Horizon Therapeutics plc Reports First-Quarter 2022 Financial Results

First-Quarter 2022 Results:

-- Net Sales of $885.2 Million --
-- GAAP Net Income of $204.3 Million; Adjusted EBITDA of $371.2 Million --
-- TEPEZZA® (teprotumumab-trbw) Net Sales of $501.5 Million --
-- KRYSTEXXA® (pegloticase injection) Net Sales of $140.7 Million --
-- Cash Position of $1.64 Billion as of March 31, 2022 --

Full-Year 2022 Guidance:

-- Maintaining Full-Year 2022 Net Sales Guidance of $3.9 Billion to $4.0 Billion, Representing 22% Growth at the Midpoint --
-- Maintaining Full-Year 2022 Adjusted EBITDA Guidance of $1.63 Billion to $1.70 Billion, Representing 30% Growth and 230 Basis Points of Margin Expansion at the Midpoint --
-- Continue to Expect TEPEZZA Net Sales Percentage Growth in the Mid-30s --
-- Continue to Expect KRYSTEXXA Net Sales Growth of More Than 20% --

Recent Company Highlights:

-- U.S. FDA Granted Priority Review of the Company's Supplemental Biologics License Application (sBLA) for Co-Treatment of KRYSTEXXA Plus Methotrexate with a July 7, 2022 PDUFA Action Date --
-- European Commission Approved UPLIZNA® (inebilizumab-cdon) for the Treatment of Adult Patients with NMOSD --
-- Initiated Launch Preparations to Support Potential Approvals for TEPEZZA and UPLIZNA in Brazil as part of Global Expansion Strategy --
-- Initiated Two Clinical Trials to Date, Five Additional Trials Expected to Initiate this Year --
-- Announced Positive Topline Data from Phase 2 Trial Evaluating Dazodalibep (HZN-4920) in Patients with Rheumatoid Arthritis (RA); Study Met Primary Endpoint and Dazodalibep was Well Tolerated --

DUBLIN – May 4, 2022 – Horizon Therapeutics plc (Nasdaq: HZNP) today announced first-quarter 2022 financial results and maintained its full-year 2022 net sales and adjusted EBITDA guidance.

"Our first quarter financial and operational performance established a strong start to the year, with meaningful progress on our strategic priorities and positioning us well for another year of top-tier growth," said Tim Walbert, chairman, president and chief executive officer, Horizon. "We advanced our pipeline with the initiation of two clinical trials, drove strong performance of our key growth drivers, TEPEZZA, KRYSTEXXA and UPLIZNA, and continued our international expansion. In addition, the FDA granted priority review of our sBLA to expand the KRYSTEXXA label to include co-treatment of KRYSTEXXA plus methotrexate, marking an important milestone in our journey to help more uncontrolled gout patients benefit from the medicine."

Financial Highlights

(in millions except for per share amounts and percentages)	Q1 22	Q1 21[1]	% Change
Net sales	$ 885.2	$ 342.4	159
Net income (loss)	204.3	(123.4)	NM
Non-GAAP net income	315.8	4.8	NM
Adjusted EBITDA	371.2	42.8	767
Earnings (loss) per share - diluted	0.87	(0.55)	NM
Non-GAAP earnings per share - diluted	1.34	0.02	NM

(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

- **FDA Granted Priority Review of sBLA for Co-Treatment of KRYSTEXXA Plus Methotrexate:** In March, the U.S. Food and Drug Administration (FDA) granted priority review of the Company's sBLA to expand the label for KRYSTEXXA to include co-treatment with methotrexate. The Company submitted an sBLA in January based on results from the MIRROR Phase 4 randomized placebo-controlled trial which demonstrated that 71% of patients receiving KRYSTEXXA plus methotrexate achieved a complete response, a more than 30 percentage-point improvement compared to patients who were randomized to receive KRYSTEXXA plus placebo ($p<0.0001$). An updated label would allow the Company's commercial team to promote KRYSTEXXA plus methotrexate to physicians. The Prescription Drug User Fee Act (PDUFA) action date is July 7, 2022.

- **UPLIZNA Approved in Europe and China for NMOSD:** In April, the European Commission approved UPLIZNA for the treatment of adult patients with neuromyelitis optica spectrum disorder (NMOSD) who are Anti-Aquaporin-4 Immunoglobulin G Seropositive (AQP4-IgG+). Germany is expected to be the first country where the Company initiates promotional and commercialization efforts in the EU. In March, the Company's strategic partner Hansoh Pharmaceutical Group Company Limited received approval of UPLIZNA for the treatment of NMOSD from the National Medical Products Administration of the People's Republic of China.

