
**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): April 11, 2022



ARDELYX, INC.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction
of incorporation)

001-36485
(Commission
File Number)

26-1303944
(IRS Employer
Identification Number)

400 FIFTH AVE., SUITE 210, WALTHAM, MASSACHUSETTS 02451
(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))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, par value \$0.0001	ARDX	The Nasdaq Global Market

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 April 11, 2022, Ardelyx, Inc. (the “Company”) entered into that certain Amendment Number 2 to License Agreement (the “Amendment”), which amended that certain License Agreement (the “Agreement”) dated as of November 27, 2017, by and between Kyowa Kirin Co., Ltd. (“Kyowa Kirin”, f/k/a Kyowa Hakko Kirin Co., Ltd.). Under the terms of the Amendment, the parties have agreed to a reduction in the royalty rate payable to the Company by Kyowa Kirin upon net sales of tenapanor in Japan. The royalty rate will be reduced from the high teens to low double digits for a two-year period of time following the first commercial sale in Japan, and then to mid-single digits for the remainder of the royalty term. As consideration for the reduction in the royalty rate, Kyowa Kirin has agreed to pay the Company up to additional U.S. \$40 million payable in two tranches, with the first payment due following Kyowa Kirin’s filing with the Japanese Ministry Health, Labour and Welfare (MHLW) of its application for marketing approval for tenapanor and the second payment due following Kyowa Kirin’s receipt of regulatory approval to market tenapanor for hyperphosphatemia in Japan.

The above summary of the material terms of the Amendment do not purport to be complete and are qualified in their entirety by reference to the Amendment, a copy of which is filed as Exhibit 10.1, respectively, to this Current Report on Form 8-K and incorporated by reference herein.

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Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description
99.1	Amendment Number 2 to License Agreement, dated as of April 11, 2022, by and among Ardelyx, Inc. and Kyowa Kirin Co., Ltd.
104	Cover Page Interactive Data File (embedded within the Inline XBRL document).

* Certain portions of this exhibit have been redacted pursuant to Item 601(b)(10) of Regulation S-K. A copy of the omitted portions will be furnished supplementally to the Securities and Exchange Commission upon request.

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: April 11, 2022

ARDELYX, INC.

By: /s/ Justin Renz

Justin Renz

Chief Financial Officer

**AMENDMENT NO.2 to
LICENSE AGREEMENT**

This **SECOND AMENDMENT** (the "Amendment"), effective as of the date last signed below (the "Effective Date"), amends that certain License Agreement dated November 27, 2017 (together with all exhibits, amendments and attachments thereto, the "Original Agreement") by and between Kyowa Kirin Co., Ltd. (f/k/a Kyowa Hakko Kirin Co., Ltd.), a Japanese corporation with a place of business at 1-9-2 Otemachi, Chiyoda-ku, Tokyo 100-0004, Japan ("KKC"), and Ardelyx, Inc., a Delaware corporation having its principal place of business at 400 Fifth Avenue, Suite 210 Waltham, MA 02451, United States of America ("Ardelyx"). KKC and Ardelyx shall each be hereinafter referred to as a "Party" and collectively as the "Parties". Capitalized terms used but not otherwise defined herein shall have the meanings ascribed to them in the Original Agreement.

WHEREAS, the Parties desire to amend the milestone payments and the royalties under Sections 6.02, 6.04 and 11.04 of the Original Agreement.

Now Therefore, in consideration of the premises and the terms and conditions contained herein, the Parties hereby agree as follows:

- 1) Amendment to the Milestone Payments.** As of the Effective Date, the table of the milestone events for a Licensed Product set forth in Section 6.02 (a) of the Original Agreement shall be deleted and replaced in its entirety as follows:

Milestone Event for a Licensed Product	Milestone Number	Milestone Payment
[***]	01	USD [***]
[***]	02	USD [***]
[***]	03	USD [***]
[***]	04	USD [***]
[***]	05	USD [***]
[***]	06	USD [***]
[***]	07	USD [***]

- 2) Amendment to the Royalties.** As of the Effective Date, Section 6.04 and Section 11.04 of the Original Agreement shall be deleted and replaced in its entirety as set forth on Exhibit A to this Amendment.

