Pharming Group reports earnings for the first nine months of 2022

- **Leniolisib remains on track for marketing authorization in the US and European Economic Area in H1 2023**
- **Revenues increased by 3% to US$151.0 million, compared to the first nine months of 2021**
- **Operating profit increased by 86% to US$28.4 million**
- **Strong balance sheet and stable sales from RUCONEST® underpinning continued investment in launch preparations for leniolisib and Pharming's long-term growth**

Leiden, The Netherlands, October 27, 2022: Pharming Group N.V. ("Pharming" or "the Company") (Euronext Amsterdam: PHARM/NASDAQ: PHAR) presents its preliminary, unaudited financial report for the first nine months ended September 30, 2022.

Chief Executive Officer, Sijmen de Vries, commented:

"In the first nine months of 2022 Pharming continued to perform well despite challenging industry conditions. Our commercialized asset RUCONEST® saw increased sales of 3% or US$151.0 million, compared to the same period last year, highlighting the continued need for a safe and effective acute hereditary angioedema therapy.

From a strategic perspective, we continued to make significant progress delivering on a number of important regulatory milestones for leniolisib, a rare immunodeficiency disease. Of note, our New Drug Application for leniolisib was accepted by the US FDA for Priority Review with a PDUFA goal date of March 29, 2023. Furthermore, we submitted a Marketing Authorisation Application for the product to the European Medicines Agency following the grant of accelerated assessment. We remain on track for the anticipated marketing authorization of leniolisib as a treatment of APDS in key markets next year.

Looking ahead, the anticipated launch and commercialization of leniolisib will be supported by our strong balance sheet and the steady sales of RUCONEST®. We will continue focusing on our strategic objectives and the internal review of our pipeline as we look to bring the unserved rare disease patient the solutions they need. We look forward to presenting more detailed plans at our full year financial results."

Strategic highlights

During the first nine months of 2022, we continued to execute on our strategic objectives of building a sustainable business by focusing on RUCONEST® sales, the approval, launch and commercialization of leniolisib, and the ongoing development and management of our pipeline as we prioritize our efforts on rare diseases.

As announced during the half year financial results in August 2022, we initiated an internal review of our pipeline with a greater and renewed focus towards rare diseases. As a result, we will advance the development of our pipeline through a combination of internal development projects - including the development of additional indications for leniolisib, as well as OTL-105 as a gene therapy for HAE - and the potential acquisition of new, late-stage assets through in-licensing and M&A opportunities.

We believe these potential acquisitions and in-licensing will be financed through a combination of positive cash flow from the RUCONEST® business, anticipated future leniolisib business, as well as available cash from our strong balance sheet. If required, Pharming will access additional funding from the capital markets.

Pipeline development

leniolisib

For leniolisib, Pharming has a three-step approach planned for the coming years.

The first step is the anticipated marketing authorization and commercial launch of leniolisib for the treatment of activated PI3K delta syndrome (APDS) in adults and adolescents aged 12 and older in the US during the first half of 2023. This will be followed by key markets in the European Economic Area (EEA) and the UK in the second half of 2023 and early 2024, respectively, dependent upon regulatory approval. The Company will evaluate additional countries and regions and will commercialize the product either directly or through strategic distribution partnerships.

The second step includes the marketing authorization and commercial launch of leniolisib as a treatment of APDS in children as young as one year of age.

The third step is the continued life cycle management of the leniolisib compound into further indications which will be disclosed when decisions have been taken.

US market

We remain on track for the anticipated commercial approval of leniolisib in the first quarter of 2023, subject to approval from the US Food and Drug Administration (FDA), followed by the commercial launch of leniolisib in the second quarter of 2023.

In the third quarter of 2022, we delivered on a number of important regulatory milestones including the filing and acceptance of a New Drug Application (NDA) for Priority Review by the FDA.

As a result of receiving Priority Review, Pharming's NDA for leniolisib was assigned a Prescription Drug User Fee Act (PDUFA) goal date of March 29, 2023.

In anticipation of a positive outcome from the FDA, we continued to grow our US field force and leverage our marketing capabilities for the commercialization of leniolisib.

