

**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): May 5, 2021

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:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Ordinary shares, nominal value \$0.0001 per share	HZNP	The 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 or Rule 12b-2 of the Securities Exchange Act of 1934.

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 May 5, 2021, Horizon Therapeutics plc issued a press release announcing its financial results for the first quarter ended March 31, 2021. A copy of this press release is attached hereto as Exhibit 99.1.

The information in this Item 2.02 and the exhibit hereto are 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 5.02 Departure of Directors or Certain Officers; Election of Directors; Appointment of Certain Officers; Compensatory Arrangements of Certain Officers.

On April 29, 2021, Barry Moze, our Executive Vice President, Chief Administrative Officer, informed us that he will be retiring in January 2022. Mr. Moze’s current responsibilities will be assumed by existing executive officers. In connection with his retirement, and in exchange for a release of claims in favor of the Company, we agreed to provide benefits to Mr. Moze consisting of (i) 18 months continuation of health benefits, (ii) continued eligibility for his annual 2021 cash bonus based on performance against pre-established goals, (iii) an amendment to his existing stock options to extend the exercise period through the term of the options and (iv) continued vesting of his restricted stock units and performance stock units (contingent upon meeting the pre-established performance metrics).

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press Release of Horizon Therapeutics plc, dated May 5, 2021.
104	Cover Page Interactive Data File (embedded within the Inline XBRL document).

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: May 5, 2021

HORIZON THERAPEUTICS PUBLIC LIMITED COMPANY

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



Horizon Therapeutics plc Reports First-Quarter 2021 Financial Results; Updating Full-Year 2021 Net Sales Guidance and Full-Year Adjusted EBITDA Guidance to Incorporate Recently Acquired Viela Bio, Inc.

— *First-Quarter 2021 Net Sales of \$342.4 Million; First-Quarter 2021 GAAP Net Loss of \$123.4 Million; Adjusted EBITDA of \$45.8 Million —*

— *First-Quarter 2021 Orphan Segment Net Sales Increased 5 Percent to \$257.5 Million; KRYSTEXXA® (pegloticase injection) First-Quarter 2021 Net Sales Increased 14 Percent to \$106.7 Million —*

— *Updating Full-Year 2021 Net Sales Guidance to \$2.75 Billion to \$2.85 Billion and Full-Year 2021 Adjusted EBITDA Guidance to \$1.02 Billion to \$1.06 Billion to Incorporate Viela, Acquired on March 15, 2021 —*

— *Resumed Supply of TEPEZZA® (teprotumumab-trbw) in April Following U.S. FDA Approval of Increased Scale of Production Process for TEPEZZA —*

— *Completed Acquisition of Viela in March to Drive Long-Term Growth by Significantly Expanding Development Pipeline and Adding to Rare Disease Medicines Portfolio —*

— *Initiated Launch Preparations to Support Potential Approval for UPLIZNA® (inebilizumab-cdon) in Europe as part of Global Expansion Strategy —*

— *Presented New UPLIZNA Data Demonstrating Long-Term Safety and Efficacy in Neuromyelitis Optica Spectrum Disorder (NMOSD) —*

DUBLIN – May 5, 2021 – Horizon Therapeutics plc (Nasdaq: HZNP) today announced first-quarter 2021 financial results. The Company updated its full-year 2021 net sales guidance and its adjusted EBITDA guidance to incorporate Viela Bio, Inc., which was acquired on March 15, 2021.

“We continued to advance our position as one of the fastest-growing biotechs, completing the milestone acquisition of Viela with its strong biologics pipeline, R&D capabilities and rare disease medicine, UPLIZNA,” said Tim Walbert, chairman, president and chief executive officer, Horizon. “We were very pleased with our performance in a quarter challenged by the supply disruption of TEPEZZA due to U.S. government-mandated COVID-19 vaccine orders. With the resumption of TEPEZZA supply, our expanded pipeline and our strong ability to execute, we are well positioned to continue to drive significant value for our patients, shareholders and all of our stakeholders.”

Financial Highlights

(in millions except for per share amounts and percentages)	Q1 21 (1)	Q1 20	% Change
Net sales	\$ 342.4	\$355.9	(4)
Net loss	(123.4)	(13.6)	NM
Non-GAAP net income	7.4	83.2	(91)
Adjusted EBITDA	45.8	107.2	(57)
Loss per share - diluted	(0.55)	(0.07)	NM
Non-GAAP earnings per share - diluted	0.03	0.40	(93)

- (1) First-quarter 2021 results were negatively impacted by a short-term TEPEZZA supply disruption due to U.S. government-mandated COVID-19 vaccine orders.

