# Pharming Group NV

Half Year Results 2018

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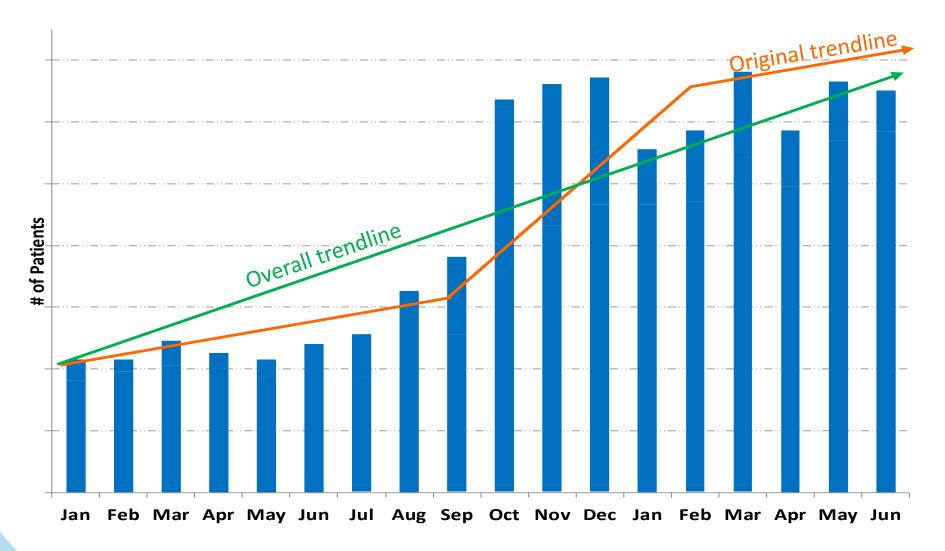
# Half year results 2018



## Operational highlights

- Continued underlying growth for RUCONEST® in the USA following stabilisation of short supply situations at major competitors, driving growth and good patient retention rates
- FDA acceptance of sBLA file for RUCONEST® for prophylaxis of HAE, with an action date set for 21 September 2018
- New versions of small vial liquid and fast-dissolving dose forms for RUCONEST® in subcutaneous, intramuscular and intradermal versions for use in clinical studies starting later in 2018/early 2019
- Five studies ongoing or starting to expand the pipeline strongly:
  - Ongoing investigator-sponsored study of RUCONEST® in a double-blind, placebo-controlled trial in contrast-induced nephropathy – top-line data expected in Q3 2018
  - New Phase I/II study of rhC1INH in pre-eclampsia to start in Q4 2018
  - Ongoing investigator-sponsored head-to-head study of RUCONEST® in a trial testing therapy failure rates in treating acute attacks of HAE top-line data expected in Q4 2018
  - Initiation of investigator-sponsored study of RUCONEST® to treat delayed graft function
  - New in-house clinical trial of Pharming's proprietary recombinant human alphaglucosidase in Pompe disease to be filed at the year end

## Continued growth in US sales





## Financial highlights

- Delivered net profitability for the half year
- Revenues from product sales for the half year increased by 96% to €59.1 million (HY 2017:
   €30.1 million), as a result of the continued increasing patient numbers
- Operating results improved by 288% to a profit of €16.3 million from €4.2 million in 2017, despite an increase in manfacturing and clinical activities related to the new indications
- The net result was a profit of €6.4 million (2017: loss of €30.2 million)
- The company's cash position increased 12% from €60.0 million at the year end 2017 (31 March 2018: €60.0 million and 30 June 2017: €25.2 million) to €66.9 million at 30 June 2018, largely due to the high sales level and improved gross margin



# Investing for Long-term Growth



### The HAE market

- All current and known future prophylaxis therapies continue to have limitation of use as result of their specific efficacy and safety characteristics
- In addition, supply constraints and limited up-scalability of plasma-derived C1 inhibitor manufacturing have been and are expected to continue to be a potential limitation and risk to supply
- Exposure to commercially-obtained blood plasma has significantly increased with the introduction of the latest plasma-derived C1 inhibitor product – understood to be 1.2 tonnes per year per patient
- RUCONEST® is a proven fast, effective treatment for all acute (and thus all break-through) attacks
- RUCONEST® is the only recombinant C1 inhibitor protein replacement therapy for HAE, currently approved for acute attacks and potentially to be approved for prophylaxis in September this year
- It will therefore continue to have further growth potential as it has increasingly become a reasonable and reliable, efficacious, safe and well tolerated alternative



