

# Pharming Group reports financial results for the first nine months of 2021

Patient enrollment and product demand driving ongoing revenue recovery to US\$52.9 million in Q3 2021

Operating profit impacted by upfront payment of US\$ 13.1 million for the in-licensing of OTL-105.

Continued strong positive cash flow from operations enable increasing investment in the pipeline to support long-term growth

**Leiden, The Netherlands, October 28, 2021:** 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, 2021.

• The Company will hold an analyst conference call at 13.30 CET/07.30 ET today. Dial in details can be found on page 6 of this report

#### Chief Executive Officer, Sijmen de Vries, commented

"We are pleased to deliver continued quarter-on-quarter revenue growth for the year to date, as expected, following the impact of COVID-19 on sales earlier in 2021, as a result of ongoing patient enrollment and increasing product demand. Supported by the strength of the underlying business; we are continuing to invest in future growth in line with our strategy to develop and expand our pipeline through leverage of our in-house expertise. This investment includes licensing of OTL-105, an investigational gene therapy for the potentially curative treatment of hereditary angioedema, from Orchard Therapeutics in July 2021. We are also investing significant and increasing amounts in preparation for the potential launch of leniolisib in Q4 2022, subject to regulatory approval. I look forward to the read-out of the registration enabling study for leniolisib, expected early in the new year, as a product with transformational potential for APDS patient's lives and also transformational commercial potential for Pharming."

### Operational highlights (Q3 2021)

- Signed a strategic collaboration with Orchard Therapeutics, a global gene therapy leader, 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). OTL-105 is designed to increase C1 esterase inhibitor (C1INH) in HAE patient serum to prevent HAE attacks.
- Entered into an exclusive license agreement with NewBridge Pharmaceuticals for the distribution of RUCONEST® in the Middle East and North Africa.
- Topline results from two randomized, open label, controlled, pilot clinical trials of patients hospitalized with COVID-19 treated with RUCONEST® for the prevention of severe SARS-CoV-2 infection. Results from these studies support Pharming's initial hypothesis on the need to control the hyper-inflammatory process in patients with severe COVID-19



- infection. The results are being analyzed to design future clinical trials with RUCONEST® for the treatment of COVID-19 and non-COVID-19 conditions.
- Continued significant investment in pipeline, including launch preparation for leniolisib, which is expected in Q4 2022, dependent on regulatory approval.

### **Financial Summary**

Amounts in US\$m except per share data	YTD 2021	YTD 2020	% Change
Income Statement			
Revenues	146.1	151.9	(4)%
Gross profit	130.6	135.3	(3)%
Operating profit	15.3	57.7	(72)%
Profit for the year	13.9	28.9	(49)%
Balance Sheet			
Cash & marketable securities	184.8	176.0	5%
Share Information			
Basic earnings per share (US\$)	0.022	0.045	(49)%
Diluted earnings per share (US\$)	0.018	0.039	(51)%

### **Financial highlights**

- Total revenues increased by 6% from US\$49.7 million in Q2 2021 to US\$52.9 million in Q3 2021, as a result of the ongoing recovery in sales following the impact of COVID-19 on the US healthcare economy earlier in Q1 2021, as previously noted in the Company's Q1 2021 and Q2 2021 financial reports. Revenues for the first nine months of 2021 were US\$146.1 million, a 4% decrease compared to the first nine months of 2020 (US\$151.9 million).
- RUCONEST® sales in the US continued to recover during Q3 2021, with quarter-on-quarter revenues increasing by 6% to US\$51.1 million (Q2 2021: US\$48.4 million), driven by an increase in patient enrollment and product demand. For the first nine months of 2021, US sales amounted to US\$141.1 million, a 3% decrease from US\$145.9 million in the first nine months of 2020.
- Revenues in Europe and RoW decreased to US\$5.0 million for the first nine months of 2021 (9M 2020: US\$6.1 million). In Q3 2021 revenue from Europe and RoW sales were US\$1.9 million, an increase of 58% on Q2 2021 (US\$1.2 million), mainly as a result of phasing of ordering.
- Gross profit for the first nine months of 2021 was US\$130.6 million a 3% decrease in comparison to the first nine months of 2020 (US\$135.3 million). However, gross profit increased by 4% compared to Q2 2021, in line with the increased quarter-on-quarter revenues.
- Operating profit for the first nine months of 2021 was US\$15.3 million, decreasing 72% on the first nine months of 2020 (US\$57.7 million). This was due to significant investments in



the pipeline, including one- off costs of the upfront payment of US\$13.1 million to inlicense OTL-105 from Orchard Therapeutics in Q3 2021 and increased costs of corporate development, including costs associated with compliance and insurances as specified further below. Without the upfront payment for OTL-105 operating profit would have come to US\$28.4 million, growing from US\$17.3 million in H1 2021.

