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 2, 2020

Horizon Therapeutics Public Limited Company
(Exact name of registrant as specified in its charter)

Ireland
(State or other jurisdiction
of incorporation)

001-35238
(Commission
File No.)

Not Applicable
(IRS Employer
Identification No.)

Connaught House, 1st Floor, 1 Burlington Road, Dublin 4, D04 C5Y6, Ireland
(Address of principal executive offices)

Registrant’s telephone number, including area code: 011-353-1-772-2100

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:

<table>
<thead>
<tr>
<th>Title of each class</th>
<th>Trading Symbol(s)</th>
<th>Name of each exchange on which registered</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ordinary shares, nominal value $0.0001 per share</td>
<td>HZNP</td>
<td>The Nasdaq Global Select Market</td>
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</tbody>
</table>

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. ☐
On April 2, 2020, Horizon Therapeutics plc announced that it has acquired Curzion Pharmaceuticals, Inc., a privately held development-stage biopharma company, and its development-stage oral selective lysophosphatidic acid 1 receptor (LPAR1) antagonist, CZN001 (renamed HZN-825). Under terms of the agreement, Horizon acquired Curzion for a $45 million upfront cash payment with additional payments contingent on the achievement of development and regulatory milestones. CZN001 was originally discovered and developed by Sanofi, which is eligible to receive contingent payments upon the achievement of development and commercialization milestones and royalties based on revenue thresholds.

Diffuse cutaneous systemic sclerosis (dcSSc) is a rare, chronic autoimmune disease marked by fibrosis, or skin thickening, in areas including hands, forearms, upper arms and thighs. Compared with limited forms of the disease, people with dcSSc are often at a higher risk of internal organ involvement, including interstitial lung disease (ILD), kidney and bowel disease. The U.S. prevalence of dcSSc is approximately 30,000 and the disease carries one of the highest mortality rates among rheumatic diseases. There are no U.S. FDA-approved treatments for dcSSc.

In five Phase 1 trials conducted by Sanofi, HZN-825 was safe and well tolerated. A short-term exploratory Phase 2a study of HZN-825 in dcSSc was completed and showed evidence of potential clinical benefit in this patient population. Longer studies are required to fully demonstrate the potential benefits of HZN-825 in this disease. Horizon plans to begin a pharmacokinetic study in 2020 and meet with the U.S. FDA to inform the Phase 2b pivotal study, which is expected to begin in the first half of 2021.

On April 2, 2020, Horizon issued a press release announcing the transaction. A copy of this press release is attached hereto as Exhibit 99.1.

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**Forward-Looking Statements**

This report contains forward-looking statements, including, but not limited to, statements related to the acquisition of Curzion Pharmaceuticals, Inc. and the benefits thereof, Horizon's strategy, plans, objectives, expectations and intentions, including with respect to HZN-825, the timing of regulatory meetings and a planned Phase 2b pivotal clinical study of HZN-825, the potential benefits of HZN-825 and other statements that are not historical facts. These forward-looking statements are based on Horizon's current expectations and inherently involve significant risks and uncertainties. Actual results and the timing of events could differ materially from those anticipated in such forward looking statements as a result of these risks and uncertainties, which include, without limitation, risks associated with clinical development, such as the risk that guidance from regulatory authorities differs from Horizon's expectations or that clinical trials are not initiated or completed on time and the fact that prior clinical results may not predict the outcome of future trials; risks associated with acquisitions, such as the risk that the businesses will not be integrated successfully, that such integration may be more difficult, time-consuming or costly than expected or that the expected benefits of the transaction will not occur, as well as those described in Horizon's filings with the United States Securities and Exchange Commission, including those factors discussed under the caption “Risk Factors” in those filings. Forward-looking statements speak only as of the date of this report and Horizon does not undertake any obligation to update or revise these statements, except as may be required by law.
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: April 2, 2020

HORIZON THERAPEUTICS PUBLIC LIMITED COMPANY

By: /s/ Paul W. Hoelscher
   Paul W. Hoelscher
   Executive Vice President, Chief Financial Officer
Horizon Therapeutics plc Acquires Curzion Pharmaceuticals, Inc. and its LPAR1 Antagonist Product Candidate to Expand Development-Stage Pipeline