First-Quarter and Recent Company Highlights

- **Completed Acquisition of Viela:** On March 15, 2021, the Company completed the acquisition of Viela, representing a significant step forward in advancing the Company's strategy to expand its pipeline to accelerate long-term sustainable growth. The acquisition advances the Company's strategy in four ways: it adds a deep, mid-stage biologics pipeline with four candidates in nine development programs; it expands the capabilities of the Company's R&D organization with Viela's early-stage research and translational capabilities and deep scientific knowledge in autoimmune and severe inflammatory diseases; it supports the Company's global expansion strategy; and it diversifies the Company's on-market medicine portfolio with the addition of UPLIZNA, an infused biologic medicine indicated for the rare disease NMOSD.
- **Resumed TEPEZZA Supply:** In March 2021, the U.S. Food and Drug Administration approved a prior approval supplement giving the Company authorization to manufacture an increased scale of TEPEZZA drug product, resulting in a greater number of vials per manufacturing slot at its third-party manufacturer, Catalent. The Company resumed supplying the market in April following a supply disruption that began in December 2020 due to U.S. government-mandated COVID-19 vaccine orders. The Company continues to make progress on adding a second drug product manufacturer by the end of 2021.
- **Advancing the Company's Global Expansion with European UPLIZNA Launch Preparations:** Today, the Company announced additional plans for its global expansion, preparing to build out its European infrastructure to support the potential approval by the first quarter of 2022 of UPLIZNA for NMOSD, which has been granted orphan designation by the European Commission. The Company is adding key infrastructure to support the potential launch of UPLIZNA in Europe in the near term as well as to support the potential launch of additional medicines over the long term. The Company anticipates building a global presence over time in several other markets outside of Europe, including Japan, one of the markets the Company is pursuing for TEPEZZA, where the Company is engaging with the Pharmaceutical and Medical Devices Agency and the Japanese medical community.

- **UPLIZNA Approved in Japan for NMOSD:** In March 2021, the Company’s strategic partner Mitsubishi Tanabe Pharma Corporation received manufacturing and marketing approval of UPLIZNA for the prevention of relapses of NMOSD from the Japanese Ministry of Health, Labour and Welfare.
- **Presented New UPLIZNA Data at Medical Meetings:** New UPLIZNA data were presented at the American Academy of Neurology’s 73rd Annual Meeting in April, including end-of-study data from the open-label extension period (OLP) of the pivotal N-MOmentum trial in patients with NMOSD. The data showed UPLIZNA was generally well-tolerated for at least four years, and that long-term UPLIZNA treatment provided a sustained reduction in NMOSD attack risk from baseline, regardless of when treatment was initiated. Data from the OLP were also recently presented at the American Committee for Treatment and Research in Multiple Sclerosis (ACTRIMS) 2021 Forum, including a poster featuring data demonstrating the safety and efficacy of UPLIZNA in those with previous rituximab exposure. Additionally, a new analysis of the N-MOmentum trial demonstrating that the medicine consistently reduced the risk of worsening disability in people living with NMOSD was published in the May issue of *Neurology Neuroimmunology & Neuroinflammation*.
- **Initiated Enrollment in KRYSTEXXA Monthly Dosing Trial:** In March 2021, the first patient was enrolled in an open-label trial to evaluate a monthly dosing regimen of KRYSTEXXA with methotrexate to treat people with uncontrolled gout. The goal of the trial is to explore whether a monthly dosing regimen can provide similar outcomes as the current dosing schedule, which is every other week.
- **Completed Enrollment in KRYSTEXXA PROTECT Trial:** In January 2021, the Company completed enrollment in its PROTECT open-label trial. The trial, which is evaluating KRYSTEXXA to improve the management of uncontrolled gout for adults with a kidney transplant, enrolled a total of 20 patients. Results are expected in the fourth quarter of 2021.
- **Progressed the TEPEZZA Subcutaneous Administration Clinical Program:** The Company completed dosing in late March for its first trial exploring a subcutaneous (SC) formulation of TEPEZZA. The trial is a small, single-dose Phase 1 pharmacokinetic trial which includes evaluating the use of the Halozyme ENHANZE® drug-delivery technology for a SC formulation, which could potentially shorten drug administration time, reducing healthcare practitioner time and offering additional flexibility and convenience for patients.
- **Received Multiple Best Workplace Awards:** The Company continued to be recognized as a best workplace. In March 2021, the Company ranked No. 1 on the “Fortune Best Workplaces in Biopharma 2021” list and was named to the “Best Workplaces in Ireland 2021” list. In April 2020, the Company was named one of Fortune’s “100 Best Companies to Work For®” in the United States and placed on Crain’s Chicago Business’ 2021 “Best Places to Work in Chicago” list for the sixth consecutive year.

Key Clinical Development Programs

- **TEPEZZA:** an insulin-like growth factor type 1 receptor (IGF-1R) antagonist monoclonal antibody.

- **Chronic Thyroid Eye Disease (TED) Trial:** Phase 4 randomized, placebo-controlled trial evaluating TEPEZZA in chronic TED expected to initiate in mid-2021.
- **Subcutaneous Administration:** Phase 1 pharmacokinetic trial exploring SC administration of TEPEZZA.
- **Diffuse Cutaneous Systemic Sclerosis (dcSSc) Exploratory Trial:** Phase 1 exploratory trial in dcSSc expected to initiate in mid-2021.
- **KRYSTEXXA:** a recombinant uricase enzyme that converts urate into a water-soluble liquid, allantoin, that can be easily excreted from the body.
 - **MIRROR Randomized Controlled Trial:** Phase 4 randomized, placebo-controlled trial evaluating KRYSTEXXA with methotrexate to increase the complete response rate in patients with uncontrolled gout.
 - **PROTECT Trial:** Phase 4 open-label trial evaluating KRYSTEXXA to improve management of uncontrolled gout in kidney transplant patients.
 - **Shorter Infusion Duration Trial:** Phase 4 open-label trial evaluating the impact of administering KRYSTEXXA with methotrexate over a shorter infusion duration in patients with uncontrolled gout.
 - **Monthly Dosing Trial:** Phase 4 open-label trial evaluating monthly dosing of KRYSTEXXA with methotrexate in patients with uncontrolled gout.
 - **Retreatment Trial:** Phase 4 open-label trial evaluating KRYSTEXXA with methotrexate in patients who have previously failed KRYSTEXXA monotherapy; expected to initiate in the second quarter of 2021.
- **UPLIZNA:** an anti-CD19 humanized monoclonal antibody that depletes B cells and the pathogenic cells that produce autoantibodies.
 - **Myasthenia Gravis Trial:** Phase 3 randomized, placebo-controlled trial evaluating UPLIZNA in patients with myasthenia gravis, a chronic, rare, autoimmune neuromuscular disease that affects voluntary muscles, especially those that control the eyes, mouth, throat and limbs.
 - **IgG4-Related Disease Trial:** Phase 3 randomized, placebo-controlled trial evaluating UPLIZNA in patients with IgG4-related disease, which is a group of disorders marked by tumor-like swelling and fibrosis of affected organs, such as the pancreas, salivary glands and kidneys.
 - **Kidney Transplant Desensitization Trial:** Phase 2 open-label trial evaluating UPLIZNA, HZN-4920, or both in highly-sensitized patients waiting for a kidney transplant, which is paused due to COVID-19.
- **HZN-825:** an oral lysophosphatidic acid receptor 1 (LPAR1) antagonist that prevents gene activation.
 - **dcSSc Trial:** Pivotal Phase 2b trial in dcSSc expected to initiate in the second quarter of 2021.
 - **Interstitial Lung Disease Trial:** Pivotal Phase 2b trial in idiopathic pulmonary fibrosis, the most common form of interstitial lung disease, expected to initiate in mid-2021.