- Other operating costs increased to US\$116.4 million compared to US\$78.5 million in the first nine months of 2020. The increase is due to investment in Pharming's long-term growth, with increased R&D expenditure, the cost of the OTL-105 license (US\$13.1 million), leniolisib pre-launch marketing preparations and manufacturing cost for leniolisib, an increase in employee numbers to support growth, a significant increase in cost of insurances due to Nasdaq listing, an increase in share-based compensation and increased compliance and control costs relating to the recent US Nasdaq listing, as previously noted in the Company's Q1 2021 and Q2 2021 financial reports.
- Net profit for the first nine months of 2021 was US\$13.9 million, a 49% decrease compared to the first nine months of 2020 (US\$28.9 million), as a result of initial inlicensing cost of OTL-105 (US\$13.1 million) leading to lower operating profit which was offset by currency exchange rates and lower funding costs.
- Cash and cash equivalents, together with restricted cash, decreased from US\$206.7 million at the end of 2020 to US\$184.8 million at the end of Q3 2021. This was as a result of positive cash flows from operating activities of US\$21.9 million remaining after the US\$ 13.1 million one- off payment to Orchard Therapeutics and reduced by investments and negative financing cash flows totaling US\$42.9 million. These US\$42.9 million include investments in production facilities and the payment of the final US\$25.0 million milestone to Bausch Health Inc. in Q2 2021 in relation to the re-acquisition of the North American RUCONEST® commercialization rights in 2016.

#### Outlook

For the remainder of 2021, we expect:

- Continued quarter on quarter increase in revenues from RUCONEST® sales due to normalizing pharmaceutical markets following the impact of COVID-19. However, we will continue to monitor the situation in all markets and could expect some periodic disruptions.
- Maintenance of positive net earnings during the remainder of the year.
- Significant and increasing investment in launch-critical medical affairs and pre-marketing activities for leniolisib as well as continued investment in ongoing clinical trials for rhC1INH and other development activities, including OTL-105.
- Investments in acquisitions and in-licensing of new development opportunities and assets

No further specific financial guidance for 2021 is provided.



#### **About Pharming Group N.V.**

Pharming Group N.V. is a global, commercial stage biopharmaceutical company developing innovative protein replacement therapies and precision medicines for the treatment of rare diseases and unmet medical needs.

The flagship of our portfolio is our recombinant human C1 esterase inhibitor (rhC1INH) franchise. C1INH is a naturally occurring protein that down regulates the complement and contact cascades in order to control inflammation in affected tissues.

Our lead product, RUCONEST®, is the first and only plasma-free rhC1INH protein replacement therapy. It is approved for the treatment of acute hereditary angioedema (HAE) attacks. We are commercializing RUCONEST® in the United States, the European Union and the United Kingdom through our own sales and marketing organization, and the rest of the world through our distribution network.

In addition, we are investigating the clinical efficacy of rhC1INH in the treatment of further indications, including pre-eclampsia, acute kidney injury and severe pneumonia as a result of COVID-19 infections.

We are also studying our oral precision medicine, leniolisib (a phosphoinositide 3-kinase delta, or PI3K delta, inhibitor), for the treatment of activated PI3K delta syndrome, or APDS, in a registration enabling Phase 2/3 study in the United States and Europe.

Additionally, we entered into a 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 HAE.

Furthermore, we are leveraging our transgenic manufacturing technology to develop next-generation protein replacement therapies, most notably for Pompe disease, which is currently in preclinical development.

#### Risk profile

The risks outlined in the 2020 Annual Report continued to apply in the first nine months of 2021 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.