- **Advancing the Company's Global Expansion with TEPEZZA and UPLIZNA Launch Preparations in Brazil:** The Company initiated its build-out of primary infrastructure in Brazil to support the potential approvals of TEPEZZA for thyroid eye disease (TED) and UPLIZNA for NMOSD. There are no on-label treatments that are commercially available for TED or NMOSD in Brazil. Brazil marks the newest market that the company is pursuing as part of its global expansion strategy.

- **Initiated Enrollment in Two Clinical Trials:**
    - In January, the first patient enrolled in a pivotal Phase 2b trial to evaluate HZN-825 in patients with idiopathic pulmonary fibrosis (IPF), the most common form of interstitial lung disease. IPF is a rare, progressive lung disease caused by inflammation and fibrosis, or scarring, of the lungs.
    - In February, the first patient enrolled in a Phase 3 trial in Japan to evaluate TEPEZZA in patients with moderate-to-severe active TED, a serious, progressive and potentially vision-threatening rare autoimmune disease. TEPEZZA has not been approved for commercial use in Japan.
- **Announced Positive Topline Proof-of-Concept Data from Dazodalibep Rheumatoid Arthritis Trial:** In May, the Company announced positive topline results from the Phase 2 randomized placebo-controlled trial of dazodalibep in patients with RA. The primary endpoint of the trial was met across all doses, a statistically significant change from baseline in DAS28-CRP, a standardized measure of disease activity in RA trials, at Day 113. In addition, dazodalibep was well tolerated across all doses. The impact observed after various doses will inform the dosing regimen for other studies with dazodalibep.

- **Presented New UPLIZNA Data at Key Medical Meetings:** In April, multiple new data were presented at the American Academy of Neurology (AAN) 2022 Annual Meeting, including new data from the Phase 3 trial showing no significant differences in attacks or Expanded Disability Status Scale (EDSS) worsening between NMOSD patients treated with UPLIZNA with one pre-study attack and those with two or more pre-study attacks. A separate new analysis of the Phase 3 trial showed long-term treatment with UPLIZNA improved pain and quality of life outcomes for at least three years. Additionally, new data from the Phase 3 trial were presented at the 48th Annual Meeting of the North American Neuro-Ophthalmology Society (NANOS 2022) in February, showing that treatment with UPLIZNA effectively reduced the severity of attacks in patients with NMOSD.

- **Presented New TEPEZZA Data at Key Medical Meeting:** In February, multiple new data were presented at NANOS 2022, including new data from a post-marketing safety analysis of hearing-related events associated with TEPEZZA. Among the thousands of patients included in the analysis, approximately 10% of all cases reported to the safety database included a hearing-related event. This rate was similar to the rate in the Company's initial trials. The majority of hearing-related adverse events in the pivotal trials and post-approval have been mild to moderate and reversible. No new safety concerns were observed in the post-marketing safety analysis.

- **New TEPEZZA Chronic TED Data Published:** In January, new data from an independent physician case study of six chronic TED patients who showed benefit after treatment with TEPEZZA were published in *Eye*, the official journal for the Royal College of Ophthalmologists. The case study adds to the growing body of evidence supporting the use of TEPEZZA in chronic TED patients, with nearly 60 chronic TED patients across multiple case studies who have demonstrated benefit.

- **Expanding East Coast R&D and Technical Operations Hub:** In January, the Company announced it entered into an agreement to lease a new 192,000-square-foot, state-of-the-art facility under construction in Rockville, Maryland that will serve as the Company's primary East Coast research and development and technical operations hub. The Company is significantly expanding and consolidating its East Coast footprint with the new facility, nearly quadrupling its current Maryland footprint acquired in the 2021 acquisition of Viela. The Company anticipates adding key R&D talent to support its growing research and development capabilities and expanded pipeline.

- **Received Multiple Best Workplace Awards:** In April, the Company was named one of Fortune's "100 Best Companies to Work For®" for the second consecutive year, retaining the highest ranked position in the biotechnology/pharmaceutical category. In March, Great Place to Work Ireland recognized Horizon as one of the "Best Workplaces in Ireland 2022" for the third consecutive year. These recognitions add to the many workplace awards the Company has received, reflecting the high level of engagement of its employees.

- **New President, Global Commercial Operations:** The Company announced today that Jacopo Leonardi will join Horizon as president, global commercial operations, reporting to Tim Walbert, chairman, president and chief executive officer, effective May 16, 2022. Leonardi is an accomplished life sciences executive with more than two decades of commercial experience, which includes commercial launch, R&D new product planning as well as accelerating growth for high performing businesses in rare disease and immunology. Leonardi will oversee the U.S. and international commercial organizations, commercial development (life-cycle management) and global medical affairs.

