

**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): **October 18, 2022**

RVL Pharmaceuticals plc

(Exact name of registrant as specified in its charter)

Ireland
(State or other jurisdiction of
incorporation)

001-38709
(Commission File Number)

Not Applicable
(IRS Employer
Identification No.)

400 Crossing Boulevard
Bridgewater, NJ
(Address of principal executive offices)

08807
(Zip Code)

(Registrant's telephone number, including area code): **(908) 809-1300**

Not Applicable

(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))

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

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Ordinary Shares	RVLP	Nasdaq Global Select 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 2.02 Results of Operations and Financial Condition.

On October 18, 2022, RVL Pharmaceuticals plc issued a press release announcing certain preliminary financial results for the quarter ended September 30, 2022. A copy of the press release is furnished herewith as Exhibit 99.1 to this Current Report on Form 8-K.

The information contained in this Current Report on Form 8-K, including Exhibit 99.1 attached hereto, is being furnished and shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), and shall not be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in such filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit

No.	Description
99.1	Press Release issued by RVL Pharmaceuticals plc on October 18, 2022
104	Cover Page Interactive Data File (formatted as Inline XBRL)

SIGNATURES

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.

RVL PHARMACEUTICALS PLC

Dated: October 18, 2022

By: /s/ Brian Markison

Brian Markison

Chief Executive Officer



FOR IMMEDIATE RELEASE

RVL Pharmaceuticals plc Announces Preliminary Third Quarter 2022 UPNEEQ® Net Product Sales

- Expects third quarter 2022 preliminary UPNEEQ net product sales of approximately \$10.0 million, representing an increase of 19% over the second quarter 2022 --
- Third quarter 2022 net product sales growth contributed to approximately \$24.4 million in sales for the nine months ended September 30, 2022 --
- Approximately 3,500 cumulative unique medical aesthetics practices placed orders for UPNEEQ through the end of the third quarter 2022, a 59% increase from the end of the second quarter 2022 --
- Anticipates fourth quarter 2022 UPNEEQ net product sales to grow approximately 20% - 40% over the third quarter 2022, representing sales of approximately \$12 - \$14 million --

BRIDGEWATER, N.J., October 18, 2022 – RVL Pharmaceuticals plc (Nasdaq: RVL) (“RVL” or the “Company”), a specialty pharmaceutical company, today announced preliminary third quarter 2022 net product sales of UPNEEQ® (oxymetazoline hydrochloride ophthalmic solution), 0.1%, the first and only U.S. Food and Drug Administration (“FDA”)-approved ophthalmic solution for blepharoptosis, or droopy eyelids, of approximately \$10.0 million. The Company also announced that from February through September of 2022 it had received orders from approximately 3,500 cumulative unique medical aesthetics practices. RVL further revised its guidance for net product sales of UPNEEQ for the fourth quarter of 2022, indicating an expectation of \$12 to \$14 million, representing sequential growth of 20% to 40% compared to the third quarter of 2022.

“We continue to demonstrate UPNEEQ’s potential within the eyecare and medical aesthetics markets. During the third quarter of 2022, we expanded the number of medical aesthetics practices that have purchased UPNEEQ with 59% growth in the number of providers since the end of the second quarter. In addition, we are working diligently to establish UPNEEQ as an integrated part of medical aesthetics practices, which resulted in nearly 1,000 practices having re-purchased UPNEEQ by the end of the third quarter – an indication of the significant potential opportunity in this market,” stated Brian Markison, Chief Executive Officer of RVL.

“With our expanded medical aesthetics salesforce now in place since late July and with the growth we have observed since then, we believe that we are well positioned to achieve 20% to 40% quarterly sequential net product sales growth in the fourth quarter of 2022,” concluded Markison.

Preliminary Financial Information

The financial and operating data for the third quarter of 2022 is preliminary and may change. This preliminary data has been prepared by, and is the responsibility of, the Company’s management and no independent accounting firm has audited, reviewed, compiled or performed any procedures with respect to this preliminary financial data. There can be no assurance that the Company’s actual results for this quarterly period will not differ from the preliminary financial and operating data and such changes could be material. In addition, the Company’s estimate of UPNEEQ net product sales for the third quarter of 2022 should not be viewed as a substitute for full financial statements for the third quarter of 2022 prepared in accordance with U.S. generally accepted accounting standards. Additional information that will be material to investors will be provided in the financial statements for the three and nine months ended September 30, 2022, and, accordingly, investors should not place undue reliance on the limited preliminary information being provided herein.