- **HZN-4920:** a CD40 ligand antagonist that blocks T cell interaction with the CD40-expressing B cells, disrupting the overactivation of the CD40 ligand co-stimulatory pathway. Several autoimmune diseases are associated with the overactivation this pathway.
 - **Sjögren's Syndrome Trial:** Phase 2b randomized, placebo-controlled trial evaluating HZN-4920 in patients with Sjögren's syndrome, a chronic, systemic autoimmune condition that impacts exocrine glands, including the salivary and tear glands.
 - **Rheumatoid Arthritis Trial:** Phase 2 randomized, placebo-controlled trial evaluating HZN-4920 in patients with rheumatoid arthritis.
 - **Kidney Transplant Rejection Trial:** Phase 2 open-label trial evaluating HZN-4920 in kidney transplant rejection patients.
- **HZN-7734:** an anti-ILT7 human monoclonal antibody that depletes certain dendritic cells. Depleting these cells may interrupt the cycle of inflammation that causes tissue damage in diseases such as lupus, dermatomyositis and a variety of other autoimmune conditions.
 - **Systemic Lupus Erythematosus (SLE) Trial:** Phase 2 trial in SLE, a disease in which the body's immune system attacks its own tissues and organs, expected to initiate in mid-2021.
 - **COVID-19-Related Acute Lung Injury Trial:** Phase 1 trial in COVID-19-related acute lung injury.
- **HZN-1116 Autoimmune Disease Trial:** Phase 1 trial in autoimmune diseases expected to initiate in mid-2021.

First-Quarter Financial Results

Note: For additional detail and reconciliation of non-GAAP financial measures to the most directly comparable GAAP financial measures, please refer to the tables at the end of this release.

- **Net Sales:** First-quarter 2021 net sales were \$342.4 million. First-quarter 2020 net sales were \$355.9 million.
- **Gross Profit:** Under U.S. GAAP, the first-quarter 2021 gross profit ratio was 70.7 percent compared to 72.6 percent in the first quarter of 2020. The non-GAAP gross profit ratio in the first quarter of 2021 was 90.9 percent compared to 90.0 percent in the first quarter of 2020.
- **Operating Expenses:** Research and development (R&D) expenses were 16.8 percent of net sales and selling, general and administrative (SG&A) expenses were 97.0 percent of net sales. Non-GAAP R&D expenses were 14.3 percent of net sales, and non-GAAP SG&A expenses were 63.8 percent of net sales.
- **Income Tax Expense:** On a GAAP basis in the first quarter of 2021, income tax benefit was \$47.8 million. First-quarter non-GAAP income tax expense was \$25.8 million.
- **Net (Loss) Income:** On a GAAP basis, first-quarter 2021 net loss was \$123.4 million. First-quarter 2021 non-GAAP net income was \$7.4 million.

- **Adjusted EBITDA:** First-quarter 2021 adjusted EBITDA was \$45.8 million.
- **(Loss) Earnings per Share:** On a GAAP basis, diluted loss per share in the first quarter of 2021 and 2020 were \$0.55 and \$0.07, respectively. Non-GAAP diluted earnings per share in the first quarter of 2021 and 2020 were \$0.03 and \$0.40, respectively. Weighted average shares outstanding used for calculating GAAP and non-GAAP diluted earnings per share in the first quarter of 2021 were 223.9 million and 234.1 million, respectively.

First-Quarter Segment Results

Management uses net sales and segment operating income to evaluate the performance of the Company's two segments, the orphan segment and the inflammation segment. While segment operating income contains certain adjustments to the directly comparable GAAP figures in the Company's consolidated financial results, it is considered to be prepared in accordance with GAAP for purposes of presenting the Company's segment operating results.