Finally, the ICD-10-CM code for APDS took effect on October 1, 2022. The assignment of the ICD-10-CM code enables physicians and payors in the US to add a diagnosis of APDS to patients' health records, which will help connect these individuals with researchers studying the prevalence and course of the disease. In addition, by allocating a specific diagnosis, the new ICD-10-CM code may help confirm medical necessity in individual patients, thus improving their access to relevant care options through US health insurance plans.

European Economic Area (EEA) and UK market

In the EEA, we announced that the European Medicines Agency's (EMA) Committee for Medicinal Products for Human Use (CHMP) had granted an accelerated assessment for the Marketing Authorisation Application (MAA) for leniolisib in adults and adolescents aged 12 and older. Upon further request, EMA will grant an accelerated assessment of an MAA if they decide the product is of major interest for public health, and in particular, from the viewpoint of therapeutic innovation. The accelerated assessment reduces the review timeframe from 210 days to 150 days.

Further positive milestones were reached in October 2022 when we announced that we had submitted a Marketing Authorisation Application for leniolisib to the EMA. We expect to receive EMA validation of the MAA at the end of October 2022, with anticipated marketing authorization in H1 2023.

Moving on to the UK market, in April 2022, the Medicines and Healthcare products Regulatory Agency (MHRA) granted Promising Innovative Medicine (PIM) designation to leniolisib for the treatment of APDS. A PIM designation is an early indication that leniolisib is a candidate for the

MHRA's Early Access to Medicines Scheme. This scheme provides an opportunity for treatment options to be used in clinical practice in parallel with the later stages of the regulatory process.

Finally, on September 30, 2022, the UK government took the decision to extend the European Commission Decision Reliance Procedure (ECDRP) by 12 months, until December 31, 2023. The ECDRP allows a company to submit a product that has received approval from EMA to the UK's MHRA. The MHRA can grant a license relying on the EMA's decision, thereby ensuring a less time consuming in-country review.

The extension of the ECDRP has several benefits including aligned EU and UK dossiers, consistent labeling across the EU and UK, and the potential for an earlier Marketing Authorisation Approval. As such, Pharming has decided that the ECDRP procedure will be used for the application of leniolisib to the MHRA. Under ECDRP, if the submission of an application is made within five days of an EMA CHMP positive opinion, the MHRA will aim to determine a decision within a 67-day timeline. The anticipated MHRA decision should be known in H2 2023.

Pediatric clinical development

As previously announced, we intend to expand access to leniolisib for the treatment of pediatric APDS. As a result, Pharming has developed a clinical plan to include children as young as one year of age. During the first half of the year, positive decisions were received from EMA and MHRA on the Pediatric Investigation Plan (PIP) for leniolisib as a treatment for APDS in children. The leniolisib PIP includes two planned, global clinical trials in pediatric patients with APDS aged 4 to 11 with a second study in patients aged 1 to 6. These two studies will support regulatory filings worldwide. Pharming expects to initiate recruitment for this pediatric program for leniolisib in the fourth quarter of 2022.

OTL-105

Pharming's strategic collaboration with Orchard Therapeutics to research, develop, manufacture and commercialize OTL-105, a newly disclosed investigational ex vivo autologous hematopoietic stem cell (HSC) gene therapy for the treatment of hereditary angioedema (HAE) is ongoing. The program has made good progress developing the lentiviral vector to enhance C1-inhibitor expression and is now testing in preclinical HAE disease models. We anticipate providing further updates as we move towards preparing an Investigational New Drug (IND) filing.

Acute Kidney Injury (AKI)

As announced at our half year 2022 financial results, following an internal review of our pipeline, we have taken the strategic decision to discontinue further development of rhC1INH therapy for Acute Kidney Injury. We are considering strategic options to gain value from the work done to

date and have de-prioritized further development and investment in the large-scale production of rhC1INH through the use of our transgenic cattle herd. The herd is being maintained to allow all possible outcomes to be explored.

The ongoing Phase IIb clinical trial is continuing as we evaluate these strategic options.

We will update the market at our full year 2022 financial results on further progress in this area.

Pompe

We continue the preclinical investigation of a next-generation alpha-glucosidase therapy for the treatment of Pompe disease and will update the market on the results as appropriate.