As full and complete consideration for the amendments to the royalty provisions of the Original Agreement KKC shall make the following payments to Ardelyx, when and if earned:

- (a) [***] U.S. dollars (U.S. [***) shall be paid to Ardelyx within [***] days following the first filing of a Drug Approval Application in the Territory for the first indication of a Licensed Product; and
- (b) [***] U.S. dollars (U.S. [***) shall be paid to Ardelyx within [***] days following KKC's first receipt of Regulatory Approval in the Territory for the first indication of a Licensed Product.

3) Publicity. Notwithstanding the provisions of Section 10.02 of the Original Agreement, the Parties agree that Ardelyx and KKC may issue a press release set forth on Exhibit B regarding this Amendment.

4) Miscellaneous. This Amendment shall be governed and construed in accordance with the laws of the State of New York, without giving effect to the conflict of law rules thereof that would require application of the laws of any other jurisdiction. Except for those amendments expressly described in this Amendment, the Original Agreement remains unchanged and in full force and effect. This Amendment may be executed in any number of counterparts, each of which shall be deemed an original and all of which taken together shall be deemed to constitute one and the same instrument.

* * *

IN WITNESS WHEREOF, the Parties have caused this Amendment to be executed by their duly authorized representatives as of the Effective Date.

Kyowa Kirin Co., Ltd.

Ardelyx, Inc.

/s/ Yasuo Fujii /s/ Michael Raab

Name: Yasuo Fujii Name: Michael Raab

Title: Executive Officer, Director,
Business Development Department

Title: President and Chief Executive Officer

Date: April 11th, 2022 Date: April 10th, 2022

EXHIBIT A

Section 6.04 Royalties.

(a) Subject to the provisions set forth below in Section 6.04(b) through Section 6.04(e) and Section 6.05, KKC shall pay to Ardelyx a royalty on aggregate Annual Net Sales of the Licensed Products made by KKC, its Affiliates, or its Sublicensees as follows:

Period	Royalty Rate
The first twenty-four (24) months after First Commercial Sale ("Royalty Period 1")	[***]
[***] after the end of the Royalty Period 1 ("Royalty Period 2")	[***]

(b) Sales between KKC, its Affiliates and Sublicensees shall not be subject to royalties hereunder. Royalties shall be calculated on KKC's, its Affiliates' and Sublicensees' sales of the Licensed Products to a Third Party, including Distributors (but excluding for the avoidance of doubt Sublicensees).

(c) If, at any time, a Generic Product receives Regulatory Approval then the royalties that would otherwise have been payable on Net Sales of such Licensed Product in the Territory under this Agreement shall be reduced as follows:

(i) Effective as of the first day of the first Calendar Quarter following the Calendar Quarter in which the NHI Price of the Licensed Product is reduced to a NHI Price being less than [***] of the NHI Price in effect immediately prior to the launch of the Generic Product:

Period	Royalty Rate
Royalty Period 1	[***]
Royalty Period 2	[***]

(ii) Effective as of the first day of the first Calendar Quarter following the Calendar Quarter in which the NHI Price of the Licensed Product is reduced to a NHI Price being less than [***] of the NHI Price in effect immediately prior to the launch of the Generic Product:

Period	Royalty Rate
Royalty Period 1	[***]
Royalty Period 2	[***]

(d) KKC's obligation to pay royalties due under this Section 6.04 shall commence with respect to each separate Licensed Product, on the date of the First Commercial Sale of such Licensed Product in the Territory and shall expire with respect to such Licensed Product, at the latest of: (i) the [***] ([***) anniversary of the First Commercial Sale of such Licensed Product in the Territory, (ii) the date on which there is no longer a Valid Claim that covers the Exploitation of the Licensed Product or the Licensed Compound contained within such Licensed Product in the Territory, and (iii) the expiration of all Regulatory Exclusivities associated with the indication of [***] for such Licensed Product in the Territory; provided that (i) under no circumstances shall KKC have an obligation to pay royalties to Ardelyx after the end of the Royalty Period 2 and (ii) in the event that the only Valid Claim that claims

the Licensed Product is a [***], the royalty that would otherwise have been payable on Net Sales of such Licensed Product shall be reduced as follows, subject to the reduction of the Third Party Compensation set out in Section 6.04(e).

Period	Royalty Rate
Royalty Period 1	[***]
Royalty Period 2	[***]

At such time as KKC's obligation to pay royalties under this Section 6.04 has expired with respect to a Licensed Product, the license granted to KKC under Section 2.01 shall automatically, and without further action on the part of Ardelyx or KKC, become non-exclusive, fully-paid, irrevocable and perpetual with respect to such Licensed Product and the Net Sales of such Licensed Product shall be excluded from royalty calculations under this Section 6.04 (including for purposes of applying thresholds and ceilings) and shall be excluded from the sales milestones set forth in Section 6.03.

