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): June 18, 2024

IONIS PHARMACEUTICALS, INC.

(Exact Name of Registrant as Specified in Charter)

Delaware
(State or Other Jurisdiction of Incorporation)

000-19125	**33-0336973**
(Commission File No.)	(IRS Employer Identification No.)

2855 Gazelle Court
Carlsbad, CA 92010
(Address of Principal Executive Offices and Zip Code)

Registrant's telephone number, including area code: **(760) 931-9200**

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	Name of each exchange on which registered
Common Stock, $.001 Par Value	"IONS"	The Nasdaq Stock Market, LLC

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (Section 230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (Section 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 June 18, 2024, Ionis Pharmaceuticals, Inc. ("***Ionis***") issued a press release announcing it has entered into an amended and restated license agreement with Otsuka Pharmaceutical Co., Ltd. ("***Otsuka***") under which Otsuka obtains exclusive rights across the Asia-Pacific region to commercialize donidalorsen, an investigational RNA-targeted prophylactic medicine for hereditary angioedema (HAE). Ionis will maintain primary responsibility for the development of donidalorsen, while Otsuka will be responsible for territory-specific development, regulatory filings and commercialization in the Asia-Pacific region and Europe.

A copy of this press release is attached as Exhibit 99.1 to this Current Report and incorporated herein by reference.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	**Description**
99.1	Press Release dated June 18, 2024.
104	Cover Page Interactive Data File (embedded within the Inline XBRL document).

SIGNATURE

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, thereunto duly authorized.

IONIS PHARMACEUTICALS, INC.

Dated: June 18, 2024

By: /s/ Patrick R. O'Neil

PATRICK R. O'NEIL
Executive Vice President, Chief Legal Officer and General Counsel

Ionis announces expanded licensing agreement with Otsuka in Asia Pacific for investigational medicine donidalorsen in hereditary angioedema

- Otsuka will be responsible for commercialization efforts for donidalorsen across both Asia Pacific and Europe
- Ionis plans to independently bring donidalorsen to U.S. patients, if approved

CARLSBAD, Calif., June 18, 2024 -- Ionis Pharmaceuticals, Inc. (Nasdaq: IONS) today announced that it has entered into a license agreement with Otsuka Pharmaceutical Co., Ltd. (Otsuka) under which Otsuka obtains exclusive rights across the Asia-Pacific region for donidalorsen, an investigational RNA-targeted prophylactic medicine for hereditary angioedema (HAE). Ionis will maintain primary responsibility for the development of donidalorsen, while Otsuka will be responsible for territory-specific development, regulatory filings and commercialization in the Asia-Pacific region and Europe.

Ionis plans to file a New Drug Application with the U.S. Food and Drug Administration (FDA) this year, and will independently launch donidalorsen in the U.S., if approved. Ionis and Otsuka previously announced a licensing agreement for donidalorsen in Europe, and Otsuka is also preparing to submit a Marketing Authorization Application to the European Medicines Agency this year.

“Ionis and Otsuka share a steadfast commitment to bring donidalorsen to as many people living with HAE as possible,” said Brett P. Monia, Ph.D., chief executive officer of Ionis. “We look forward to working alongside Otsuka to advance regulatory discussions across Europe and the Asia-Pacific region based on our positive Phase 3 results for donidalorsen, which were presented late last month. In the U.S., we’ve built a robust commercial infrastructure in preparation for our near-term anticipated launches for olezarsen in familial chylomicronemia syndrome and donidalorsen in HAE.”

Under the terms of the Asia-Pacific agreement, Ionis will receive a $20 million upfront payment and milestone payments based on achievement of regulatory and sales targets. Ionis is also eligible to earn tiered royalties, with similar economic terms to the previous agreement for Europe. Originating in Japan, Otsuka brings deep knowledge of regional and local regulations across the Asia-Pacific region, as well as global expertise in delivering rare disease medicines to patients and a robust commercial infrastructure.

Ionis recently reported positive results from the Phase 3 OASIS-HAE and OASISplus studies, presented at the 2024 European Academy of Allergy and Clinical Immunology (EAACI) Annual Congress in Valencia, Spain and published in *The New England Journal of Medicine*.

About Hereditary Angioedema (HAE)
HAE is a rare and potentially life-threatening genetic condition that involves recurrent attacks of severe swelling (angioedema) in various parts of the body, including the hands, feet, genitals, stomach, face and/or throat. HAE is estimated to affect more than 20,000 patients in the U.S. and Europe. In the U.S., doctors frequently use prophylactic treatment approaches to prevent and reduce the severity of HAE attacks in patients.

About Donidalorsen
Donidalorsen is an investigational **LI**gand-**C**onjugated **A**ntisense (LICA) medicine designed to target prekallikrein (PKK), which plays an important role in activating inflammatory mediators associated with acute attacks of hereditary angioedema (HAE). By reducing the production of PKK, donidalorsen could be an effective prophylactic approach to preventing HAE attacks.

About Ionis Pharmaceuticals, Inc.
For three decades, Ionis has invented medicines that bring better futures to people with serious diseases. Ionis currently has five marketed medicines and a leading pipeline in neurology, cardiology, and other areas of high patient need. As the pioneer in RNA-targeted medicines, Ionis continues to drive innovation in RNA therapies in addition to advancing new approaches in gene editing. A deep understanding of disease biology and industry-leading technology propels our work, coupled with a passion and urgency to deliver life-changing advances for patients.

To learn more about Ionis, visit Ionis.com and follow us on X (Twitter) and LinkedIn.

Ionis Forward-looking Statements
This press release includes forward-looking statements regarding Ionis' business, financial guidance and the therapeutic and commercial potential of our commercial medicines, donidalorsen, additional medicines in development and technologies. Any statement describing Ionis' goals, expectations, financial or other projections, intentions or beliefs is a forward-looking statement and should be considered an at-risk statement. Such statements are subject to certain risks and uncertainties including those inherent in the process of discovering, developing and commercializing medicines that are safe and effective for use as human therapeutics, and in the endeavor of building a business around such medicines. Ionis' forward-looking statements also involve assumptions that, if they never materialize or prove correct, could cause its results to differ materially from those expressed or implied by such forward-looking statements. Although Ionis' forward-looking statements reflect the good faith judgment of its management, these statements are based only on facts and factors currently known by Ionis. Except as required by law, we undertake no obligation to update any forward-looking statements for any reason. As a result, you are cautioned not to rely on these forward-looking statements. These and other risks concerning Ionis' programs are described in additional detail in Ionis' annual report on Form 10-K for the year ended December 31, 2023, and most recent Form 10-Q, which are on file with the Securities and Exchange Commission. Copies of these and other documents are available from the Company.

In this press release, unless the context requires otherwise, "Ionis," "Company," "we," "our" and "us" all refer to Ionis Pharmaceuticals and its subsidiaries.

Ionis Pharmaceuticals® is a registered trademark of Ionis Pharmaceuticals, Inc.

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