### Label expansion and improving patient convenience

#### New label extensions for recombinant C1 esterase inhibitor (RUCONEST®)

- Prophylaxis of HAE attacks (under FDA review, with action date 21 September)
- Treatment of young HAE patients (pediatric label, under review after positive opinion)

New routes of administration and product forms to improve convenience for recombinant C1 esterase inhibitor (RUCONEST®) in HAE

- Liquid version to be introduced next year
- Low-volume concentrated vials to be tested for subcutaneous and intramuscular dosing for prophylaxis and acute attacks of HAE starting later this year, with new 'painless' intradermal technology to enter clinical development during 2019



### New indications to drive long-term value

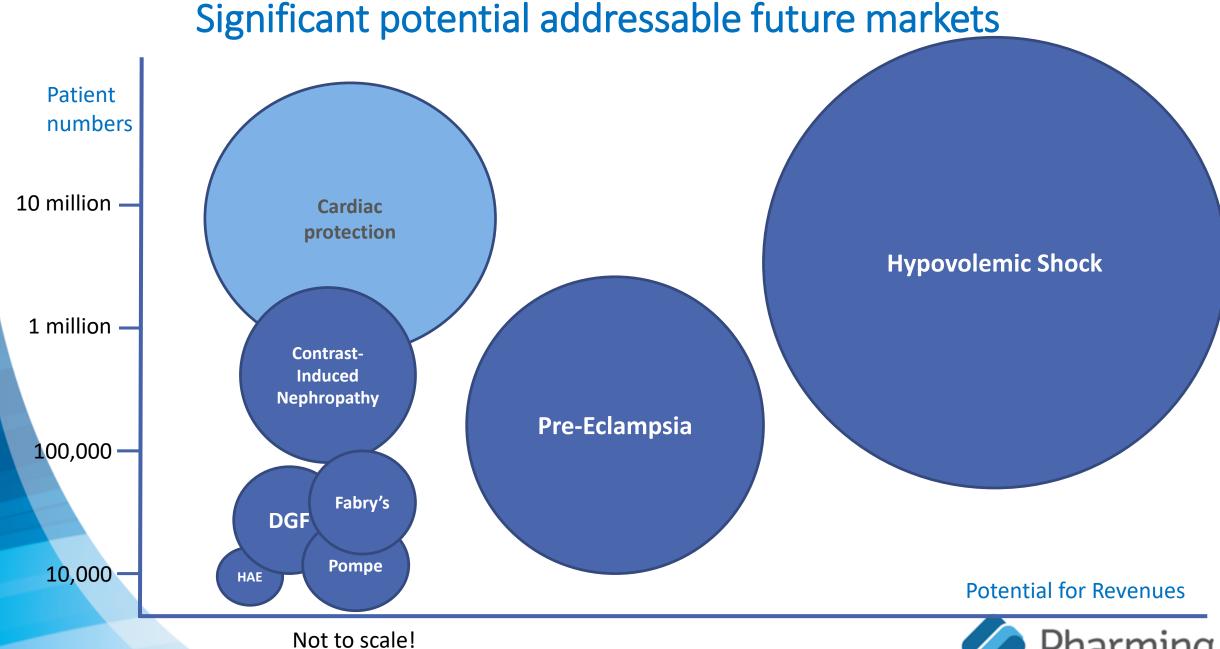
#### New large indications for recombinant C1 esterase inhibitor (RUCONEST®)

- Contrast-induced nephropathy ("CIN": large life-threatening indication with ~1 million patients, no approved therapy)
- Potentially cardiac protection (very large new indication depends on signal from CIN study)
- Pre-eclampsia (very large life-threatening indication with ~250k patients in US and EU, no approved therapy)