Key Clinical Development Programs

- **Daxdilimab (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, and a variety of other autoimmune conditions.
    - **Systemic Lupus Erythematosus (SLE) Trial:** Phase 2 randomized placebo-controlled trial underway to evaluate daxdilimab in patients with SLE, a disease in which the body's immune system attacks its own tissues and organs.
    - **Alopecia Areata Trial:** Phase 2 trial to evaluate daxdilimab in patients with alopecia areata, an autoimmune disorder characterized by nonscarring hair loss, expected to initiate in the second quarter of 2022.
    - **Discoid Lupus Erythematosus (DLE) Trial:** Phase 2 trial to evaluate daxdilimab in patients with DLE, a rare, chronic, inflammatory skin condition characterized by lesions that result in scarring, expected to initiate by mid-year 2022.
    - **Lupus Nephritis Trial:** Phase 2 trial to evaluate daxdilimab in patients with lupus nephritis, a rare, autoimmune and inflammatory condition of the kidney, expected to initiate in the third quarter of 2022.
    - **Dermatomyositis Trial:** Phase 2 trial to evaluate daxdilimab in patients with dermatomyositis, a rare, autoimmune disorder characterized by rashes, debilitating muscle weakness and interstitial lung disease, expected to initiate in the fourth quarter of 2022.

- **Dazodalibep (HZN-4920)**, a CD40 ligand antagonist that blocks T-cell interaction with CD40-expressing B-cells, disrupting the overactivation of the CD40 ligand co-stimulatory pathway. Several autoimmune diseases are associated with the overactivation of this pathway.
    - **Sjögren's Syndrome Trial:** Phase 2 randomized placebo-controlled trial underway to evaluate dazodalibep in patients with Sjögren's syndrome, a chronic, systemic autoimmune condition that impacts exocrine glands, including the salivary and tear glands. The trial completed enrollment in April 2022.
    - **Rheumatoid Arthritis Trial:** Phase 2 randomized placebo-controlled trial to evaluate dazodalibep in patients with RA. Topline results were announced in May 2022. The trial met the primary endpoint and dazodalibep was well tolerated.
    - **Kidney Transplant Rejection Trial:** Phase 2 open-label trial underway to evaluate dazodalibep in kidney transplant rejection patients.
    - **Focal Segmental Glomerulosclerosis (FSGS) Trial:** Phase 2 trial to evaluate dazodalibep in patients with FSGS, a rare kidney disorder characterized by scarring of glomeruli, expected to initiate in the fourth quarter of 2022.

- **HZN-825**, an oral lysophosphatidic acid receptor 1 ($LPAR_1$) antagonist designed to prevent gene activation.
    - **Diffuse Cutaneous Systemic Sclerosis Trial:** Pivotal Phase 2b trial underway to evaluate HZN-825 in diffuse cutaneous systemic sclerosis.
    - **Idiopathic Pulmonary Fibrosis Trial:** Pivotal Phase 2b trial initiated in January 2022 to evaluate HZN-825 in idiopathic pulmonary fibrosis, the most common form of interstitial lung disease.

- **UPLIZNA**, an anti-CD19 humanized monoclonal antibody that depletes B-cells, including the pathogenic cells that produce autoantibodies.
    - **Myasthenia Gravis Trial:** Phase 3 randomized placebo-controlled trial underway to evaluate 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 underway to evaluate 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.

- **TEPEZZA**, an insulin-like growth factor type 1 receptor (IGF-1R) antagonist monoclonal antibody.
    - **Chronic TED Trial:** Phase 4 randomized placebo-controlled trial underway to evaluate TEPEZZA in chronic TED.
    - **TED in Japan (OPTIC-J) Trial:** Phase 3 randomized placebo-controlled trial in Japan initiated in February 2022 to evaluate TEPEZZA in patients with moderate-to-severe active TED.

- **Subcutaneous (SC) Administration Trial:** Phase 1b trial to explore the pharmacokinetics, safety, tolerability, efficacy and immunogenicity of subcutaneous administration of TEPEZZA in patients with TED, expected to initiate by mid-year 2022.
- **Diffuse Cutaneous Systemic Sclerosis Exploratory Trial:** Phase 1 exploratory trial underway to evaluate TEPEZZA in diffuse cutaneous systemic sclerosis.