Financial Summary

Amounts in US$m except per share data	YTD 2022	YTD 2021	% Change
Income Statement			
Revenues	**151.0**	**146.1**	**3%**
Gross profit	**139.7**	**130.6**	**7%**
Operating profit	**28.4**	**15.3**	**86%**
Profit for the year	**28.3**	**13.9**	**104%**
Balance Sheet			
Cash & marketable securities	**189.9**	**184.8**	**3%**
Share Information			
Basic earnings per share (US$)	**0.043**	**0.022**	**95%**
Diluted earnings per share (US$)	**0.040**	**0.018**	**122%**

Financial highlights

YTD Q3 2022

Revenues for the first nine months of 2022 were US$151.0 million, a 3% increase compared to the first nine months of 2021 (US$146.1 million).

Gross profit for the first nine months of 2022 increased 7% to US$139.7 million. This increase was driven by growth in revenues, production efficiencies and a favorable tailwind in currency translation effects.

Operating costs for the first nine months of 2022 increased by US$9.8 million to US$126.9 million versus the same period last year. The increase results from a combination of increased R&D

expenditure, launch preparation and manufacturing costs for leniolisib, and an increase in travel related expenses post-COVID-19. This increase was partly offset by significant one-off costs in Q3 2021 relating to the in-licensing of OTL-105 from Orchard Therapeutics.

Operating profit for the first nine months of 2022 was US$28.4 million, increasing 86% versus the same period last year. This was mainly driven by the increase in other income of US$13.8 million as a result of a reduced minority stake in BioConnection communicated in our H1 2022 press release.

Net profit for the first nine months of 2022 was US$28.3 million, a 104% increase compared to the same period last year (US$13.9 million). This was driven by the increase in other income of US$13.8 million.

Cash and cash equivalents, together with restricted cash, decreased from US$193.0 million at the end of 2021, to US$189.9 million at the end of the third quarter 2022.

Outlook

For the financial year of 2022:

- Single digit growth in Group revenues from RUCONEST® sales. Quarterly fluctuations are expected.

- Subject to a positive outcome from the FDA review, we anticipate marketing authorization in the US for leniolisib at the end of Q1 2023, with an anticipated launch and commercialization in Q2 2023.

- Subject to a positive outcome from the EMA review, we anticipate a positive opinion from the CHMP for leniolisib, followed by the issuance of an MAA by the European Commission towards the end of H1 2023. Initial commercial launches in EU markets are planned for H2 2023.

- Following an anticipated positive CHMP opinion, we intend to submit an ECDRP filing for leniolisib with the MHRA in the UK in H2 2023.

- Pharming will continue to allocate resources towards the anticipated launch and commercialization of leniolisib with the view of accelerating future growth. Investments in launch preparations and focused clinical development for leniolisib will continue to impact profit for the remainder of 2022 and throughout 2023. However, no additional

financing to support the current business is expected with the continued cash flow from RUCONEST® funding these investments.

- Investment and continued focus on potential acquisitions and in-licensing of new, late-stage development opportunities and assets in rare diseases. Financing, if required, would come via a combination of our strong balance sheet and access to capital markets.

No further specific financial guidance for 2022 is provided.

Additional information

Presentation

The conference call presentation will be available on the Pharming.com website from 10:30 CET on October 27, 2022.

Conference Call

The conference call will begin at 13:30 CET on October 27, 2022. A transcript of the call will be available on the Pharming.com website the following day at 14:30 CET.

Please note, the Company will only take questions from dial-in attendees.

Dial-in numbers for conference call

Netherlands (Local) +31 85 888 7233
United Kingdom +44 800 640 6441
United Kingdom (Local) +44 20 3936 2999
United States +1 855 979 6654
United States (Local) +1 646 664 1960
All other locations +44 20 3936 2999

Access code: 497472

Webcast link

https://webcast.openbriefing.com/pharming-q32022/

Financial calendar 2022

Credit Suisse 31st Annual Healthcare Conference: November 8 - 10

Stifel Healthcare Conference 2022:	November 15 - 16
Jefferies London Healthcare Conference:	November 15 - 17

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About Pharming Group N.V.

Pharming Group N.V. (Euronext Amsterdam: PHARM/Nasdaq: PHAR) is a global biopharmaceutical company dedicated to transforming the lives of patients with rare, debilitating, and life-threatening diseases. Pharming is commercializing and developing an innovative portfolio of protein replacement therapies and precision medicines, including small molecules, biologics, and gene therapies that are in early to late-stage development. Pharming is headquartered in Leiden, Netherlands, and has employees around the globe who serve patients in over 30 markets in North America, Europe, the Middle East, Africa, and Asia-Pacific. For more information, visit www.pharming.com and find us on LinkedIn.