-- Gained Rights to Product Candidate, CZN001 (renamed HZN-825), a Potential Treatment for Diffuse Cutaneous Systemic Sclerosis; a Rare Rheumatic Disease with No FDA-Approved Treatment --

-- Compelling Fit with Horizon's Strategy to Acquire and Develop Medicines Targeting Diseases with High Unmet Need with Focus on Its Core Therapeutic Areas --

DUBLIN – April 2, 2020 — Horizon Therapeutics plc (Nasdaq: HZNP) announced today that it has acquired Curzion Pharmaceuticals, Inc., a privately held development-stage biopharma company, and its development-stage oral selective lysophosphatidic acid 1 receptor (LPAR1) antagonist, CZN001 (renamed HZN-825). Under terms of the agreement, Horizon acquired Curzion for a $45 million upfront cash payment with additional payments contingent on the achievement of development and regulatory milestones.

CZN001 was originally discovered and developed by Sanofi, which is eligible to receive contingent payments upon the achievement of development and commercialization milestones and royalties based on revenue thresholds.

Diffuse cutaneous systemic sclerosis (dcSSc) is a rare, chronic autoimmune disease marked by fibrosis, or skin thickening, in areas including hands, forearms, upper arms and thighs. Compared with limited forms of the disease, people with dcSSc are often at a higher risk of internal organ involvement, including interstitial lung disease (ILD), kidney and bowel disease. The U.S. prevalence of dcSSc is approximately 30,000 and the disease carries one of the highest mortality rates among rheumatic diseases. There are no U.S. FDA-approved treatments for dcSSc.

“This acquisition is one of several transactions we intend to make that directly aligns with our strategy to expand our development-stage pipeline, with a focus on our core therapeutic areas of rheumatology, nephrology, endocrinology and ophthalmology,” said Tim Walbert, chairman, president and chief executive officer, Horizon. “We look forward to meeting with regulatory authorities to define the development pathway for HZN-825 to potentially offer help to those who are impacted by this devastating disease.”

In five Phase 1 trials conducted by Sanofi, HZN-825 was safe and well tolerated. A short-term exploratory Phase 2a study of HZN-825 in dcSSc was completed and showed evidence of potential clinical benefit in this patient population. Longer studies are required to fully demonstrate the potential benefits of HZN-825 in this disease. Horizon plans to begin a pharmacokinetic study in 2020 and meet with the U.S. FDA to inform the Phase 2b pivotal study, which is expected to begin in the first half of 2021.

About Horizon
Horizon is focused on researching, developing and commercializing medicines that address critical needs for people impacted by rare and rheumatic diseases. Our pipeline is purposeful: we apply scientific expertise and courage to bring clinically meaningful therapies to patients. We believe science and compassion must work together to transform lives. For more information on how we go to incredible lengths to impact lives, please visit www.horizontherapeutics.com and follow us on Twitter, LinkedIn, Instagram and Facebook.

Horizon Therapeutics plc
Forward Looking Statements
This press release contains forward-looking statements, including, but not limited to, statements related to the acquisition of Curzion Pharmaceuticals, Inc. and the benefits thereof, Horizon’s strategy, plans, objectives, expectations and intentions, including with respect to HZN-825, the timing of regulatory meetings and a planned Phase 2b pivotal clinical study of HZN-825, the potential benefits of HZN-825 and other statements that are not historical facts. These forward-looking statements are based on Horizon’s current expectations and inherently involve significant risks and uncertainties. Actual results and the timing of events could differ materially from those anticipated in such forward looking statements as a result of these risks and uncertainties, which include, without limitation, risks associated with clinical development, such as the risk that guidance from regulatory authorities differs from Horizon’s expectations or that clinical trials are not initiated or completed on time and the fact that prior clinical results may not predict the outcome of future trials; risks associated with acquisitions, such as the risk that the businesses will not be integrated successfully, that such integration may be more difficult, time-consuming or costly than expected or that the expected benefits of the transaction will not occur, as well as those described in Horizon’s filings with the United States Securities and Exchange Commission, including those factors discussed under the caption “Risk Factors” in those filings. Forward-looking statements speak only as of the date of this press release and Horizon does not undertake any obligation to update or revise these statements, except as may be required by law.

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Horizon Therapeutics plc