- **KRYSTEXXA,** a recombinant uricase enzyme that converts urate into a water-soluble liquid, allantoin, that can be easily excreted from the body.
  - **Shorter Infusion Duration Trial:** Phase 4 open-label trial underway to evaluate the impact of administering KRYSTEXXA plus methotrexate over a shorter infusion duration in patients with uncontrolled gout.
  - **Monthly Dosing Trial:** Phase 4 open-label trial underway to evaluate monthly dosing of KRYSTEXXA plus methotrexate in patients with uncontrolled gout.
  - **Retreatment Trial:** Phase 4 open-label trial underway to evaluate KRYSTEXXA plus methotrexate in patients who were not complete responders to KRYSTEXXA monotherapy.

- **HZN-1116,** a fully human monoclonal antibody designed to bind and neutralize the function of the FLT3-ligand, thereby reducing both conventional and plasmacytoid dendritic cells.
  - **Autoimmune Disease Trial:** Phase 1 trial underway to evaluate HZN-1116 in patients with autoimmune diseases.

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 2022 net sales were $885.2 million, an increase of 159% compared to the first quarter of 2021. First-quarter 2021 results were negatively impacted by a short-term TEPEZZA supply disruption due to U.S. government-mandated COVID 19-vaccine orders.

- **Gross Profit:** Under U.S. GAAP, the first-quarter 2022 gross profit ratio was 75.7% compared to 70.7% in the first quarter of 2021. The non-GAAP gross profit ratio in the first quarter of 2022 was 88.9% compared to 90.9% in the first quarter of 2021.

- **Operating Expenses:** R&D expenses were 11.7% of net sales and SG&A expenses were 42.1% of net sales in the first quarter of 2022. First-quarter non-GAAP R&D expenses were 10.4% of net sales and non-GAAP SG&A expenses were 37.1% of net sales.

- **Income Tax Expense (Benefit):** On a GAAP basis in the first quarter of 2022, income tax benefit was $31.5 million. First-quarter non-GAAP income tax expense was $35.7 million.

- **Net Income:** In the first-quarter of 2022, net income on a GAAP and non-GAAP basis was $204.3 million and $315.8 million, respectively.

- **Adjusted EBITDA:** First-quarter 2022 adjusted EBITDA was $371.2 million.

- **Earnings (Loss) per Share:** On a GAAP basis, diluted earnings (loss) per share in the first quarter of 2022 and 2021 were $0.87 and $(0.55). Non-GAAP diluted earnings per share in the first quarter of 2022 and 2021 were $1.34 and $0.02, respectively. Weighted average shares outstanding used for calculating GAAP and non-GAAP diluted earnings per share in the first quarter of 2022 were 236.0 million.

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, such as the exclusion of upfront and milestone payments related to license and collaboration agreements, 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 22	Q1 21	% Change
TEPEZZA®(1)	$ 501.5	$ 2.1	NM
KRYSTEXXA®	140.7	106.7	32
RAVICTI®	78.3	72.8	7
PROCYSBI®	49.6	43.4	14
ACTIMMUNE®	31.3	28.8	9
UPLIZNA®(2)	30.5	1.8	NM
BUPHENYL®	2.2	1.7	30
QUINSAIR™	0.3	0.2	41
Orphan Net Sales	**$ 834.4**	**$ 257.5**	**224**
Orphan Segment Operating Income	**$ 351.5**	**$ 1.1**	**NM**

(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.
(2) UPLIZNA was acquired on March 15, 2021. First-quarter 2022 UPLIZNA net sales included $5.2 million in revenue and milestone payments from the Company's international partners.

- First-quarter 2022 net sales of the orphan segment, the Company's strategic growth segment, were $834.4 million, driven by the strong performance of TEPEZZA, KRYSTEXXA, RAVICTI, PROCYSBI, ACTIMMUNE and UPLIZNA. First-quarter 2022 orphan segment operating income was $351.5 million.

Inflammation Segment

(in millions except for percentages)	Q1 22	Q1 21	% Change
PENNSAID 2%®	$ 35.4	$ 45.8	(23)
RAYOS®	13.5	15.3	(12)
DUEXIS®[(1)]	1.1	19.5	(94)
VIMOVO®	0.9	4.3	(79)
Inflammation Net Sales	**$ 50.9**	**$ 84.9**	**(40)**
Inflammation Segment Operating Income	**$ 15.3**	**$ 42.7**	**(64)**

(1) On Aug. 4, 2021, Alkem Laboratories, Inc. initiated an at-risk launch of generic DUEXIS in the United States.

- First-quarter 2022 net sales of the inflammation segment were $50.9 million and segment operating income was $15.3 million.