(e) If, during the Term, (i) KKC obtains a license to Exploit any Third Party Patent in the Territory that (i) [***] required for KKC to Develop, Manufacture and Commercialize the Lead Licensed Compound or the Lead Licensed Product (as Manufactured and formulated by Ardelyx prior to the transfer of the responsibility to KKC for the Manufacture of Lead Licensed Product and with regard to the Lead Licensed Compound prior to the exercise of the Manufacturing Option, if such exercise occurred) in accordance with the terms of this Agreement [***], and (ii) which [***] would, in the absence of such license, be infringed by the Development, Manufacture or Commercialization of the Licensed Compound or the Licensed Product (as Manufactured and formulated by Ardelyx prior to the transfer of the responsibility to KKC for the Manufacture of the Lead Licensed Product and with regard to the Lead Licensed Compound prior to the exercise of the Manufacturing Option, if such exercise occurred) in the Territory [***], (iii) KKC does not have any other [***] available to avoid such infringement, and (iv) KKC is required to pay to such Third Party a royalty, milestone payments or other monetary compensation in consideration for the grant of such license ("**Third Party Compensation**"), then for the period during which KKC owes royalties to Ardelyx hereunder, the amounts that would otherwise have been payable as royalties to Ardelyx under this Agreement shall be reduced by [***] Third Party Compensation payable by or on behalf of KKC to such Third Party; provided, however, that in no event shall the amount of the royalties payable by KKC to Ardelyx be reduced by more than [***] percent ([***]).

[***] = Certain confidential information contained in this document, marked by [***], has been omitted because it is both (i) not material and (ii) is the type that the registrant treats as private or confidential.

Section 11.04 Consequences of Ardelyx Triggered Termination (or Right to Terminate) .

If KKC is entitled to terminate this Agreement pursuant to Section 11.02 (a) as a result of a material breach by Ardelyx or Section 11.02 (e) for an insolvency or other transaction described therein affecting Ardelyx, KKC may elect to terminate this Agreement subject to the provisions set forth in Section 11.04 (a), or to continue the Agreement subject to the provisions set forth in Section 11.04 (b).

- (a) If KKC terminates the Agreement under Section 11.02 (a) or under Section 11.02 (e), Section 11.03 shall apply as if such termination were an KKC Triggered Termination, except that (i) [***] and (ii) in consideration of the [***] and any other rights granted under the above provisions in Section 11.03, if this Agreement is terminated pursuant to Section 11.02 (a) by KKC after the First Commercial Sale of the Licensed Product in the Territory, Ardelyx shall [***]; provided however that the [***]. The foregoing shall be [***] in connection with its termination pursuant to Section 11.02(a).
- (i) [***]; and
 - (ii) [***].
- (b) If KKC has the right to terminate this Agreement under Section 11.02 (a) or Section 11.02 (e), but elects to continue this Agreement, this Agreement shall continue in full force and effect except that if KKC is entitled to terminate this Agreement under Section 11.02 (a) due to Ardelyx breach (but not if KKC's right to terminate is based solely on Ardelyx's insolvency pursuant to Section 11.02 (e)), the royalties that Ardelyx shall be entitled to receive on Net Sales of Licensed Products by KKC, its Affiliates, or its Sublicensees as set forth in Section 6.04 shall each be reduced to [***] percent ([***]) in Royalty Period 1 and [***] percent ([***]) in Royalty Period 2, provided that when a Generic Product is launched in the Territory, the royalty rate shall be further reduced to [***] percent ([***]) in Royalty Period 1 and [***] percent ([***]) in Royalty Period 2, subject to the reduction of the Third Party Compensation as set out in Section 6.04 (e).
- (c) Except where expressly provided for otherwise in this Agreement, termination of this Agreement by either Party shall not relieve the Parties of any liability, including without limitation any obligation to make payments hereunder, which accrued hereunder prior to the effective date of such termination, nor preclude any Party from pursuing all rights and remedies it may have hereunder or at law or in equity with respect to any breach of this Agreement, nor prejudice any Party's right to obtain performance of any obligation. In the event of such termination, this Section 11.04 (c) shall survive in addition to others specified in this Agreement to survive in such event.