Orphan Segment

(in millions except for percentages)	Q1 21	Q1 20	% Change
KRYSTEXXA®	106.7	93.3	14
RAVICTI®(1)	72.8	61.2	19
PROCYSBI®	43.4	38.3	13
ACTIMMUNE®	28.8	26.5	8
TEPEZZA®(2)	2.1	23.5	(91)
UPLIZNA®(3)	1.8	—	NM
BUPHENYL®(1)	1.7	2.3	(28)
QUINSAIR™	0.2	0.3	(25)
Orphan Net Sales	\$257.5	\$245.4	5
Orphan Segment Operating Income	\$ 1.1	\$ 54.4	(98)

- (1) On Oct. 27, 2020, the Company sold its rights to develop and commercialize RAVICTI and BUPHENYL in Japan to Medical Need Europe AB, part of the Immedica Group. The Company has retained the rights to RAVICTI and BUPHENYL in North America.
- (2) First-quarter 2021 TEPEZZA net sales relate to an adjustment of 2020 gross-to-net reserves recorded in the first quarter of 2021.
- (3) UPLIZNA was acquired on March 15, 2021.

- First-quarter 2021 net sales of the orphan segment, the Company's strategic growth segment, were \$257.5 million, an increase of 5 percent over the prior year's quarter, driven by strong performance of KRYSTEXXA, RAVICTI, PROCYSBI and ACTIMMUNE. First-quarter 2021 net sales include a partial quarter of UPLIZNA net sales. First-quarter 2021 TEPEZZA net sales were negatively impacted by a short-term supply disruption due to U.S. government-mandated COVID-19 vaccine orders.



Inflammation Segment

(in millions except for percentages)	Q1 21	Q1 20	% Change
PENNSAID 2%®	45.8	41.6	10
DUEXIS®	19.5	31.3	(38)
RAYOS®	15.3	18.2	(16)
VIMOVO®(1)	4.3	19.4	(78)
Inflammation Net Sales	\$84.9	\$110.5	(23)
Inflammation Segment Operating Income	\$42.7	\$ 51.9	(18)

(1) On Feb. 27, 2020, Dr. Reddy's Laboratory initiated an at-risk launch of generic VIMOVO in the United States.

- First-quarter 2021 net sales of the inflammation segment were \$84.9 million, and segment operating income was \$42.7 million.

Cash Flow Statement and Balance Sheet Highlights

- On a GAAP basis in the first quarter of 2021, cash used in operating activities was \$3.7 million. Non-GAAP operating cash flow was \$63.5 million.
- As of March 31, 2021, the Company had cash and cash equivalents of \$811.6 million.
- As of March 31, 2021, the total principal amount of debt outstanding was \$2.618 billion. As of March 31, 2021, the gross-debt-to-last-12-months adjusted EBITDA leverage ratio was 2.8 times.

2021 Guidance

The Company now expects full-year 2021 net sales to range between \$2.75 billion and \$2.85 billion, updated from the previous range of \$2.70 billion and \$2.80 billion. Full-year 2021 adjusted EBITDA is now expected to range between \$1.02 billion and \$1.06 billion, updated from the previous guidance of \$1.14 billion and \$1.18 billion. The updated guidance ranges incorporate Viela, which was acquired on March 15, 2021. The Company continues to expect TEPEZZA full-year 2021 net sales of greater than \$1.275 billion and KRYSTEXXA full-year 2021 net sales of greater than \$500 million.

Webcast

At 8 a.m. EST / 1 p.m. IST today, the Company will host a live webcast to review its financial and operating results and provide a general business update. The live webcast and a replay may be accessed at <http://ir.horizontherapeutics.com>. Please connect to the Company's website at least 15 minutes prior to the live webcast to ensure adequate time for any software download that may be needed to access the webcast. A replay of the webcast will be available approximately two hours after the live webcast.

About Horizon

Horizon is focused on the discovery, development and commercialization of medicines that address critical needs for people impacted by rare, autoimmune and severe inflammatory 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](#).

Note Regarding Use of Non-GAAP Financial Measures

EBITDA, or earnings before interest, taxes, depreciation and amortization, and adjusted EBITDA are used and provided by Horizon as non-GAAP financial measures. Horizon provides certain other financial measures such as non-GAAP net income, non-GAAP diluted earnings per share, non-GAAP gross profit and gross profit ratio, non-GAAP operating expenses, non-GAAP operating income, non-GAAP tax expense and tax rate and non-GAAP operating cash flow, each of which include adjustments to GAAP figures. These non-GAAP measures are intended to provide additional information on Horizon's performance, operations, expenses, profitability and cash flows. Adjustments to Horizon's GAAP figures as well as EBITDA exclude acquisition and/or divestiture-related expenses, gain or loss from divestiture, gain or loss from sale of assets, upfront, progress and milestone payments related to license and collaboration agreements, litigation settlements, loss on debt extinguishment, costs of debt refinancing, drug manufacturing harmonization costs, restructuring and realignment costs, the income tax effect on pre-tax non-GAAP adjustments and other non-GAAP income tax adjustments, as well as non-cash items such as share-based compensation, depreciation and amortization, non-cash interest expense, long-lived asset impairment charges 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 maintains an established non-GAAP cost policy that guides the determination of what costs will be excluded in non-GAAP measures. Horizon believes that these non-GAAP financial measures, when considered together with the GAAP figures, can enhance an overall understanding of Horizon'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 2021 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's management uses for planning and forecasting purposes and measuring the Company's performance. For example, adjusted EBITDA is used by Horizon 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 a reconciliation of its full-year 2021 adjusted EBITDA outlook to an expected net income (loss) outlook because certain items such as acquisition/divestiture-related expenses and share-based compensation that are a component of net income (loss) cannot be reasonably projected due to the significant impact of changes in Horizon's stock price, the variability associated with the size or timing of acquisitions/divestitures and other factors. These components of net income (loss) could significantly impact Horizon's actual net income (loss).

