

# Pharming Group NV

Half Year Results 2019

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25 July 2019



# Forward looking statements

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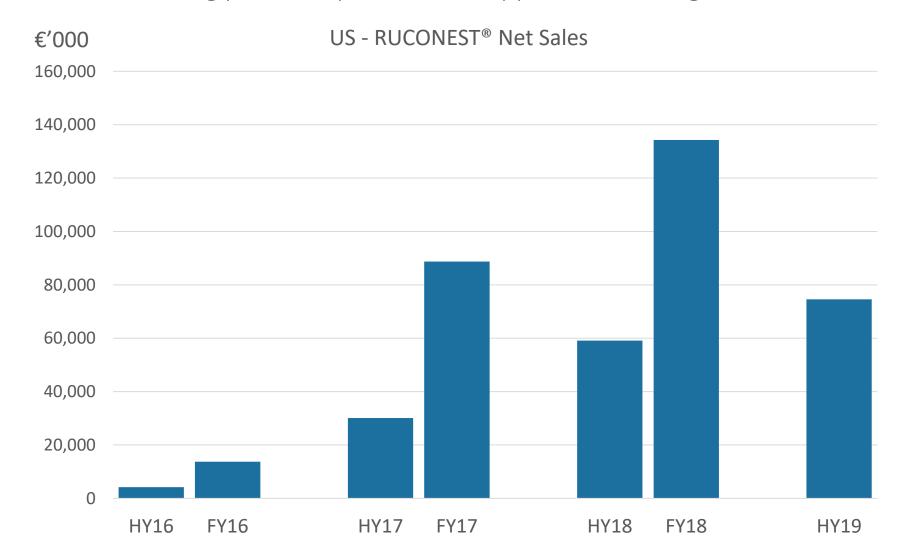


Half year results 2019

## Strong execution of commercial strategy



Continued growth from existing and new patients using RUCONEST® to treat acute HAE attacks, and increasingly also as a preferred therapy for breakthrough HAE attack





Behind the growth

### Differentiating RUCONEST® in changing HAE landscape



- Multiple treatment options provide better management of HAE
  - Severely affected patients need reliable C1 product to treat attacks and have come to recognise the power of RUCONEST®
  - Recent launches of subcutaneous plasma-derived C1 inhibitor product and subcutaneous long-acting antibody increase competitive pressure in prophylaxis segment
  - New treatments offer better attack reduction rates than previous IV plasma-derived C1inhibitor prophylaxis treatment
  - Over half of patients using prophylaxis treatments have breakthrough attacks, some frequently, according to published data and FDA analyses
- Therefore, there is a need recognised by for effective and reliable C1 treatment for breakthrough attacks
  - Continued growth opportunity for RUCONEST® for treatment of breakthrough attacks associated with new prophylaxis products

#### Investment to increase capacity due to strong demand



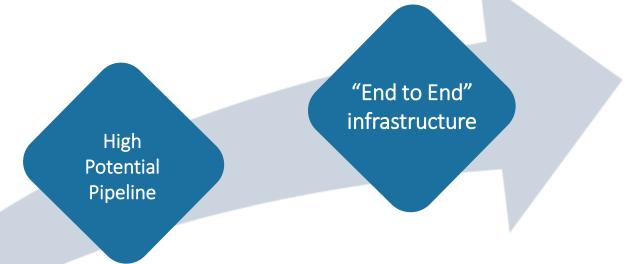
- New second production facility in Netherlands already built, with a larger third in building design stage with construction to start in not too distant future and an even larger fourth unit to follow
  - Underlying demand for RUCONEST® increasing further in both US and rest of the world
  - Higher frequency of ad hoc supplies in various EU markets as a result of 'temporary' shortages of competitor plasma-derived products has resulted in short-term pressure on supplies of product for the European market
  - We can currently sell more than we can release, which is putting pressure on inventories
- We will be able to produce enough RUCONEST® to eliminate supply pressure once approved by either main regulator, which is anticipated by the end of Q1 2020
- The new site more than doubles existing capacity. The third site will add 60% more capacity on top of this.



Investing for long-term sustainable revenue growth

### Pharming:- Built to Grow





Solid, profitable revenue generation

Pharming has all the capabilities needed for sustainable, high growth

Today, we are a profitable, growing international biotech, with one launched product with multiple opportunities, ~\$600M market capitalization, fully integrated from primary research through production platform to commercialization

Tomorrow, we aim to become a (global) pharmaceutical company with multiple products with blockbuster potential in rare and specialty diseases and in large unmet indications