Cash Flow Statement and Balance Sheet Highlights

- First-quarter 2022 operating cash flow on a GAAP and non-GAAP basis was $215.8 million and $222.6 million, respectively.

- As of March 31, 2022, the Company had cash and cash equivalents of $1.64 billion.

- As of March 31, 2022, the total principal amount of debt outstanding was $2.60 billion.

2022 Guidance

The Company continues to expect full-year 2022 net sales to range between $3.9 billion and $4.0 billion, representing 22% growth at the midpoint. The Company continues to expect TEPEZZA full-year 2022 net sales percentage growth in the mid-30s and KRYSTEXXA full-year 2022 net sales growth of more than 20%. The Company continues to expect full-year 2022 adjusted EBITDA to range between $1.63 billion and $1.70 billion, representing 30% growth and 230 basis points of margin expansion at the midpoint.

Webcast

At 8 a.m. EDT / 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, visit www.horizontherapeutics.com and follow us on Twitter, LinkedIn, Instagram and Facebook.

Note Regarding Use of Non-GAAP Financial Measures

Horizon provides certain non-GAAP financial measures, including EBITDA, or earnings before interest, taxes, depreciation and amortization, adjusted EBITDA, 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 benefit (expense) and tax rate, non-GAAP operating cash flow and certain other non-GAAP income statement line items, 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 exclude acquisition and/or divestiture-related costs, manufacturing plant start-up costs, restructuring and realignment costs and litigation settlements, as well as non-cash items such as share-based compensation, inventory step-up expense, depreciation and amortization, non-cash interest expense, long-lived assets impairment charges, gain (loss) on equity security investments 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 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. 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 2022 adjusted EBITDA and associated margin expansion 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) and margins.

Forward-Looking Statements

This press release contains forward-looking statements, including, but not limited to, statements related to Horizon's full-year 2022 net sales, adjusted EBITDA and margin expansion guidance; expected financial performance and operating results in future periods, including potential growth in net sales of certain of Horizon's medicines; development, manufacturing and commercialization plans; expected timing of clinical trials, availability of clinical data and regulatory submissions; potential market opportunities 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; impacts of the on-going war between Russia and Ukraine; the fact that Horizon's full-year 2022 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 manufacturing and 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,	
	2022	**2021**
Net sales	$ 885,245	$ 342,406
Cost of goods sold	215,062	100,368
Gross profit	**670,183**	**242,038**
OPERATING EXPENSES:		
Research and development	103,132	57,693
Selling, general and administrative	372,734	331,992
Impairment of long-lived asset	-	12,371
Total operating expenses	**475,866**	**402,056**
Operating income (loss)	**194,317**	**(160,018)**
OTHER EXPENSE, NET:		
Interest expense, net	(21,256)	(13,460)
Foreign exchange gain (loss)	420	(848)
Other (expense) income, net	(742)	3,224
Total other expense, net	**(21,578)**	**(11,084)**
Income (loss) before benefit for income taxes	**172,739**	**(171,102)**
Benefit for income taxes	(31,522)	(47,751)
Net income (loss)	**$ 204,261**	**$ (123,351)**
Net income (loss) per ordinary share - basic	$ 0.89	$ (0.55)
Weighted average ordinary shares outstanding - basic	229,094,311	223,920,768
Net income (loss) per ordinary share - diluted	$ 0.87	$ (0.55)
Weighted average ordinary shares outstanding - diluted	235,953,318	223,920,768

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

	As of	
	March 31, 2022	**December 31, 2021**
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$ 1,643,129	$ 1,580,317
Restricted cash	4,136	3,839
Accounts receivable, net	684,507	632,775
Inventories, net	226,524	225,730
Prepaid expenses and other current assets	389,435	357,106
Total current assets	**2,947,731**	**2,799,767**
Property, plant and equipment, net	295,147	292,298
Developed technology and other intangible assets, net	2,871,979	2,960,118
In-process research and development	880,000	880,000
Goodwill	1,066,709	1,066,709
Deferred tax assets, net	516,317	538,098
Other assets	162,455	140,738
Total assets	**$ 8,740,338**	**$ 8,677,728**
LIABILITIES AND SHAREHOLDERS' EQUITY		
CURRENT LIABILITIES:		
Accounts payable	$ 67,014	$ 30,125
Accrued expenses and other current liabilities	377,433	523,015
Accrued trade discounts and rebates	364,732	317,431
Long-term debt—current portion	16,000	16,000
Total current liabilities	**825,179**	**886,571**
LONG-TERM LIABILITIES:		
Long-term debt, net	2,552,741	2,555,233
Deferred tax liabilities, net	334,778	390,455
Other long-term liabilities	209,811	173,076
Total long-term liabilities	**3,097,330**	**3,118,764**
COMMITMENTS AND CONTINGENCIES		
SHAREHOLDERS' EQUITY:		
Ordinary shares, $0.0001 nominal value; 600,000,000 shares authorized at March 31, 2022 and December 31, 2021; 229,873,900 and 227,760,936 shares issued at March 31, 2022 and December 31, 2021, respectively; and 229,489,534 and 227,376,570 shares outstanding at March 31, 2022 and December 31, 2021, respectively	23	23
Treasury stock, 384,366 ordinary shares at March 31, 2022 and December 31, 2021	(4,585)	(4,585)
Additional paid-in capital	4,314,647	4,373,337
Accumulated other comprehensive loss	(15,122)	(14,987)
Retained earnings	522,866	318,605
Total shareholders' equity	**4,817,829**	**4,672,393**
Total liabilities and shareholders' equity	**$ 8,740,338**	**$ 8,677,728**