#### **Auditor's involvement**

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



#### **Forward-looking Statements**

This press release contains forward-looking statements, including with respect to timing and progress of Pharming's preclinical studies and clinical trials of its product candidates, Pharming's clinical and commercial prospects, Pharming's ability to overcome the challenges posed by the COVID-19 pandemic to the conduct of its business, 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 2020 Annual Report and the Annual Report on Form 20-F for the year ended December 31, 2020 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. 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.

#### **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.

#### For further public information, contact:

Pharming Group, Leiden, The Netherlands

Sijmen de Vries, CEO: T: +31 71 524 7400

Susanne Embleton, Investor Relations Manager: T: +31 71 524 7400 E: investor@pharming.com

FTI Consulting, London, UK

Victoria Foster Mitchell/Alex Shaw

T: +44 203 727 1000

FTI Consulting, USA

Jim Polson

T: +1 (312) 553-6730

LifeSpring Life Sciences Communication, Amsterdam, The Netherlands

Leon Melens

T: +31 6 53 81 64 27

E: pharming@lifespring.nl



#### **Conference call dial-in information**

### Thursday October, 28, 2021 13:30CET/07:30ET

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

#### Dial-in details:

Netherlands (Local) 085 888 7233

United Kingdom 0800 640 6441

United Kingdom (Local) 020 3936 2999

United States (Local) 1 646 664 1960

All other locations +44 20 3936 2999

Access code: 147906

#### Webcast Link:

https://webcast.openbriefing.com/pharming-q321/



## **Pharming Group N.V.**

**Condensed Consolidated Interim Financial Statements in US Dollars (unaudited)** 

For the period ended 30 September 2021

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

Appendix: Main condensed consolidated Interim Financial Statements reported in Euros (unaudited)

(This appendix is not part of the Condensed Consolidated Financial Statements)

- Condensed consolidated statement of profit and loss in Euros
- Condensed consolidated statement balance sheet in Euros
- Condensed consolidated statement of cash flows in Euros



#### CONDENSED CONSOLIDATED STATEMENT OF PROFIT AND LOSS

#### For the 9-month period ended 30 September

Amounts in US\$ '000	YTD 2021	YTD 2020
Revenues	146,101	151,874
Costs of sales	(15,500)	(16,566)
Gross profit	130,601	135,308
Other income	1,808	810
Research and development	(37,580)	(26,842)
OTL-105 in-licensing	(13,105)	0
General and administrative	(22,510)	(15,411)
Marketing and sales	(43,880)	(36,204)
Other Operating Costs	(117,075)	(78,457)
Operating profit	15,334	57,661
Fair value gain (loss) on revaluation derivatives	59	147
Other finance income	9,907	655
Other finance expenses	(4,466)	(20,614)
Finance cost net	5,500	(19,812)
Share of net profits in associates using the equity method	511	219
Profit before tax	21,345	38,068
Income tax credit (expense)	(7,412)	(9,212)
Profit for the year	13,933	28,856
Basic earnings per share (US\$)	0.022	0.045
Fully-diluted earnings per share (US\$)	0.018	0.039



## **CONDENSED CONSOLIDATED STATEMENT OF COMPREHENSIVE INCOME**For the 9-month period ended 30 September

Amounts in US\$ '000	YTD 2021	YTD 2020
Profit for the year	13,933	28,856
Currency translation differences	(10,506)	497
Fair value remeasurement investments	(1,475)	0
Items that may be subsequently reclassified to profit or loss	(11,981)	497
Other comprehensive income (loss), net of tax	(11,981)	497
Total comprehensive income (loss) for the year	1,952	29,353



## CONDENSED CONSOLIDATED BALANCE SHEET

As at 30 September

Amounts in US\$ '000	30 September 2021	31 December 2020
Non-current assets		
Intangible assets	89,009	94,083
Property, plant and equipment	16,914	12,226
Right-of-use assets	20,982	9,427
Long-term prepayments	198	0
Deferred tax assets	21,473	31,877
Investments accounted for using the equity method	7,187	7,118
Investment in equity instruments designated as at FVTOCI	2,483	0
Restricted cash	481	510
Total non-current assets	158,727	155,241
Current assets		
Inventories	25,098	21,157
Trade and other receivables	32,810	35,901
Restricted cash	981	995
Cash and cash equivalents	183,324	205,159
Total current assets	242,213	263,212
Total assets	400,940	418,453