Forward Looking Statements

This press release includes statements that express the Company's opinions, expectations, beliefs, plans, objectives, assumptions or projections regarding future events or future results and therefore are, or may be deemed to be, "forward-looking statements." The Company's actual results may vary significantly from the results anticipated in these forward-looking statements, which can generally be identified by the use of forward-looking terminology, including the terms "believes," "expects," "may," "will," "should," "seeks," "projects," "approximately," "intends," "plans," "estimates" or "anticipates," or, in each case, their negatives or other variations or comparable terminology. These forward-looking statements include all matters that are not historical facts. They include statements regarding the Company's intentions, beliefs or current expectations concerning, among other things, its results of operations, financial condition, liquidity, prospects, financial guidance, growth plan, strategies, trends and other events, particularly relating to sales of UPNEEQ and FDA and other regulatory applications, approvals and actions, the continuation of historical trends, our ability to manage costs and service our debt and the sufficiency of our cash balances and cash generated from operating and financing activities for future liquidity and capital resource needs. By their nature, forward-looking statements involve risks and uncertainties because they relate to events and depend on circumstances that may or may not occur in the future. We may not achieve the plans, intentions or expectations disclosed in our forward-looking statements, and you should not place significant reliance on our forward-looking statements. Actual results or events could differ materially from the plans, intentions and expectations disclosed in the forward-looking statements we make. Important factors that could cause actual results and events to differ materially from those indicated in the forward-looking statements include the following: UPNEEQ's ability to reach market acceptance by clinicians and patients; our ability to successfully commercialize UPNEEQ; our customers' willingness to pay the price we charge for UPNEEQ; the results of our marketing and sales expenditures; our dependence on third-party suppliers and distributors for UPNEEQ; UPNEEQ's ability to produce its intended effects; failures of or delays in clinical trials or other delays in obtaining regulatory approval or commencing product sales for new products; the impact of legal proceedings; and other risks and uncertainties more fully described in the "Risk Factors" section of our Annual Report on Form 10-K filed on March 30, 2022 and other filings that the Company makes with the Securities and Exchange Commission. These forward-looking statements speak only as of the time of this release and we do not undertake to publicly update or revise them, whether as a result of new information, future events or otherwise, except as required by law.

IMPORTANT SAFETY INFORMATION

INDICATION

UPNEEQ[®] (oxymetazoline hydrochloride ophthalmic solution), 0.1% is indicated for the treatment of acquired blepharoptosis in adults.

WARNINGS AND PRECAUTIONS

- Ptosis may be associated with neurologic or orbital diseases such as stroke and/or cerebral aneurysm, Horner syndrome, myasthenia gravis, external ophthalmoplegia, orbital infection and orbital masses. Consideration should be given to these conditions in the presence of ptosis with decreased levator muscle function and/or other neurologic signs.
- Alpha-adrenergic agonists as a class may impact blood pressure. Advise UPNEEQ patients with cardiovascular disease, orthostatic hypotension, and/or uncontrolled hypertension or hypotension to seek medical care if their condition worsens.
- Use UPNEEQ with caution in patients with cerebral or coronary insufficiency or Sjögren's syndrome. Advise patients to seek medical care if signs and symptoms of potentiation of vascular insufficiency develop.
- UPNEEQ may increase the risk of angle closure glaucoma in patients with untreated narrow-angle glaucoma. Advise patients to seek immediate medical care if signs and symptoms of acute narrow-angle glaucoma develop.
- Patients should not touch the tip of the single patient-use container to their eye or to any surface, in order to avoid eye injury or contamination of the solution.

ADVERSE REACTIONS

Adverse reactions that occurred in 1-5% of subjects treated with UPNEEQ were punctate keratitis, conjunctival hyperemia, dry eye, blurred vision, instillation site pain, eye irritation and headache.

DRUG INTERACTIONS

- Alpha-adrenergic agonists, as a class, may impact blood pressure. Caution in using drugs such as betablockers, anti-hypertensives, and/or cardiac glycosides is advised. Caution should also be exercised in patients receiving alpha adrenergic receptor antagonists such as in the treatment of cardiovascular disease, or benign prostatic hypertrophy.
- Caution is advised in patients taking monoamine oxidase inhibitors which can affect the metabolism and uptake of circulating amines.

About RVL Pharmaceuticals plc

RVL Pharmaceuticals plc is a specialty pharmaceutical company focused on the commercialization of UPNEEQ® (oxymetazoline hydrochloride ophthalmic solution), 0.1%, for the treatment of acquired blepharoptosis, or low-lying eyelid, in adults. UPNEEQ is the first non-surgical treatment option approved by the FDA for acquired blepharoptosis.

Investor and Media Relations for RVL Pharmaceuticals plc

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