### New indications for RUCONEST® – pre-eclampsia



- Pre-eclampsia (PE) is a life-threatening multisystem condition in pregnancies leading to increased maternal and neonatal mortality and morbidity
- 2.5 million cases, and 50,000 maternal deaths globally p.a. for patients who proceed to eclampsia, while many more are caused by long-term irreversible damage to organs caused by PE
- Treatments include termination of pregnancy or premature birth
  - Over half of PE newborns suffer from growth restrictions, learning difficulties or moderate to severe disabilities
  - Premature birth is not a viable option for early PE (from week 20 of pregnancy)
  - There are no approved therapies
- Following approval from the Dutch investigating centre's ethics committee, Pharming is working to commence a phase I/II clinical study of the effects of its recombinant human C1 esterase inhibitor (RUCONEST®) in patients with PE. Australian authority in final stages of review.
- The main goal of therapy is to prolong a safe pregnancy for PE patients as long as possible to improve the chances of a good outcome from delivery

#### New indications for RUCONEST® – acute kidney injury



- Acute kidney injury (AKI) as a result of exposure to medical imaging contrast material
  - o 40 million contrast examinations in the US alone, and 100 million worldwide, with around 20% (8 million in US) on patients with known or suspected kidney function impairment
  - 6%-21% of these patients go on to suffer serious kidney injury, often irreversible despite ICU care, depending on type of scan and medium used
- Prior data supports further investigation of RUCONEST® in patients with AKI
  - Positive results from Phase II investigator-initiated study of RUCONEST® in patients at risk of nephropathy resulting from contrast-enhanced examinations
  - Statistically significant effect in reducing Neutrophil Gelatinase-Associated Lipocalin (NGAL), the primary endpoint for the study, in patients undergoing percutaneous coronary intervention (PCI)
- Subject to approval of regulatory authority approval: We foresee to be able to initiate a clinical trial in H2 2019 with RUCONEST® to prevent/treat acute kidney injury in patients undergoing PCI, led by Dr Michael Osthoff, with likely up to 5-6 centres in Switzerland and Germany
- 160 patients in three dose arms and a placebo arm, measuring NGAL as primary endpoint as well as creatinine at a 6 month follow-up

#### Other investments



#### Pompe disease

- Invested in production of  $\alpha$ -glucosidase from our proprietary technology platform
- Dialogues ongoing with key opinion leaders on future clinical program designs
- Current plan is for multidose Phase I/II study, which means starting later (due to amount of material required) but finishing at same time as previous single-dose Phase I start plan
- Confirmation will be sought from regulatory authorities

#### BioConnection B.V.

- Completed investment in fill & finish partner, which manufactures the final sealed vials of RUCONEST® and  $\alpha$ -glucosidase
- A fast-growing profitable private company with a global customer base
- Strategic investment supports capacity expansion that will help Pharming to meet growing demand for RUCONEST® and long-term expansion of pipeline



# Financial statements

#### Delivering record revenues



- Record H1 revenues increase of 31% to €77.9m in H1 2019 (H1 2018: €59.5m
  - Quarter on Quarter growth: 21% to €42.7m in Q2 2019 (Q1 2019: €35.2m)

- US product sales increased 33% to €75.0m in H1 2019 (H1 2018: €56.3m
  - Quarter on Quarter growth: 21% to €40.9m in Q2 2019 (Q1 2019: €33.7m), reflecting strong growth despite a more competitive marketplace

- EU and RoW product sales flat at €2.5m for H2 2019 (H1 2018: €2.5m
  - Increased competition in certain Eastern European markets affecting SOBI following new product launches
  - Balanced by limited growth for Pharming direct markets which are affected by national revenue caps

#### Increased investment in growth



- Operating profit increased 51% to €24.6m in H2 2019 (H1 2018: €16.3m)
  - o reflects an improvement in gross margin and better cost controls
- Net profit increased by 60% to €13.6m in H2 2019 (H1 2018: €8.5m)
- Increased investment in pipeline and infrastructure to support long-term growth
  - Increased expenditure in Q2 2019 (compared to Q1) on pre-eclampsia and acute kidney injury studies, production of  $\alpha$ -glucosidase product for Pompe disease and capacity improvements
  - Net effect of increased sales and increased/delayed costs for investment resulted in a stable cash position of €65.3m at H1 2019 (Q1 2019: €66.5m and H1 2018: €66.9m)

### Income statement – operating profit



Amounts in € '000	notes	HY 2019	HY 2018 restated *
Revenues	7	77,935	59,454
Costs of sales	8	(10,956)	(9,473)
Gross profit		66,979	49,981
Other income		148	300
Research and development		(14,877)	(12,013)
General and administrative		(6,842)	(5,242)
Marketing and sales		(20,776)	(16,736)
Costs	8	(42,495)	(33,991)
Operating result		24,632	16,290

<sup>\*</sup>Prior year's interim financial statements restated due to an adjustment in the accounting of the convertible bond redemption