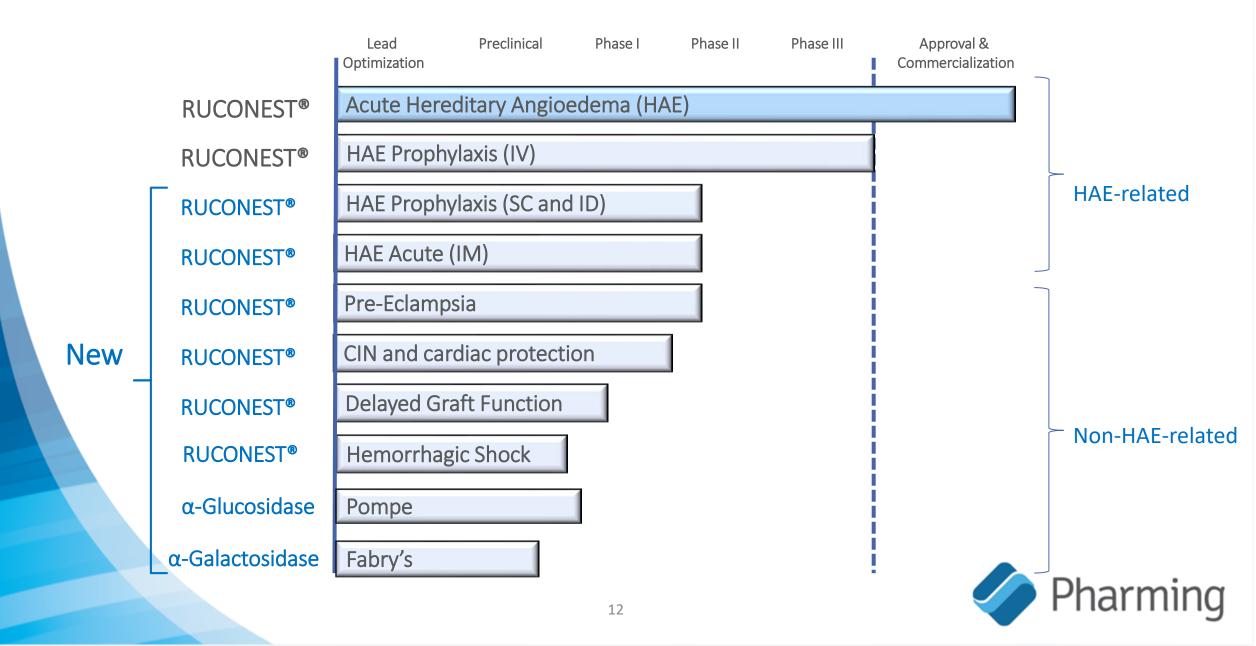
#### New version of recombinant C1 esterase inhibitor (RUCONEST®)

- Cattle version to be restarted using previous successful bulls
- Enables large indications to be fully supplied (unlikely to be possible with plasma-derived versions)
- Even closer to natural human enzyme than rabbit version



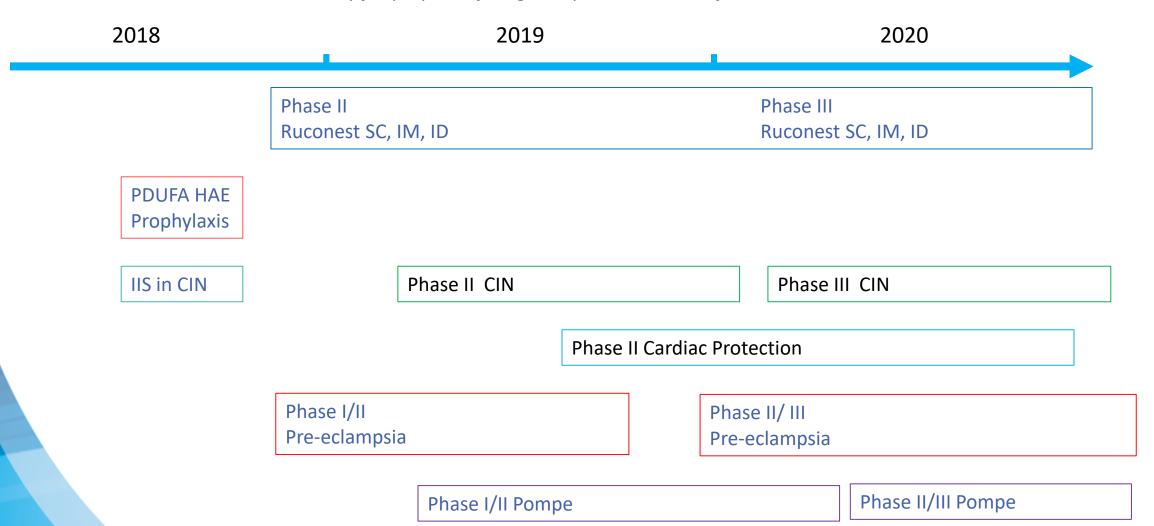


### Expansion of Pharming to a wide market, multiple product franchise



## Potential for significant clinical newsflow over the coming years

Assumed solely for purpose of diagram: positive results of studies





### Financial information & statements



### Income statement

Amounts in €'000	HY 2018	HY 2017
	50.054	20.400
Product sales	59,051	30,109
License fees	403	536
Revenues	59,454	30,645
Costs of sales	(9,473)	(3,657)
Gross profit	49,981	26,988
Other income	300	167
Research and development	(12,013)	(9,154)
General and administrative	(5,242)	(2,628)
Marketing and sales	(16,736)	(11,140)
Costs	(33,991)	(22,922)
Operating result	16,290	4,233
Fair value gain (loss) on revaluation derivatives	(1,218)	(1,225)
Other financial income and expenses	(7,785)	(33,226)
Financial income and expenses	(9,003)	(34,451)
Result before income tax	7,287	(30,218)
Income tax expense	(932)	-
Net result for the period	6,355	(30,218)
Attributable to:		
Owners of the parent	6,355	(30,218)
Total net result	6,355	(30,218)

