Horizon Pharma plc
Form 8-K
October 11, 2016

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 11, 2016

Horizon Pharma Public Limited Company

(Exact name of registrant as specified in its charter)

Ireland	**001-35238**	**Not Applicable**
(State or other jurisdiction of incorporation)	**(Commission File No.)**	**(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))

Horizon Pharma is providing estimates of certain third-quarter 2016 results, confirming expected net sales on a non-GAAP adjusted basis at the low end of its previously announced full-year net sales guidance range and revising its full-year 2016 adjusted EBITDA guidance range, reflecting higher fourth-quarter investment spending. The additional operating expenses reflect strategic investments the Company is making to support future growth opportunities, particularly as it transitions its business mix toward orphan disease medicines and builds a more durable primary care business. The Company s full-year 2016 guidance does not include the previously announced expected acquisition of Raptor Pharmaceutical Corp.

The information in Item 2.02 and 7.01 of this report is being furnished and shall not be deemed to be filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the Exchange Act), or otherwise subject to the liability of that section, nor shall they 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 a filing.

Item 2.02 Results of Operations and Financial Condition.

Estimated Third-Quarter 2016 Results

The Company estimates, on a GAAP basis including the previously announced $65 million settlement with Express Scripts as a one-time reduction in GAAP net sales, its third-quarter 2016 net sales were in the range of $207 to $209 million. The Company estimates that non-GAAP adjusted net sales, which exclude the $65 million settlement with Express Scripts, were in the range of $272 to $274 million. The exclusion of the $65 million settlement from GAAP net sales is the only adjustment reflected in third-quarter non-GAAP adjusted net sales.

The Company expects that third-quarter 2016 adjusted EBITDA will be in the range of $139 to $141 million, which would represent an adjusted EBITDA margin of approximately 51 percent and sequential quarterly growth versus the second quarter of 2016 of approximately 15 percent. See Note Regarding Use of Non-GAAP Financial Measures below for a discussion of the unavailability of expected third-quarter net income and the significance of information that would be needed to estimate third-quarter net income.

Estimated cash and cash equivalents as of September 30, 2016, were approximately $550 million. Cash and cash equivalents as of June 30, 2016, were $424.5 million.

The estimated financial results for the third quarter of 2016 are preliminary and are subject to completion of financial closing procedures. As a result, these amounts may differ from the amounts that will be reflected in the Company s consolidated financial statements as of and for the quarter ended September 30, 2016.

The Company will provide additional information on its third-quarter earnings conference call scheduled for 8:00 a.m. ET on November 7, 2016.

Item 7.01 Regulation FD Disclosure.

Full-Year 2016 Guidance

The Company anticipates, on a GAAP basis including the previously announced $65 million settlement with Express Scripts as a one-time reduction in GAAP net sales, its full-year 2016 net sales will be approximately $960 million. Excluding the $65 million settlement, the Company now expects that net sales on a non-GAAP adjusted basis will be at the low end of its previously announced full-year net sales guidance range of $1.025 billion to $1.050 billion, or approximately $1.025 billion. The exclusion of the $65 million settlement from GAAP net sales guidance is the only adjustment reflected in Horizon Pharma s full-year 2016 non-GAAP adjusted net sales guidance.

The Company is revising its full-year 2016 adjusted EBITDA guidance range as the result of expected net sales at the low end of its non-GAAP adjusted net sales guidance range and anticipated higher investment spending in the fourth quarter of 2016 and now expects adjusted EBITDA to be in the range of $450 to $460 million (prior range was $495 to $510 million). The revised guidance range for adjusted EBITDA reflects anticipated higher operating expenses primarily related to the following future growth opportunities:

Additional investment to expand the Company s managed care organization to account for a broader contracting strategy with pharmacy benefit managers (PBMs) and payers, including the addition of national and regional account managers expected to provide long-term durability to the Company s primary care medicines DUEXIS®, VIMOVO® and PENNSAID® 2%. The Company has secured formulary status with two PBMs that represent approximately 35 percent of covered lives in the U.S. and is in discussions and negotiations with other PBMs and payers with the goal of further increasing access to its medicines.

Additional investment in marketing, medical education and commercial infrastructure to support long-term growth of KRYSTEXXA®, including new patient access managers to focus on account support of additional KRYSTEXXA treatment sites. KRYSTEXXA benefit investigations continue to increase, which are a leading indicator of new patient starts.