Forward-Looking Statements

This press release contains forward-looking statements, including, but not limited to, statements related to Horizon's full-year 2021 net sales and adjusted EBITDA guidance; expected financial performance and operating results in future periods, including potential growth in net sales of certain of Horizon's medicines; the potential benefits and other impacts of the Viela Bio acquisition; development and commercialization plans; expected timing of clinical trials, studies and regulatory submissions; potential market opportunity for and benefits of Horizon's medicines and medicine candidates; and business 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 that Horizon's actual future financial and operating results may differ from its expectations or goals; Horizon's ability to grow net sales from existing medicines; impacts of the COVID-19 pandemic and actions taken to slow its spread, including impacts on supplies and net sales of Horizon's medicines and potential delays in clinical trials; the fact that Horizon's full-year 2021 net sales, adjusted EBITDA and TEPEZZA net sales guidance and the expected timing of certain TEPEZZA clinical trials assume that future committed manufacturing slots for TEPEZZA are not cancelled and are run successfully, which could be impacted by additional government-mandated COVID-19 vaccine production orders and other risks associated with the manufacture of biologic medicines; 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; the availability of coverage and adequate reimbursement and pricing from government and third-party payers; risks relating to Horizon's ability to successfully implement its business strategies, including its global expansion strategy; risks inherent in developing novel medicine candidates and existing medicines for new indications; risks associated with regulatory approvals; risks in the ability to recruit, train and retain qualified personnel; competition, including potential generic competition; the ability to protect intellectual property and defend patents; regulatory obligations and oversight, including any changes in the legal and regulatory environment in which Horizon operates and those risks detailed from time-to-time under the caption "Risk Factors" and elsewhere in Horizon's filings and reports with the SEC. Horizon undertakes no duty or obligation to update any forward-looking statements contained in this press release as a result of new information.

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Horizon Therapeutics plc
Condensed Consolidated Statements of Operations (Unaudited)
(in thousands, except share and per share data)

	Three Months Ended March 31,	
	2021	2020
Net sales	\$ 342,406	\$ 355,909
Cost of goods sold	100,368	97,416
Gross profit	242,038	258,493
OPERATING EXPENSES:		
Research and development	57,693	27,209
Selling, general and administrative	331,992	247,775
Impairment of long-lived assets	12,371	—
Total operating expenses	402,056	274,984
Operating loss	(160,018)	(16,491)
OTHER EXPENSE, NET:		
Interest expense, net	(13,460)	(17,344)
Foreign exchange (loss) gain	(848)	776
Other income, net	3,224	442
Total other expense, net	(11,084)	(16,126)
Loss before benefit for income taxes	(171,102)	(32,617)
Benefit for income taxes	(47,751)	(19,026)
Net loss	\$ (123,351)	\$ (13,591)
Net loss per ordinary share - basic and diluted	\$ (0.55)	\$ (0.07)
Weighted average ordinary shares outstanding - basic and diluted	223,920,768	190,072,112



Horizon Therapeutics plc
Condensed Consolidated Balance Sheets
(in thousands, except share data)

	As of	
	March 31, 2021	December 31, 2020
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	\$ 811,609	\$ 2,079,906
Restricted cash	3,839	3,573
Accounts receivable, net	443,172	659,701
Inventories, net	238,306	75,283
Prepaid expenses and other current assets	334,442	251,945
Total current assets	1,831,368	3,070,408
Property and equipment, net	201,857	189,037
Developed technology and other intangible assets, net	3,210,221	1,782,962
In-process research and development	880,000	—
Goodwill	1,076,388	413,669
Deferred tax assets, net	589,618	560,841
Other assets	57,158	55,699
Total assets	\$7,846,610	\$ 6,072,616
LIABILITIES AND SHAREHOLDERS' EQUITY		
CURRENT LIABILITIES:		
Accounts payable	\$ 42,986	\$ 37,710
Accrued expenses	389,626	485,567
Accrued trade discounts and rebates	325,232	352,463
Long-term debt—current portion	16,000	—
Total current liabilities	773,844	875,740
LONG-TERM LIABILITIES:		
Long-term debt, net	2,562,517	1,003,379
Deferred tax liabilities, net	524,407	66,474
Other long-term liabilities	131,072	101,672
Total long-term liabilities	3,217,996	1,171,525
COMMITMENTS AND CONTINGENCIES		
SHAREHOLDERS' EQUITY:		
Ordinary shares, \$0.0001 nominal value; 600,000,000 shares authorized at March 31, 2021 and December 31, 2020; 225,027,621 and 221,721,674 shares issued at March 31, 2021 and December 31, 2020, respectively; and 224,643,255 and 221,337,308 shares outstanding at March 31, 2021 and December 31, 2020, respectively	22	22
Treasury stock, 384,366 ordinary shares at December 31, 2020 and December 31, 2019	(4,585)	(4,585)
Additional paid-in capital	4,199,823	4,245,945
Accumulated other comprehensive loss	(1,253)	(145)
Accumulated deficit	(339,237)	(215,886)
Total shareholders' equity	3,854,770	4,025,351
Total liabilities and shareholders' equity	\$7,846,610	\$ 6,072,616



Horizon Therapeutics plc
Condensed Consolidated Statements of Cash Flows
(in thousands)