### Balance sheet - Assets

Amounts in €'000	Notes	30 June	31 December
		2018	2017
Intangible assets Property, plant and equipment Long term prepayment Deferred tax asset Restricted cash		55,843 8,291 1,865 8,526 1,366	56,631 8,234 2,296 9,442 1,336
Non-current assets		75,891	77,939
Inventories Trade and other receivables Cash and cash equivalents Current assets	9	23,162 16,775 65,539 <b>105,476</b>	18,334 11,260 58,657 <b>88,251</b>
Total assets		181,367	166,190



### **Balance Sheet - Liabilities**

Amounts in €'000	Notes	30 June 2018	31 December 2017
Share capital		6,104	5,790
Share premium		387,760	370,220
Legal reserves		(1,098)	(938)
Accumulated deficit		(352,101)	(356,270)
Shareholders' equity	10	40,665	18,802
Loans and borrowings	11	47,860	58,684
Deferred license fees income		1,067	1,467
Finance lease liabilities		247	390
Other financial liabilities		27,155	28,319
Non-current liabilities		76,329	88,860
Loans and borrowings	11	35,174	21,962
Deferred license fees income		800	804
Derivative financial liabilities	12	1,382	8,301
Trade and other payables		26,754	27,198
Finance lease liabilities		263	263
Current liabilities		64,373	58,528
Total equity and liabilities		181,367	166,190



## **Cash flow - Operating Activities**

Amounts in €'000	HY 2018	HY 2017
Operating result	16,290	4,233
Non-cash adjustments:		
Depreciation, amortization	1,903	1,689
Accrued employee benefits	1,750	872
Deferred license fees	(403)	(536)
Operating cash flows before changes in working capital	19,540	6,258
Changes in working capital:		
Inventories	(4,829)	468
Trade and other receivables	(5,515)	(6,015)
Payables and other current liabilities	(444)	(1,792)
Total changes in working capital	(10,788)	(7,339)
Changes in non-current assets, liabilities and equity	814	(3,109)
Cash generated from (used in) operations before interest and taxes	9,566	(4,190)



### Cash flow - Overall

Amounts in €'000	HY 2018	HY 2017
Net cash flows generated from (used in) operating activities	9,566	(4,190)
Capital expenditure for property, plant and equipment	(1,380)	(1,457)
Investment intangible assets	(634)	(598)
Net cash flows used in investing activities	(2,014)	(2,055)
Proceeds of loans and borrowings		89,139
Payments of transaction fees and expenses		(16,051)
Prepayments and interests on loans and borrowings	(7,622)	(73,399)
Proceeds of equity and warrants	6,907	284
Net cash flows generated from (used in) financing activities	(715)	(27)
Increase (decrease) of cash	6,837	(6,272)
Exchange rate effects	75	(620)
Cash and cash equivalents at 1 January	59,993	32,137
Total cash and cash equivalents at 30 June	66,905	25,245
Of which restricted cash	1,366	248
Cash and cash equivalents at 30 June	65,539	24,997



# Outlook 2018



### Outlook for 2018

For the remainder of 2018, the Company expects:

- Continued growth in revenues from sales of RUCONEST®, mainly driven by the US operations
- Achievement of additional positive quarterly (operating and net) results throughout the remainder of the year
- Continued investment in the production of RUCONEST® in order to ensure continuity of supply to the growing markets in the US, Europe and the rest of the world
- Investment in RUCONEST® in prophylaxis of HAE (following approval) and in the development of new subcutaneous, intramuscular and painless intradermal versions of RUCONEST®
- Investment in clinical trial development for RUCONEST® in other indications where the drug's unique properties may help solve large unmet medical needs
- Continued investment in our pipeline programs in Pompe disease and Fabry's disease
- We will look to acquire additional development opportunities and assets as they occur
- Increasing marketing activity where profitable for Pharming

No further financial guidance for 2018 is provided



Tickers:

**ENXTAM: PHARM** 

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