Additional investment in clinical development, regulatory and commercial functions for a potential launch of ACTIMMUNE® for Friedreich s ataxia (FA). The Company expects to have top-line results from the ACTIMMUNE FA Phase 3 clinical trial (STEADFAST) in late December 2016.

Note Regarding Use of Non-GAAP Financial Measures

EBITDA, or earnings before interest, taxes, depreciation and amortization, adjusted EBITDA and non-GAAP adjusted net sales are used and provided by Horizon Pharma as non-GAAP financial measures. Adjusted EBITDA and non-GAAP adjusted net sales are intended to provide additional information on Horizon Pharma s performance, operations, profitability and cash flows. Adjustments to Horizon Pharma s GAAP figures as well as EBITDA exclude acquisition-related expenses, an upfront fee for a license of a patent and settlement amounts in relation to prior litigation, as well as non-cash items such as share-based compensation, depreciation and amortization, royalty accretion, non-cash interest expense and other non-cash adjustments. Certain other special items or substantive events may also be included in the non-GAAP adjustments periodically when their magnitude is significant within the periods incurred. Horizon Pharma maintains an established non-GAAP cost policy that guides the determination of what costs will be excluded in non-GAAP measures. Horizon Pharma believes that these non-GAAP financial measures, when considered together with the GAAP figures, can enhance an overall understanding of Horizon Pharma s financial and operating performance. The non-GAAP financial measures are included with the intent of providing investors with a more complete understanding of the Company s historical and expected 2016 financial results and trends and to facilitate comparisons between periods and with respect to projected information. In addition, these non-GAAP financial measures are among the indicators Horizon Pharma s management uses for planning and forecasting purposes and measuring the Company s performance. For example, adjusted EBITDA is used by Horizon Pharma as one measure of management performance under certain incentive compensation arrangements. These non-GAAP financial measures should be considered in addition to, and not as a substitute for, or superior to, financial measures calculated in accordance with GAAP. The non-GAAP financial measures used by the Company may be calculated differently from, and therefore may not be comparable to, non-GAAP financial measures used by other companies. Horizon has not provided reconciliations of its estimated third-quarter or full-year 2016 adjusted EBITDA outlook to an expected net income (loss) outlook because certain items, such as acquisition-related expenses and share-based compensation, that are a component of net income (loss) and impact GAAP income taxes expenses, cannot be reasonably estimated at this time or projected due to the significant impact of changes in Horizon Pharma s stock price and forecasted full-year income by country, the variability associated with the size or timing of acquisitions and other factors. These components of net income (loss) could significantly impact Horizon Pharma s actual net income (loss).

Forward-Looking Statements

This report contains forward-looking statements, including, but not limited to, statements related to Horizon Pharma s expected third quarter and full-year 2016 net sales, non-GAAP adjusted net sales and adjusted EBITDA, expected cash and cash equivalents at of September 30, 2016, expected timing of clinical, regulatory and

commercial events, including with respect to ACTIMMUNE as a potential treatment of FA, anticipated operating expenses related to growth opportunities, the expected impact of a settlement with Express Scripts on Horizon Pharma s future financial results, potential benefits of Horizon Pharma s contracting strategy with PBMs and payers, potential growth of Horizon Pharma s business and other statements that are not historical facts. These forward-looking statements are based on Horizon Pharma 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 that Horizon s actual third quarter and full-year 2016 financial and operating results may differ from its current estimates and expectations; Horizon Pharma s ability to grow net sales from existing products; the availability of coverage and adequate reimbursement and pricing from government and third-party payers and risks relating to the success and costs of Horizon s patient support program; whether Horizon Pharma is able to enter into additional business arrangements with PBMs and payers on favorable terms or at all or whether such arrangements result in the benefits that Horizon Pharma expects; risks associated with clinical development and regulatory approvals; risks that Horizon Pharma s anticipated expenses or investments in growth opportunities will be higher or lower than expected and Horizon Pharma s ability to fund planned expenses and development programs; regulatory obligations and oversight, including any changes in the legal and regulatory environment in which Horizon Pharma operates and those risks detailed from time-to-time under the caption Risk Factors and elsewhere in Horizon Pharma s filings and reports with the SEC. Horizon Pharma undertakes no duty or obligation to update any forward-looking statements contained in this presentation as a result of new information.

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.

Date: October 11, 2016

HORIZON PHARMA PUBLIC LIMITED COMPANY

By: /s/ Paul W. Hoelscher
Paul W. Hoelscher
Executive Vice President, Chief Financial Officer