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

	Three Months Ended March 31,	
	2022	2021
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net income (loss)	$ 204,261	$ (123,351)
Adjustments to reconcile net income (loss) to net cash provided by (used in) operating activities:		
Depreciation and amortization expense	95,112	70,820
Equity-settled share-based compensation	47,300	61,166
Acquired in-process research and development expense	2,000	-
Impairment of long-lived asset	-	12,371
Amortization of debt discount and deferred financing costs	1,577	773
Deferred income taxes	(33,896)	(28,771)
Foreign exchange and other adjustments	1,190	(5,440)
Changes in operating assets and liabilities:		
Accounts receivable	(51,665)	224,575
Inventories	(785)	(13,660)
Prepaid expenses and other current assets	(33,205)	(65,575)
Accounts payable	36,067	993
Accrued trade discounts and rebates	47,279	(28,736)
Accrued expenses and other current liabilities	(113,775)	(111,963)
Other non-current assets and liabilities	14,331	3,070
Net cash provided by (used in) operating activities	**215,791**	**(3,728)**
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchases of property, plant and equipment	(14,198)	(18,333)
Receipts (payments) for long-term investments, net	1,596	(3,808)
Payments for acquisitions, net of cash acquired	(3,122)	(2,707,358)
Payment related to license agreement	(25,000)	-
Net cash used in investing activities	**(40,724)**	**(2,729,499)**
CASH FLOWS FROM FINANCING ACTIVITIES:		
Repayment of term loans	(4,000)	-
Net proceeds from term loans	-	1,577,612
Proceeds from the issuance of ordinary shares in connection with stock option exercises	9,071	19,843
Payment of employee withholding taxes relating to share-based awards	(115,108)	(128,261)
Net cash (used in) provided by financing activities	**(110,037)**	**1,469,194**
Effect of foreign exchange rate changes on cash, cash equivalents and restricted cash	**(1,921)**	**(3,998)**
Net increase (decrease) in cash, cash equivalents and restricted cash	63,109	(1,268,031)
Cash, cash equivalents and restricted cash, beginning of the period[(1)]	1,584,156	2,083,479
Cash, cash equivalents and restricted cash, end of the period[(1)]	**$ 1,647,265**	**$ 815,448**

(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,	
	2022	**2021**
GAAP net income (loss)	**$ 204,261**	**$ (123,351)**
Non-GAAP adjustments:		
Acquisition/divestiture-related costs	1,589	49,108
Loss on equity security investments	4,646	-
Restructuring and realignment costs	537	6,093
Manufacturing plant start-up costs	807	-
Amortization and step-up:		
Intangible amortization expense	89,260	66,369
Inventory step-up expense	27,201	911
Amortization of debt discount and deferred financing costs	1,577	773
Impairment of long-lived asset	-	12,371
Share-based compensation	47,300	61,166
Depreciation	5,852	4,451
Total of pre-tax non-GAAP adjustments	**178,769**	**201,242**
Income tax effect of pre-tax non-GAAP adjustments	(67,212)	(73,129)
Total of non-GAAP adjustments	**111,557**	**128,113**
Non-GAAP net income	**$ 315,818**	**$ 4,762**
Non-GAAP Earnings Per Share:		
Weighted average ordinary shares - Basic	**229,094,311**	**223,920,768**
Non-GAAP Earnings Per Share - Basic:		
GAAP earnings (loss) per share - Basic	**$ 0.89**	**$ (0.55)**
Non-GAAP adjustments	0.49	0.57
Non-GAAP earnings per share - Basic	**$ 1.38**	**$ 0.02**
Weighted average ordinary shares - Diluted		
Weighted average ordinary shares - Basic	229,094,311	223,920,768
Ordinary share equivalents	6,859,007	10,190,012
Weighted average ordinary shares - Diluted	**235,953,318**	**234,110,780**
Non-GAAP Earnings Per Share - Diluted		
GAAP earnings (loss) per share - Diluted	**$ 0.87**	**$ (0.55)**
Non-GAAP adjustments	0.47	0.57
Non-GAAP earnings per share - Diluted	**$ 1.34**	**$ 0.02**