Equity		
Share capital	7,259	7,163
Share premium	453,476	444,940
Legal reserves	9,864	19,859
Accumulated deficit	(277,053)	(288,527)
Shareholders' equity	193,546	183,435
Non-current liabilities		
Convertible bonds	140,962	149,727
Lease liabilities	19,323	8,230
Other financial liabilities	386	212
Total non-current liabilities	160,671	158,169
Current liabilities		
Convertible bonds	1,923	2,040
Derivative financial liabilities	54	181
Trade and other payables	42,151	47,666
Lease liabilities	2,595	1,962
Other financial liabilities	0	25,000
Total current liabilities	46,723	76,849
Total equity and liabilities	400,940	418,453



## **CONDENSED CONSOLIDATED STATEMENT OF CASH FLOWS in US Dollar** For the period ended 30 September

Amounts in US\$ '000	YTD 2021	YTD 2020
Profit before tax	21,345	38,068
Non-cash adjustments:		
Depreciation, amortization, impairment	6,867	5,741
Equity settled share based payments	5,706	2,365
Fair value gain (loss) on revaluation of derivatives	(59)	(148)
Other finance income	(9,907)	(655)
Other finance expense	4,466	20,616
Share of net profits in associates using the equity method	(511)	(220)
Other	272	2,489
Operating cash flows before changes in working capital	28,179	68,256
Changes in working capital:		
Inventories	(3,941)	(2,159)
Trade and other receivables	3,092	(799)
Payables and other current liabilities	(5,514)	(1,979)
Restricted Cash	42	1,074
Total changes in working capital	(6,321)	(3,863)
lotal changes in working capital	(0,321)	(3,803)
Interest received	51	655
Income taxes paid	0	(2,741)
Net cash flows generated from (used in) operating activities	21,909	62,307
Capital expenditure for property, plant and equipment	(7,451)	(1,551)
Investment intangible assets	(1,544)	(374)
Investment in equity instruments designated as at FVTOCI	(4,589)	0
Acquisition of license	(1,593)	(9,523)
Net cash flows used in investing activities	(15,177)	(11,448)
Repayment on loans and borrowings	0	(56,273)
Payment on contingent consideration	(25,000)	(20,445)
Payment of lease liabilities	(2,476)	(1,489)
Proceeds of issued convertible bonds	0	138,312
Interests on loans and leases	(4,493)	(3,072)
Proceeds of equity and warrants	` ' '	2,294
Proceeds of equity and warrants	4,237	2,294
Net cash flows generated from (used in) financing activities	(27,732)	59,327
Increase (decrease) of cash	(21,000)	110,816
Exchange rate effects	(835)	(3,486)
Cash and cash equivalents at 1 January	205,159	74,348
Total cash and cash equivalents at 30 September	183,324	181,048
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#### **Appendix: Main Condensed Consolidated Financial Statements reported in Euro's**

These statements are not part of the original Interim Financial Statements. The original Interim Financial Statements are reported in US Dollars. In case of differences of interpretation between the Financial Statements in US dollars and the Financial Statements in Euros, the Financial Statements in US Dollars will prevail.

#### Exchange rates (USD:EUR) used:

Statement of income YTD 2020	1.1274
Statement of income YTD 2021	1,1982
Balance sheet at September 2020	1.1696
Balance sheet at December 2020	1.2280
Balance sheet at September 2021	1.1600
Cash flow YTD 2020	1.1274
Cash flow YTD 2021	1,1982
Cash balance as per 1 January 2020	1.1214
Cash balance as per 31 December 2020	1.2280
Cash balance as per 1 January 2021	1.2280
Cash balance as per 30 September 2021	1.1600



