

ARDELYX, INC.
Form 8-K
November 28, 2017

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 27, 2017

ARDELYX, INC.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction

of incorporation)

001-36485
(Commission

File Number)
34175 Ardenwood Blvd., Suite 200

26-1303944
(IRS Employer

Identification Number)

Fremont, CA 94555

(Address of principal executive offices, including Zip Code)

Registrant's telephone number, including area code: (510) 745-1700

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.

Item 1.01 Entry into a Material Definitive Agreement.

On November 27, 2017, Ardelyx, Inc. (the Company) entered into a license agreement (License Agreement) with Kyowa Hakko Kirin Co., Ltd (KHK) under which the Company granted KHK an exclusive license to develop and commercialize tenapanor in Japan for the treatment of cardiorenal diseases and conditions, excluding cancer (Field). The Company retained the rights to tenapanor outside of Japan, and also retained the rights to tenapanor in Japan for indications other than those in the Field. Pursuant to the License Agreement, KHK is responsible for all of the development and commercialization costs for tenapanor in the Field in Japan.

Under the License Agreement, the Company is responsible for supplying the tenapanor drug product for KHK's use in development and during commercialization until KHK has assumed such responsibility. Additionally, the Company is responsible for supplying the tenapanor drug substance for KHK's use in development and commercialization throughout the term of the License Agreement, provided that KHK may exercise an option to manufacture the tenapanor drug substance under certain conditions.

Under the terms of the License Agreement, the Company will receive a \$30.0 million upfront payment and is eligible to receive up to an additional \$130.0 million in development and commercialization milestones, based upon currency exchange rates as of the effective date of License Agreement.

The Company is also eligible to receive royalties based on aggregate annual net sales of the licensed products at a high teen percentage, subject to certain single digit reductions under certain circumstances described in the License Agreement.

The License Agreement will continue until all of KHK's applicable payment obligations under the License Agreement have been performed or have expired, or the agreement is earlier terminated. Under the terms of the License Agreement, the Company and KHK each have the right to terminate the agreement for material breach by the other party. In addition, KHK may terminate the agreement for convenience; for certain safety reasons or if certain primary endpoints under an applicable development plan are not met despite KHK's commercially reasonable efforts and KHK reasonably determines that it cannot obtain regulatory approval. KHK may also terminate the agreement if certain pivotal clinical trials conducted by the Company do not meet their primary endpoints. The Company may terminate the License Agreement if KHK challenges any patents licensed to KHK under the agreement.

The License Agreement includes various representations, warranties, covenants, dispute escalation and resolution mechanisms, indemnities and other provisions customary for transactions of this nature.

The foregoing description of the License Agreement is qualified in its entirety by reference to the License Agreement, a copy of which will be filed as an exhibit to the Company's Annual Report on Form 10-K for the year ended December 31, 2017.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Date: November 27, 2017

ARDELYX, INC.

By: /s/ Mark Kaufmann
Mark Kaufmann
Chief Financial Officer