Auditor's involvement

The Condensed Consolidated Interim Financial Statements have not been audited by the Company's statutory auditor.

Risk profile

The risks outlined in the 2021 Annual Report continued to apply in the first nine months of 2022 and are expected to apply for the rest of the financial year. We continue to closely monitor the key risks and opportunities, and will respond appropriately to any emerging risk.

Related party transactions

There are no material changes in the nature, scope, and (relative) scale in this reporting period compared to last year.

Forward-looking Statements

This press release may contain forward-looking statements. Forward-looking statements are statements of future expectations that are based on management's current expectations and assumptions and involve known and unknown risks and uncertainties that could cause actual results, performance, or events to differ materially from those expressed or implied in these statements. These forward-looking statements are identified by their use of terms and phrases such as "aim", "ambition", ''anticipate'', ''believe'', ''could'', ''estimate'', ''expect'', ''goals'', ''intend'', ''may'', "milestones", ''objectives'', ''outlook'', ''plan'', ''probably'', ''project'', ''risks'', "schedule", ''seek'', ''should'', ''target'', ''will'' and similar terms and phrases. Examples of forward-looking statements may include statements with respect to timing and progress of Pharming's preclinical studies and clinical trials of its product candidates, Pharming's clinical and commercial prospects, and Pharming's expectations regarding its projected working capital requirements and cash resources, which statements are subject to a number of risks, uncertainties and assumptions, including, but not limited to the scope, progress and expansion of Pharming's clinical trials and ramifications for the cost thereof; and clinical, scientific, regulatory and technical developments. In light of these risks and uncertainties, and other risks and uncertainties that are described in Pharming's 2021 Annual Report and the Annual Report on Form 20-F for the year ended December 31, 2021, filed with the U.S. Securities and Exchange Commission, the events and circumstances discussed in such forward-looking statements may not occur, and Pharming's actual results could differ materially and adversely from those anticipated or implied thereby. All forward-looking statements contained in this press release are expressly qualified in their entirety by the cautionary statements contained or referred to in this section. Readers should not place undue reliance on forward-looking statements. Any forward-looking statements speak only as of the date of this press release and are based on information available to Pharming as of the date

of this release. Pharming does not undertake any obligation to publicly update or revise any forward-looking statement as a result of new information, future events or other information.

Inside Information

This press release relates to the disclosure of information that qualifies, or may have qualified, as inside information within the meaning of Article 7(1) of the EU Market Abuse Regulation.

Pharming Group N.V.

Condensed Consolidated Interim Financial Statements in US Dollars (unaudited)

For the period ended 30 September 2022

- Condensed consolidated statement of profit and loss
- Condensed consolidated statement of comprehensive income
- Condensed consolidated balance sheet
- Condensed consolidated statement of cash flow

CONDENSED CONSOLIDATED STATEMENT OF PROFIT AND LOSS

For the 9-month period ended 30 September 2022

Amounts in US$ '000	YTD 2022	YTD 2021
Revenues	**151.001**	**146.101**
Costs of sales	**(11.288)**	**(15.500)**
Gross profit	**139.712**	**130.601**
Other income	**15.602**	**1.808**
Research and development	(41.639)	(37.580)
OTL-105 in-licensing	0	(13.105)
General and administrative	(28.446)	(22.510)
Marketing and sales	(56.819)	(43.880)
Other Operating Costs	**(126.904)**	**(117.075)**
Operating profit	**28.410**	**15.334**
Fair value gain (loss) on revaluation derivatives	0	59
Other finance income	9.297	9.907
Other finance expenses	(3.978)	(4.466)
Finance cost net	**5.319**	**5.500**
Share of net profits in associates using the equity method	**(660)**	**511**
Profit before tax	**33.069**	**21.345**
Income tax credit (expense)	(4.765)	(7.412)
Profit for the year	**28.304**	**13.933**
Basic earnings per share (US$)	0.043	0.022
Fully-diluted earnings per share (US$)	0.040	0.018