	<u>Three Months Ended March 31,</u>	
	<u>2021</u>	<u>2020</u>
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	\$ (123,351)	\$ (13,591)
Adjustments to reconcile net loss to net cash provided by operating activities:		
Depreciation and amortization expense	70,820	65,741
Equity-settled share-based compensation	61,166	56,421
Impairment of long-lived assets	12,371	—
Amortization of debt discount and deferred financing costs	773	5,569
Deferred income taxes	(28,771)	(2,082)
Foreign exchange and other adjustments	(5,440)	(190)
Changes in operating assets and liabilities:		
Accounts receivable	224,575	(16,869)
Inventories	(13,660)	(14,444)
Prepaid expenses and other current assets	(65,575)	(24,953)
Accounts payable	993	28,551
Accrued trade discounts and rebates	(28,736)	(129,940)
Accrued expenses	(111,963)	(28,087)
Other non-current assets and liabilities	3,070	11,281
Net cash used in operating activities	(3,728)	(62,593)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchases of property and equipment	(18,333)	(119,004)
Payments for long-term investments, net	(3,808)	—
Payments for acquisitions, net of cash acquired	(2,707,358)	(105,200)
Change in escrow deposit for property purchase	—	6,000
Net cash used in investing activities	(2,729,499)	(218,204)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Net proceeds from term loans	1,577,612	—
Proceeds from the issuance of ordinary shares in connection with stock option exercises	19,843	7,050
Payment of employee withholding taxes relating to share-based awards	(128,261)	(46,664)
Net cash provided by (used in) financing activities	1,469,194	(39,614)
Effect of foreign exchange rate changes on cash, cash equivalents and restricted cash	(3,998)	(1,366)
Net decrease in cash, cash equivalents and restricted cash	(1,268,031)	(321,777)
Cash, cash equivalents and restricted cash, beginning of the period ⁽¹⁾	2,083,479	1,080,039
Cash, cash equivalents and restricted cash, end of the period⁽¹⁾	\$ 815,448	\$ 758,262

(1) Amounts include restricted cash balance in accordance with ASU No. 2016-18. Cash and cash equivalents excluding restricted cash are shown on the balance sheet.



Horizon Therapeutics plc
GAAP to Non-GAAP Reconciliations
Net Income and Earnings Per Share (Unaudited)
(in thousands, except share and per share data)

	Three Months Ended March 31,	
	2021	2020
GAAP net loss	\$ (123,351)	\$ (13,591)
Non-GAAP adjustments:		
Acquisition/divestiture-related costs	49,108	(6)
Restructuring and realignment costs	6,093	—
Amortization and step-up:		
Intangible amortization expense	66,369	58,575
Inventory step-up expense	911	—
Amortization of debt discount and deferred financing costs	773	5,569
Impairment of long-lived assets	12,371	—
Share-based compensation	61,166	56,421
Depreciation	4,451	7,165
Upfront, progress and milestone payments related to license and collaboration agreements	3,000	—
Fees related to refinancing activities	—	54
Drug substance harmonization costs	—	290
Total of pre-tax non-GAAP adjustments	204,242	128,068
Income tax effect of pre-tax non-GAAP adjustments	(73,504)	(31,262)
Total of non-GAAP adjustments	130,738	96,806
Non-GAAP Net income	\$ 7,387	\$ 83,215
Non-GAAP Earnings Per Share:		
Weighted average ordinary shares - Basic	223,920,768	190,072,112
Non-GAAP Earnings Per Share - Basic:		
GAAP loss per share - Basic	\$ (0.55)	\$ (0.07)
Non-GAAP adjustments	0.58	0.51
Non-GAAP earnings per share - Basic	\$ 0.03	\$ 0.44
Non-GAAP Net income	\$ 7,387	\$ 83,215
Effect of assumed exchange of Exchangeable Senior Notes, net of tax	—	1,875
Numerator - non-GAAP Net income	\$ 7,387	\$ 85,090
Weighted average ordinary shares - Diluted		
Weighted average ordinary shares - Basic	223,920,768	190,072,112
Ordinary share equivalents	10,190,012	22,984,847
Denominator - weighted average ordinary shares – Diluted	234,110,780	213,056,959
Non-GAAP Earnings Per Share - Diluted		
GAAP loss per share - Diluted	\$ (0.55)	\$ (0.07)
Non-GAAP adjustments	0.58	0.51
Diluted earnings per share effect of ordinary share equivalents	—	(0.04)
Non-GAAP earnings per share - Diluted	\$ 0.03	\$ 0.40



Horizon Therapeutics plc
GAAP to Non-GAAP Reconciliations
EBITDA (Unaudited)
(in thousands)

	Three Months Ended March 31,	
	2021	2020
GAAP net loss	\$ (123,351)	\$ (13,591)
Depreciation	4,451	7,165
Amortization and step-up:		
Intangible amortization expense	66,369	58,575
Inventory step-up expense	911	—
Interest expense, net (including amortization of debt discount and deferred financing costs)	13,460	17,344
Benefit for income taxes	(47,751)	(19,026)
EBITDA	\$ (85,911)	\$ 50,467
Other non-GAAP adjustments:		
Acquisition/divestiture-related costs	49,108	(6)
Restructuring and realignment costs	6,093	—
Impairment of long-lived assets	12,371	—
Share-based compensation	61,166	56,421
Upfront, progress and milestone payments related to license and collaboration agreements	3,000	—
Fees related to refinancing activities	—	54
Drug substance harmonization costs	—	290
Total of other non-GAAP adjustments	131,738	56,759
Adjusted EBITDA	\$ 45,827	\$ 107,226



Horizon Therapeutics plc
GAAP to Non-GAAP Reconciliations
Operating Income (Unaudited)
(in thousands)