### Income statement – net result



Amounts in € '000	notes	HY 2019	HY 2018 restated *
Operating result		24,632	16,290
Fair value gain (loss) on revaluation derivatives		(8)	(1,218)
Other financial income	9	506	1,181
Other financial expenses *	9	(6,767)	(6,802)
Financial income and expenses		(6,269)	(6,839)
Share of net profits in associates using the equity method	10	299	-
Result before income tax		18,662	9,451
Income tax credit (expense)		(5,068)	(932)
Net result for the year		13,594	8,519
Basic earnings per share (€)	15	0.022	0.014
Fully-diluted earnings per share (€)	15	0.020	0.013

### Balance sheet – assets



Amounts in € '000	notes	30 June 2019	31 December 2018
Non-current assets		2013	2010
Intangible assets		51,516	52,435
Property, plant and equipment		8,758	8,402
Right-of-use assets	11	6,264	-
Long-term prepayments		-	2,006
Deferred tax assets		31,286	35,082
Investments accounted for using the equity method	10	5,377	-
Restricted cash		1,379	1,204
Total non-current assets		104,580	99,129
Current assets			
Inventories	12	12,705	17,315
Trade and other receivables		24,624	17,814
Cash and cash equivalents		63,886	80,311
Total current assets		101,215	115,440
Total assets		205,795	214,569

### Balance sheet – liabilities



Amounts in € '000	notes	30 June 2019	31 December 2018
Equity		2013	2010
Share capital		6,257	6,215
Share premium		389,310	387,525
Legal reserves		1,757	1,647
Accumulated deficit		(319,834)	(333,636)
Shareholders' equity	13	77,490	61,751
Non-current liabilities			
Loans and borrowings	14	25,262	37,267
Deferred tax liabilities		55	87
Contract liabilities		267	667
Leaseliabilities	11	4,745	164
Other financial liabilities		32,003	32,034
Total non-current liabilities		62,332	70,219
Current liabilities			
Loans and borrowings	14	33,607	35,235
Contract liabilities		800	800
Derivative financial liabilities		127	228
Trade and other payables		29,438	28,589
Leaseliabilities	11	2,001	263
Other financial liabilities		-	17,484
Total current liabilities		65,973	82,599
Total equity and liabilities		205,795	214,569

# Cash flow – operating activities



Amounts in €'000	HY 2019	HY 2018
Operating result	24,632	16,290
Non-cash adjustments:		
Depreciation, amortisation, impairment	2,794	1,903
Accrued employee benefits	1,350	1,750
Release contract liabilities	(400)	(403)
Operating cash flows before changes in working capital	28,376	19,540
Changes in working capital:		
Inventories	4,610	(4,829)
Trade and other receivables	(7,379)	(5,515)
Payables and other current liabilities	170	(444)
Total changes in working capital	(2,599)	(10,788)
Changes in non-current assets, liabilities and equity	(605)	814
Cash generated from (used in) operations before interest and taxes	25,172	9,566
Interest received	475	-
Income taxes paid	(625)	-
Net cash flows generated from (used in) operating activities	25,022	9,566

### Cash flow – overall



Amounts in €'000	HY 2019	HY 2018
Net cash flows generated from (used in) operating activities	25,022	9,566
Capital expenditure for property, plant and equipment	(1,216)	(1,380)
Investment intangible assets	(521)	(634)
Investment in associates	(2,503)	-
Net cash flows used in investing activities	(4,240)	(2,014)
Repayment on loans and borrowings	(15,533)	(2,238)
Payment on contingent consideration	(17,635)	-
Interests on loans	(4,830)	(5,384)
Principle element of lease payments	(619)	-
Proceeds of equity and warrants	992	6,907
Net cash flows generated from (used in) financing activities	(37,625)	(715)
Increase (decrease) of cash	(16,843)	6,837
Exchange rate effects	593	75
Cash and cash equivalents at 1 January	81,515	59,993
Total cash and cash equivalents at 30 June	65,265	66,905



Outlook for Full Year 2019

#### Strong start to 2019, and confident in full year outlook



#### For the remainder of 2019, the Company expects:

- Continued growth in revenues from sales of RUCONEST®, mainly driven by the US and Western Europe operations
- Continued achievement of positive net earnings during the year
- Continued investment in the expansion of production of RUCONEST® to supply the growing demand for RUCONEST® internationally
- Investment in clinical trials for pre-eclampsia and acute kidney injury, and support for investigators wishing to explore additional indications for RUCONEST®
- Re-evaluation of the most advantageous new routes of administration while we focus on supplying all patients looking to receive RUCONEST® therapy
- Investment in development of the new pipeline programs in Pompe disease and Fabry's disease, and purchase or license of other new development opportunities and assets
- Supporting all our teams and marketing partners in order to enable the maximisation of the sales and distribution potential of RUCONEST® for patients in all territories



#### Tickers:

• ENXTAM: PHARM

• Bloomberg: PHAR.AS