CONDENSED CONSOLIDATED STATEMENT OF COMPREHENSIVE INCOME

For the 9-month period ended 30 September 2022

Amounts in US$ '000	YTD 2022	YTD 2021
Profit for the year	**28.304**	**13.933**
Currency translation differences	(26.313)	(10.506)
Fair value remeasurement investments	(573)	(1.475)
Items that may be subsequently reclassified to profit or loss	**(26.886)**	**(11.981)**
Other comprehensive income (loss), net of tax	**(26.886)**	**(11.981)**
Total comprehensive income (loss) for the year	**1.418**	**1.952**

CONDENSED CONSOLIDATED BALANCE SHEET

As at 30 September 2022

Amounts in US$ '000	30 September 2022	31 December 2021
Non-current assets		
Intangible assets	70.123	83.834
Property, plant and equipment	10.812	13.222
Right-of-use assets	16.970	19.943
Long-term prepayments	210	194
Deferred tax assets	21.187	21.216
Investments accounted for using the equity method	2.845	7.201
Investment in equity instruments designated as at FVTOCI	545	1.449
Investment in debt instruments designated as at FVTPL	7.386	0
Restricted cash	197	812
Total non-current assets	**130.275**	**147.871**
Current assets		
Inventories	33.506	27.310
Trade and other receivables	28.828	29.983
Restricted cash	1.011	227
Cash and cash equivalents	188.703	191.924
Total current assets	**252.048**	**249.444**
Total assets	**382.323**	**397.315**

Equity		
Share capital	7.482	7.429
Share premium	459.450	455.254
Legal reserves	(24.145)	3.400
Accumulated deficit	(242.533)	(273.167)
Shareholders' equity	**200.254**	**192.916**
Non-current liabilities		
Convertible bonds	120.005	139.007
Lease liabilities	15.227	18.456
Other financial liabilities	143	165
Total non-current liabilities	**135.375**	**157.628**
Current liabilities		
Convertible bonds	1.627	1.879
Derivative financial liabilities	0	0
Trade and other payables	42.744	42.473
Lease liabilities	2.323	2.419
Total current liabilities	**46.694**	**46.771**
Total equity and liabilities	**382.323**	**397.315**

Pharming

CONDENSED CONSOLIDATED STATEMENT OF CASH FLOWS in US Dollar

For the 9-month period ended 30 September 2022

Amounts in $'000	YTD 2022	YTD 2021
Profit before tax	**33.069**	**21.345**
Non-cash adjustments:		
Depreciation, amortization, impairment	6.216	6.867
Equity settled share based payments	4.522	5.706
Fair value gain (loss) on revaluation of derivatives	0	(59)
Gain on disposal of investment in associate	(12.382)	0
Other finance income	(9.296)	(9.907)
Other finance expense	3.978	4.466
Share of net profits in associates using the equity method	660	(511)
Other	0	272
Operating cash flows before changes in working capital	**26.767**	**28.179**
Changes in working capital:		
Inventories	(6.196)	(3.941)
Trade and other receivables	1.155	3.092
Payables and other current liabilities	272	(5.514)
Restricted Cash	169	42
Total changes in working capital	**(4.600)**	**(6.321)**
Interest received	31	51
Income taxes paid	(4.975)	0
Net cash flows generated from (used in) operating activities	**17.223**	**21.909**
Capital expenditure for property, plant and equipment	(1.071)	(7.451)
Investment intangible assets	(591)	(1.544)
Investment in equity instruments designated as at FVTOCI	0	(4.589)
Investment in associate	7.384	0
Acquisition of license	0	(1.593)
Net cash flows used in investing activities	**5.722**	**(15.177)**
Repayment on loans and borrowings	0	0
Payment on contingent consideration	0	(25.000)
Payment of lease liabilities	(2.385)	(2.476)
Proceeds of issued convertible bonds	0	0
Interests on loans and leases	(3.999)	(4.493)
Proceeds of equity and warrants	1.124	4.237
Net cash flows generated from (used in) financing activities	**(5.260)**	**(27.732)**
Increase (decrease) of cash	**17.685**	**(21.000)**
Exchange rate effects	(20.906)	(835)
Cash and cash equivalents at 1 January	191.924	205.159
Total cash and cash equivalents at 30 September	**188.703**	**183.324**