## **CONDENSED CONSOLIDATED STATEMENT OF PROFIT AND LOSS - EUR**For the 9-month period ended 30 September

Amounts in € '000	YTD 2021	YTD 2020
Revenues	121,934	134,714
Costs of sales	(12,936)	(14,694)
Gross profit	108,998	120,020
Other income	1,509	718
Research and development	(31,364)	(23,810)
OTL-105 in-licensing	(10,937)	0
General and administrative	(18,786)	(13,670)
Marketing and sales	(36,621)	(32,113)
Other Operating Costs	(97,709)	(69,593)
Operating profit	12,798	51,145
Fair value gain (loss) on revaluation derivatives	49	131
Other finance income	8,268	581
Other finance expenses	(3,728)	(18,285)
Finance cost net	4,589	(17,573)
Share of net profits in associates using the equity method	427	195
Profit before tax	17,815	33,767
Income tax expense	(6,188)	(8,171)
Profit for the year	11,627	25,596
Basic earnings per share (€)	0.018	0.040
Fully-diluted earnings per share (€)	0.015	0.035



#### **CONDENSED CONSOLIDATED BALANCE SHEET - EUR**

#### As at 30 September

Amounts in € ′000	30 September	31 December
Non-current assets		
Intangible assets	76,732	76,615
Property, plant and equipment	14,581	9,956
Right-of-use assets	18,088	7,676
Long-term prepayments	171	0
Deferred tax assets	18,510	25,957
Investments accounted for using the equity method	6,196	5,796
Investment in equity instruments designated as at FVTOCI	2,434	0
Restricted cash	415	415
Total non-current assets	136,833	126,415
Current assets		
Inventories	21,636	17,229
Trade and other receivables	28,285	29,236
Restricted cash	846	810
Cash and cash equivalents	158,037	167,068
Total current assets	208,804	214,343
Total assets	345,637	340,758

Equity Share capital Share premium Legal reserves	6,258 390,928 8,504	6,388 396,799 4,341
Share premium	390,928 8,504	396,799
Logal reserves	,	4.341
Legarreserves	(220,020)	,
Accumulated deficit	(238,839)	(258,151)
Shareholders' equity	166,851	149,377
Non-current liabilities		
Convertible bonds	121,519	121,927
Lease liabilities	16,657	6,702
Other financial liabilities	333	173
Total non-current liabilities	138,509	128,802
Current liabilities		
Convertible bonds	1,657	1,661
Derivative financial liabilities	47	147
Trade and other payables	36,337	38,816
Lease liabilities	2,237	1,598
Other financial liabilities	0	20,357
Total current liabilities	40,277	62,579
Total equity and liabilities	345,637	340,758



## **CONDENSED CONSOLIDATED STATEMENT OF CASH FLOWS - EUR** For the period ended 30 September

Amounts in €'000	YTD 2021	YTD 2020
Profit before tax	17.816	33.767
Non-cash adjustments:		
Depreciation, amortization, impairment	5.730	5,092
Equity settled share-based payments	4.763	2,098
Fair value gain (loss) on revaluation of derivatives	-49	-131
Other finance income	-8.268	-581
Other finance expense	3.728	18,285
Share of net profits in associates using the equity method	-427	-195
Other	226	2,208
Operating cash flows before changes in working capital	23.519	60,543
Changes in working capital:		
Inventories	-3,289	-1,915
Trade and other receivables	2,580	-709
Payables and other current liabilities	-4,602	-1,755
Restricted Cash	35	1,012
Total changes in working capital	-5,276	-3,367
Total changes in working capital	3,270	3,307
Interest received	43	581
Income taxes paid	0	-2,431
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Net cash flows generated from (used in) operating activities	18,286	55,326
Capital expenditure for property, plant and equipment	-6,219	-1,376
Investment intangible assets	-1,289	-332
Investment in equity instruments designated as at FVTOCI	-3,830	0
Acquisition of license	-1,330	-8,447
Net each flavor word in investing asticities	12.000	10.155
Net cash flows used in investing activities	-12,668	-10,155
Repayment on loans and borrowings	0	-49,914
Payment on contingent consideration	-20,865	-18,135
Payment of lease liabilities	-2,067	-1,321
Proceeds of issued convertible bonds	0	122,682
Interests on loans and leases	-3,750	-2,725
Proceeds of equity and warrants	3,536	2,035
	2,330	_,555
Net cash flows generated from (used in) financing activities	-23,146	52,622
Increase (decrease) of cash	-17,528	97,793
Exchange rate effects	8,497	-9,297
•	1167.068	166.299
Cash and cash equivalents at 1 January	167,068	66,299