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

	Three Months Ended March 31,	
	2022	**2021**
GAAP net income (loss)	**$ 204,261**	**$ (123,351)**
Depreciation	5,852	4,451
Amortization and step-up:		
Intangible amortization expense	89,260	66,369
Inventory step-up expense	27,201	911
Interest expense, net (including amortization of debt discount and deferred financing costs)	21,256	13,460
Benefit for income taxes	(31,522)	(47,751)
EBITDA	**$ 316,308**	**$ (85,911)**
Other non-GAAP adjustments:		
Acquisition/divestiture-related costs	1,589	49,108
Loss on equity security investments	4,646	-
Restructuring and realignment costs	537	6,093
Manufacturing plant start-up costs	807	-
Impairment of long-lived asset	-	12,371
Share-based compensation	47,300	61,166
Total of other non-GAAP adjustments	**54,879**	**128,738**
Adjusted EBITDA	**$ 371,187**	**$ 42,827**

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

	Three Months Ended March 31,	
	2022	**2021**
GAAP operating income (loss)	**$ 194,317**	**$ (160,018)**
Non-GAAP adjustments:		
Acquisition/divestiture-related costs	1,589	49,391
Restructuring and realignment costs	537	6,093
Manufacturing plant start-up costs	807	-
Amortization and step-up:		
Intangible amortization expense	89,260	66,369
Inventory step-up expense	27,201	911
Impairment of long-lived asset	-	12,371
Share-based compensation	47,300	61,166
Depreciation	5,852	4,451
Total of non-GAAP adjustments	**172,546**	**200,752**
Non-GAAP operating income	**$ 366,863**	**$ 40,734**
Foreign exchange gain (loss)	420	(848)
Other income, net	3,904	2,941
Adjusted EBITDA	**$ 371,187**	**$ 42,827**

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

	Three Months Ended March 31,	
	2022	**2021**
Non-GAAP Gross Profit:		
GAAP gross profit	**$ 670,183**	**$ 242,038**
Non-GAAP gross profit adjustments:		
Acquisition/divestiture-related costs	(1,304)	205
Intangible amortization expense	88,725	66,169
Inventory step-up expense	27,201	911
Share-based compensation	2,177	1,936
Depreciation	56	115
Total of Non-GAAP adjustments	**116,855**	**69,336**
Non-GAAP gross profit	**$ 787,038**	**$ 311,374**
GAAP gross profit %	75.7%	70.7%
Non-GAAP gross profit %	88.9%	90.9%
GAAP cash provided by (used in) operating activities	**$ 215,791**	**$ (3,728)**
Cash payments for acquisition/divestiture-related costs	4,448	64,192
Cash payments for restructuring and realignment costs	574	-
Cash payments for manufacturing start-up costs	1,768	-
Non-GAAP operating cash flow	**$ 222,581**	**$ 60,464**

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

	Q1 2022				
	Pre-tax Net Income	Income Tax (Benefit) Expense	Tax Rate	Net Income	Diluted Earnings Per Share
As reported - GAAP	$ 172.7	$ (31.5)	(18.2)%	$ 204.3	$ 0.87
Non-GAAP adjustments	178.8	67.2		111.6	
Non-GAAP	**$ 351.5**	**$ 35.7**	**10.2%**	**$ 315.8**	**$ 1.34**

	Q1 2021				
	Pre-tax Net Income (loss)	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	201.2	73.1		128.1	
Non-GAAP	**$ 30.1**	**$ 25.4**	**84.2%**	**$ 4.7**	**$ 0.02**

Horizon Therapeutics plc
Certain Income Statement Line Items - Non-GAAP Adjusted
For the Three Months Ended March 31, 2022 and March 31, 2021 (Unaudited)
(in thousands)

Horizon Therapeutics plc
Certain Income Statement Line Items - Non-GAAP Adjusted
For the Three Months Ended March 31, 2022 (Unaudited)
(in thousands)