	Three Months Ended March 31,	
	2021	2020
GAAP operating loss	\$ (160,018)	\$ (16,491)
Non-GAAP adjustments:		
Acquisition/divestiture-related costs	49,391	284
Restructuring and realignment costs	6,093	—
Amortization and step-up:		
Intangible amortization expense	66,369	58,575
Inventory step-up expense	911	—
Impairment of long-lived assets	12,371	—
Share-based compensation	61,166	56,421
Depreciation	4,451	7,165
Upfront, progress and milestone payments related to license and collaboration agreements	3,000	—
Fees related to refinancing activities	—	54
Drug substance harmonization costs	—	290
Total of non-GAAP adjustments	203,752	122,789
Non-GAAP operating income	\$ 43,734	\$ 106,298
Orphan segment operating income	1,054	54,356
Inflammation segment operating income	42,680	51,942
Total segment operating income	\$ 43,734	\$ 106,298
Foreign exchange (loss)/gain	(848)	776
Other income, net	2,941	152
Adjusted EBITDA	\$ 45,827	\$ 107,226



Horizon Therapeutics plc
GAAP to Non-GAAP Reconciliations
Gross Profit and Operating Cash Flow (Unaudited)
(in thousands, except percentages)

	<u>Three Months Ended March 31,</u>	
	<u>2021</u>	<u>2020</u>
Non-GAAP Gross Profit:		
GAAP gross profit	\$ 242,038	\$ 258,493
Non-GAAP gross profit adjustments:		
Acquisition/divestiture-related costs	205	—
Intangible amortization expense	66,169	58,374
Inventory step-up expense	911	—
Share-based compensation	1,936	2,689
Depreciation	115	328
Drug substance harmonization costs	—	290
Total of Non-GAAP adjustments	69,336	61,681
Non-GAAP gross profit	\$ 311,374	\$ 320,174
GAAP gross profit %	70.7%	72.6%
Non-GAAP gross profit %	90.9%	90.0%
GAAP cash used in operating activities	\$ (3,728)	\$ (62,593)
Cash payments for acquisition/divestiture-related costs	64,192	(17)
Cash payments for restructuring and realignment costs	—	95
Cash payments for upfront, progress and milestone payments related to license and collaboration agreement	3,000	—
Cash payments relating to refinancing activities	—	73
Non-GAAP operating cash flow	\$ 63,464	\$ (62,442)



Horizon Therapeutics plc
GAAP to Non-GAAP Reconciliations
EBITDA (Unaudited) - 2020
(in thousands)

	<u>Twelve Months</u> <u>Ended December 31,</u> <u>2020</u>
GAAP net income	\$ 389,796
Depreciation	24,303
Amortization and step-up:	
Intangible amortization expense	255,148
Inventory step-up expense	—
Interest expense, net (including amortization of debt discount and deferred financing costs)	59,616
Expense for income taxes	11,849
EBITDA	\$ 740,712
Other non-GAAP adjustments:	
Acquisition/divestiture-related costs	49,196
Restructuring and realignment costs	(141)
Impairment of long-lived assets	1,713
Gain on sale of assets	(4,883)
Share-based compensation	146,627
Upfront, progress and milestone payments related to license and collaboration agreements	33,000
Fees related to refinancing activities	54
Loss on debt extinguishment	31,856
Drug substance harmonization costs	542
Total of other non-GAAP adjustments	257,964
Adjusted EBITDA	\$ 998,676



Horizon Therapeutics plc
GAAP to Non-GAAP Tax Rate Reconciliation (Unaudited)
(in millions, except percentages and per share amounts)

	Q1 2021				
	Pre-tax Net (Loss) Income	Income Tax (Benefit) Expense	Tax Rate	Net Income (Loss)	Diluted Earnings (Loss) Per Share
As reported - GAAP	\$ (171.1)	\$ (47.8)	27.9%	\$ (123.4)	\$ (0.55)
Non-GAAP adjustments	204.2	73.5		130.7	
Non-GAAP	<u>\$ 33.1</u>	<u>\$ 25.8</u>	<u>77.7%</u>	<u>\$ 7.4</u>	<u>\$ 0.03</u>

	Q1 2020				
	Pre-tax Net (Loss) Income	Income Tax (Benefit) Expense	Tax Rate	Net Income (Loss)	Diluted Earnings (Loss) Per Share
As reported - GAAP	\$ (32.6)	\$ (19.0)	58.3%	\$ (13.6)	\$ (0.07)
Non-GAAP adjustments	128.1	31.3		96.8	
Non-GAAP	<u>\$ 95.5</u>	<u>\$ 12.2</u>	<u>12.8%</u>	<u>\$ 83.2</u>	<u>\$ 0.40</u>



Horizon Therapeutics plc
Certain Income Statement Line Items - Non-GAAP Adjusted
For the Three Months Ended March 31, 2021
(Unaudited)

	COGS	Research & Development	Selling, General & Administrative	Impairment of Long-Lived Assets	Interest Expense	Other Expense	Income Tax Benefit (Expense)
GAAP as reported	\$(100,368)	\$ (57,693)	\$ (331,992)	\$ (12,371)	\$(13,460)	\$3,224	\$ 47,751
Non-GAAP Adjustments (in thousands):							
Acquisition/divestiture-related costs ⁽¹⁾	205	3	49,183	—	—	(283)	—
Restructuring and realignment costs ⁽²⁾	—	—	6,093	—	—	—	—
Amortization and step-up:							
Intangible amortization expense ⁽³⁾	66,169	—	200	—	—	—	—
Inventory step-up expense ⁽⁴⁾	911	—	—	—	—	—	—
Amortization of debt discount and deferred financing costs ⁽⁵⁾	—	—	—	—	773	—	—
Impairment of long lived assets ⁽⁶⁾	—	—	—	12,371	—	—	—
Share-based compensation ⁽⁷⁾	1,936	5,616	53,614	—	—	—	—
Depreciation ⁽⁸⁾	115	49	4,287	—	—	—	—
Upfront, progress and milestone payments related to license and collaboration agreements ⁽⁹⁾	—	3,000	—	—	—	—	—
Income tax effect on pre-tax non-GAAP adjustments ⁽¹⁰⁾	—	—	—	—	—	—	(73,504)
Total of non-GAAP adjustments	69,336	8,668	113,377	12,371	773	(283)	(73,504)
Non-GAAP	\$ (31,032)	\$ (49,025)	\$ (218,615)	\$ —	\$(12,687)	\$2,941	\$ (25,753)

