, 2010 (the **Existing License Agreement**). When the transactions contemplated by the Novartis Agreement become effective, the Existing License Agreement will terminate.

Novartis s divestiture of the binimetinib assets to Array and the termination of the Existing License Agreement 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 Transactions**) on 22 April 2014.

The Novartis Agreement requires that Novartis, at its expense, transfer or exclusively license to Array all assets, including intellectual property, regulatory filings, technology, inventory and contract rights, owned by Novartis or its affiliates that relate to binimetinib worldwide. Array will receive an up-front payment of up to $85 million within 30 days of the Effective Date. Following the Effective Date, Array will have full rights to develop, manufacture and commercialize binimetinib and will not be required to pay its portion of accrued co-development costs, including a $15 million payment for fiscal year 2014, as a result of the termination of the Existing License Agreement.

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 binimetinib assets, including (1) a Transition Agreement pursuant to which Novartis and its affiliates will provide certain regulatory assistance, development technology transfer, companion diagnostic assistance and other transition services, and financial support to Array; (2) certain clinical trial agreements to address the parties rights and obligations with respect to clinical trials involving binimetinib; (3) a Supply Agreement pursuant to which Novartis and its affiliates will manufacture and supply to Array binimetinib for use in clinical trials and provide manufacturing technology transfer services to Array and/or its contract manufacturing organizations; and (4) certain license agreements relating to the use by the parties of certain intellectual property that is currently used both on the binimetinib program and on other Novartis programs to enable Novartis to use such intellectual property on programs other than binimetinib and to enable Array to use such intellectual property on the binimetinib program after the Effective Date. The parties will also form a transition team comprised of representatives of Array and Novartis to facilitate the transition of the binimetinib assets and the ongoing clinical trials.

Novartis will be responsible for continued conduct and funding of the COLUMBUS trial. This obligation will transfer to any future owner of LGX818 (encorafenib).

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

- NEMO trial: Novartis will conduct and solely fund the Phase 3 NRAS melanoma clinical trial (NEMO) through June 30, 2016. For all NEMO activities required following that date, Array would be responsible for conducting the trial and Novartis would provide the financial support to Array described above.

- MILO trial: Array will continue conduct and complete the Phase 3 low grade serous ovarian cancer trial (MILO) and Novartis will provide financial support to Array as described above.

- Novartis will conduct and fund, and transfer at designated times all other Novartis sponsored trials, including a series of planned clinical pharmacology and pediatric trials, through 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.

- On the Effective Date, Novartis will transfer at designated times, 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 remain responsible for conducting and funding development of the NRAS melanoma companion diagnostic until Premarket Approval is received from the U.S. Food and Drug Administration. Following approval, Novartis will transfer the product and Premarket Approval to a diagnostic vendor of Array s designation.

Novartis also retains binimetinib supply obligations for all clinical and commercial needs for up to 30 months after closing and will also assist Array in the technology and manufacturing transfer of binimetinib. 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 binimetinib.

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 and to a general release of claims relating to the Existing License Agreement. 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.

Array issued a press release on December 3, 2014 announcing the Novartis Agreement and return of rights to binimetinib, a copy of which is attached to this Form 8-K as Exhibit 99.1.

Item 1.02 Termination of a Material Definitive Agreement

As described under Item 1.01 above, the Novartis Agreement provides for the termination of the Existing License Agreement upon the Effective Date and that all rights, licenses and obligations under the Existing License Agreement will be terminated, discharged and superseded by the Novartis Agreement. The disclosure in Item 1.01 above is hereby incorporated by reference in this Item 1.02.

The Existing License Agreement granted NIP the exclusive worldwide right to co-develop and commercialize binimetinib, as well as other specified MEK inhibitors. Under the agreement, NIP was responsible for all ongoing development activities and for the commercialization of products under the agreement, subject to Array s right to conduct certain clinical studies and option to co-detail approved drugs in the U.S. In consideration for the rights granted to NIP under the agreement, Array received $45 million, comprising an up-front and milestone payment, in the fourth quarter of fiscal 2010 and subsequently received an aggregate of $15 million in clinical milestone payments. Up to approximately $407.5 million in aggregate milestone payments were payable by NIP if all remaining clinical, regulatory and commercial milestones specified in the agreement were achieved. NIP had also agreed to pay Array royalties on worldwide sales of any approved drugs with a higher rate applicable to U.S. sales so long as Array continued to fund its share of co-development costs under the program.

Item 9.01 **Financial Statements and Exhibits.**

(d) Exhibits

Exhibit No.	Description
99.1	Press Release Announcing Array to Regain Rights to Binimetinib

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: December 3, 2014

Array BioPharma Inc.

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

EXHIBIT INDEX

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