	COGS	Research & Development	Selling, General & Administrative	Interest Expense	Other Income, net	Income Tax Benefit (Expense)
GAAP as reported	**$ (215,062)**	**$ (103,132)**	**$ (372,734)**	**$ (21,256)**	**$ (742)**	**$ 31,522**
Non-GAAP Adjustments:						
Acquisition/divestiture-related costs[1]	(1,304)	2,001	892	-	-	-
Loss on equity security investments[2]	-	-	-	-	4,646	-
Restructuring and realignment costs[3]	-	-	537	-	-	-
Manufacturing plant start-up costs[4]	-	-	807	-	-	-
Amortization and step-up:						
Intangible amortization expense[5]	88,725	-	535	-	-	-
Inventory step-up expense[6]	27,201	-	-	-	-	-
Amortization of debt discount and deferred financing costs[7]	-	-	-	1,577	-	-
Share-based compensation[8]	2,177	8,976	36,147	-	-	-
Depreciation[9]	56	225	5,571	-	-	-
Income tax effect on pre-tax non-GAAP adjustments[10]	-	-	-	-	-	(67,212)
Total of non-GAAP adjustments [12]	**116,855**	**11,202**	**44,489**	**1,577**	**4,646**	**(67,212)**
Non-GAAP [12]	**$ (98,207)**	**$ (91,930)**	**$ (328,245)**	**$ (19,679)**	**$ 3,904**	**$ (35,690)**

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

	COGS	Research & Development	Selling, General & Administrative	Impairment of Long-Lived Assets	Interest Expense	Other Income, net	Income Tax Benefit (Expense)
GAAP as reported	**$ (100,368)**	**$ (57,693)**	**$ (331,992)**	**$ (12,371)**	**$ (13,460)**	**$ 3,224**	**$ 47,751**
Non-GAAP Adjustments:							
Acquisition/divestiture-related costs[1]	205	3	49,183	-	-	(283)	-
Restructuring and realignment costs[3]	-	-	6,093	-	-	-	-
Amortization and step-up:							
Intangible amortization expense[5]	66,169	-	200	-	-	-	-
Inventory step-up expense[6]	911	-	-	-	-	-	-
Amortization of debt discount and deferred financing costs[7]	-	-	-	-	773	-	-
Impairment of long lived asset[11]	-	-	-	12,371	-	-	-
Share-based compensation[8]	1,936	5,616	53,614	-	-	-	-
Depreciation[9]	115	49	4,287	-	-	-	-
Income tax effect on pre-tax non-GAAP adjustments[10]	-	-	-	-	-	-	(73,129)
Total of non-GAAP adjustments [12]	**69,336**	**5,668**	**113,377**	**12,371**	**773**	**(283)**	**(73,129)**
Non-GAAP [12]	**$ (31,032)**	**$ (52,025)**	**$ (218,615)**	**$ -**	**$ (12,687)**	**$ 2,941**	**$ (25,378)**

NOTES FOR CERTAIN INCOME STATEMENT LINE ITEMS - NON-GAAP

1. Primarily 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. We held investments in equity securities with readily determinable fair values of $8.5 million as of March 31, 2022, which are included in other assets in the condensed consolidated balance sheet. For the three months ended March 31, 2022, we recognized a net unrealized loss of $4.6 million due to the change in fair value of these securities.

3. Represents rent and maintenance charges as a result of vacating the leased Lake Forest office in the first quarter of 2021.

4. During the three months ended March 31, 2022, we recorded $0.8 million of manufacturing plant start-up costs related to the Waterford biologic drug product manufacturing facility purchased from EirGen in July 2021.

5. Intangible amortization expenses are primarily associated with our developed technology related to TEPEZZA, KRYSTEXXA, RAVICTI, PROCYSBI, ACTIMMUNE, UPLIZNA, BUPHENYL, PENNSAID 2% and RAYOS.

6. During the three months ended March 31, 2022 and 2021, we recognized in cost of goods sold $27.2 million and $0.9 million, respectively, 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 income for all affected periods, we exclude inventory step-up expense from our non-GAAP financial measures.

7. Represents amortization of debt discount and deferred financing costs associated with our debt.

8. 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.

9. Represents depreciation expense related to our property, plant, equipment, software and leasehold improvements.

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. 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.

12. Following consultation with the staff of the Division of Corporation Finance of the U.S. Securities and Exchange Commission, we no longer exclude upfront and milestone payments related to license and collaboration agreements from our non-GAAP financial measures and its line-item components. Adjusted EBITDA and non-GAAP net income for the three months ended March 31, 2021, includes $3.0 million of upfront and milestone payments related to license and collaboration agreements. These amounts continue to be excluded from our segment operating income and from certain measures contained in our credit agreement that are relevant to, among other things, the calculation of the interest rate.