Horizon Therapeutics plc
Certain Income Statement Line Items - Non-GAAP Adjusted
For the Three Months Ended March 31, 2020
(Unaudited)

	COGS	Research & Development	Selling, General & Administrative	Interest Expense	Other Income, net	Income Tax Benefit (Expense)
GAAP as reported	\$ (97,416)	\$ (27,209)	\$ (247,775)	\$ (17,344)	\$ 442	\$ 19,026
Non-GAAP Adjustments (in thousands):						
Acquisition/divestiture-related costs ⁽¹⁾	—	—	284	—	(290)	—
Amortization and step-up:						
Intangible amortization expense ⁽³⁾	58,374	—	201	—	—	—
Amortization of debt discount and deferred financing costs ⁽⁵⁾	—	—	—	5,569	—	—
Share-based compensation ⁽⁷⁾	2,689	6,376	47,356	—	—	—
Depreciation ⁽⁸⁾	328	25	6,812	—	—	—
Fees related to refinancing activities ⁽¹¹⁾	—	—	54	—	—	—
Drug substance harmonization costs ⁽¹²⁾	290	—	—	—	—	—
Income tax effect on pre-tax non-GAAP adjustments ⁽¹⁰⁾	—	—	—	—	—	(31,262)
Total of non-GAAP adjustments	61,681	6,401	54,707	5,569	(290)	(31,262)
Non-GAAP	\$ (35,735)	\$ (20,808)	\$ (193,068)	\$ (11,775)	\$ 152	\$ (12,236)

NOTES FOR CERTAIN INCOME STATEMENT LINE ITEMS - NON-GAAP

1. Represents transaction and integration costs, including advisory, legal, consulting and certain employee-related costs, incurred in connection with our acquisitions and divestitures. Costs recovered from subleases of acquired facilities and reimbursed expenses incurred under transition arrangements for divestitures are also reflected in this line item.
2. Represents the recording of a liability for maintenance charges as a result of vacating the leased Lake Forest office.
3. Intangible amortization expenses are associated with our intellectual property rights, developed technology and customer relationships related to TEPEZZA, KRYSTEXXA, RAVICTI, PROCYSBI, ACTIMMUNE, BUPHENYL, UPLIZNA, PENNSAID 2% and RAYOS.
4. During the three months ended March 31, 2021, we recognized in cost of goods sold \$0.9 million for inventory step-up expense related to UPLIZNA inventory revalued in connection with the Viela acquisition. Because inventory step-up expense is related to an acquisition, will not continue indefinitely and has a significant effect on our gross profit, gross margin percentage and net loss for all affected periods, the Company excludes inventory step-up expense from its non-GAAP financial measures.
5. Represents amortization of debt discount and deferred financing costs associated with our debt.
6. During the three months ended March 31, 2021, we recorded a right-of-use asset impairment charge of \$12.4 million as a result of vacating the leased Lake Forest office.
7. Represents share-based compensation expense associated with our stock option, restricted stock unit and performance stock unit grants to our employees and non-employee directors, and our employee share purchase plan.
8. Represents depreciation expense related to our property, equipment, software and leasehold improvements.
9. During the three months ended March 31, 2021, we recognized a \$3.0 million progress payment in relation to the collaboration agreement with HemoShear.
10. Income tax adjustments on pre-tax non-GAAP adjustments represent the estimated income tax impact of each pre-tax non-GAAP adjustment based on the statutory income tax rate of the applicable jurisdictions for each non-GAAP adjustment.
11. Represents arrangement and other fees relating to our refinancing activities.
12. During the year ended December 31, 2016, we entered into a definitive agreement to acquire certain rights to interferon gamma-1b, marketed as IMUKIN in an estimated thirty countries primarily in Europe and the Middle East, or the IMUKIN purchase agreement. We already owned the rights to interferon gamma-1b marketed as ACTIMMUNE in the United States, Canada and

Japan. In connection with the IMUKIN purchase agreement, we also committed to pay our contract manufacturer certain amounts related to the harmonization of the manufacturing processes for ACTIMMUNE and IMUKIN drug substance, or the harmonization program. At the time we entered into the IMUKIN purchase agreement and the harmonization program commitment was made, we had anticipated achieving certain benefits should the Phase 3 clinical trial evaluating ACTIMMUNE for the treatment of Friedreich's ataxia, be successful. If the study had been successful and if U.S. marketing approval had subsequently been obtained, we had forecasted significant increases in demand for the medicine and the harmonization program would have resulted in significant benefits for us. Following our discontinuation of the Friedreich's ataxia program, we determined that certain assets, including an upfront payment related to the IMUKIN purchase agreement, were impaired, and the costs under the harmonization program would no longer have benefit to us and should be expensed as incurred.