

# ANNUAL REPORT 2018

Transforming the future for our patients

CHIEF EXECUTIVE OFFICER'S STATEMENT OPERATIONAL AND FINANCIAL HIGHLIGHTS

**FINANCIAL STATEMENTS** 



# **ANNUAL REPORT PHARMING 2018**









#### FORWARD-LOOKING STATEMENTS

This Annual Report 2018 of Pharming Group N.V. and its subsidiaries ("Pharming", the "Company" or the "Group") may contain forward-looking statements including without limitation those regarding Pharming's financial projections, market expectations, developments, partnerships, plans, strategies and capital expenditures. The Company cautions that such forward-looking statements may involve certain risks and uncertainties, and actual results may differ. Risks and uncertainties include without limitation the effect of competitive, political and economic factors, legal claims, the Company's ability to protect intellectual property, fluctuations in exchange and interest rates, changes in taxation laws or rates, changes in legislation or accountancy practices and the Company's ability to identify, develop and successfully commercialise new products, markets or technologies. As a result, the Company's actual performance, position and financial results and statements may differ materially from the plans, goals and expectations set forth in such forward-looking statements. The Company assumes no obligation to update any forward-looking statements or information, which should be taken as of their respective dates of issue, unless required by laws or regulations.

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The following sections of this annual report form the director's report within the meaning of section 2:391 of the Dutch Civil Code: Operational Hightlights 2018, Financial Hightlights 2018, About Pharming Group, Chief Executive Officer's Statement, Management Report, Statement of the Board of Management, Management Structure, Corporate Governance and Risk Management, Report of the Remuneration Committee, Corporate Social Responsibility.

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# 2018 OPERATIONAL HIGHLIGHTS

#### THROUGHOUT THE YEAR,

we have been achieving good sales growth in the USA of RUCONEST® (C1 esterase inhibitor [recombinant]) for the treatment of acute hereditary angioedema (HAE) attacks, as a result of the investments in our commercial infrastructure in North America. We have also been increasing sales in our European territories, principally Germany, France and the UK. These two activities have resulted in worldwide product sales growth in 2018 of 51.4%, up from €88.7 million in 2017 to €134.3 million in 2018. In the USA, the growth was even more marked, from US\$94.6 million in 2017 to US\$149.3 million in 2018, a gain of 57.8%. These large differences reflect the underlying growth in patient numbers, which were boosted in both years by temporary supply shortages at competitors but following normalisation of supplies and despite new competitive entrants continue to grow steadily. This sales performance coupled with tight cost control and conversion of debt instruments enabled us to produce net profits for the first time in Pharming's history, and we did so throughout the year. As a result, we were able to increase R&D investment significantly, enabling us to expand our product development activities and capacity.

#### IN JUNE,

we held our first Capital Market Day in New York with a live webcast to the rest of the world. At this Capital Markets Day, the Company provided an update on its ongoing activities and the strategy for its growing research and development pipeline, both for its recombinant human C1 esterase inhibitor (rhC1INH) opportunities and for new protein replacement products. In particular, the update covered Pharming's three pillars of growth:

- new developments of its lead product RUCONEST® (a form of rhC1INH) within the HAE space to meet patients' needs;
- 2 New development of rhC1INH outside HAE to tackle a number of other major unmet medical needs for which there are no current approved or effective therapies; and
- 3 Clinical development of new protein replacement products which address significant shortcomings of existing therapies.

The Capital Markets Day included presentations from top key opinion leaders in HAE and Pre-eclampsia. Professor Marc Riedl, Professor of Medicine at the University of California, San Diego and Clinical Director of the US HAEA Angioedema Center and a world expert on the diagnosis, treatment and etiology of hereditary angioedema, and Professor Gustaaf Dekker, of the school of Obstetrics and Gynaecology at the University of Adelaide and a world expert on the diagnosis, etiology and treatment of pre-eclampsia, made presentations of the potential value of rhCiINH in these two indications.

#### IN SEPTEMBER,

the Company received a Complete Response Letter (CRL) from the U.S. Food and Drug Administration (FDA) regarding the supplemental Biologics License Application (sBLA) for RUCONEST® to expand the current indication to include prophylaxis in patients with hereditary angioedema (HAE). In November 2017, following feedback from FDA on two completed trials of RUCONEST® for prophylaxis of HAE attacks, Pharming had filed an sBLA to expand the approved indication. In January 2018, the U.S. Food and Drug Administration (FDA) had accepted the file and indicated that the sBLA was sufficiently complete to permit a substantive review. The Phase II studies, an open-label study and a separate randomised, double-blind, placebo-controlled trial with 4-8 week treatment periods, showed consistent efficacy and safety results. Unfortunately, as a result of the limited nature of these studies and the treatment periods, the statistical hurdle for a final review question on a small subgroup of patients could not be reached. Based on their review, the FDA requested additional data to clarify the effectiveness of RUCONEST® further in HAE prophylaxis in this subgroup. This additional data will be gathered as part of the new acute and prophylaxis studies of RUCONEST® in other forms of delivery (intramuscular, subcutaneous and intradermal routes of administration) designed to increase convenience for patients.

#### IN OCTOBER,

Pharming announced positive results from a Phase II investigator-initiated study of RUCONEST® in a doubleblind, placebo-controlled clinical trial in patients at risk of nephropathy resulting from contrast-enhanced examinations. The study was led by Dr. Michael Osthoff at the University Hospital Basel, Basel, Switzerland.

The positive results were especially clear in the sub-group of patients undergoing percutaneous coronary interventions (PCIs) such as stent insertions. The intent-to-treat analysis in this group showed that patients on RUCONEST® had a median increase in peak urinary NGAL concentration within 48 hours of 1.8 ng/ml compared with an increase of 26.2 ng/ml in the placebo arm (p=0.04). This corresponds to a clear difference in the median percentage change in the peak urinary NGAL level within 48 hours of 11.3% in the RUCONEST® arm and 205.2% in the placebo arm (p=0.001). The overall assessment of the study also showed trends that patients undergoing more invasive interventions and procedures requiring higher volumes of contrast medium experienced a stronger benefit from the RUCONEST® treatment.

This data clearly supports additional clinical investigations for the use of rhC1INH in this new large indication where there is significant unmet medical need in patients at risk of serious kidney damage and even death. We are therefore preparing a follow-on study to be initiated once feedback from regulators can be incorporated in the design.

#### IN DECEMBER,

Pharming announced the results from an investigatorinitiated comparative ("real world" observational) study of therapies used in acute attacks of HAE: the first of its kind. The study examined and compared re-dosing rates *inter alia* for human C1 esterase inhibitor in recombinant form (RUCONEST®) and plasma-derived forms (such as Berinert®, Cinryze®) to icatibant (Firazyr®) in seven individual patients at risk of HAE attacks. A total of 69 attacks were recorded. The study was led by Professor Dr Marcus Magerl of the Department of Dermatology and Allergy at the Charité Universitätsmedizin Berlin, Berlin, Germany. The main outcome of the study confirmed that treatment with recombinant C1 therapy RUCONEST® and plasma-derived C1 treatments requires significantly less redosing than icatibant to resolve HAE attacks.

# 2018 FINANCIAL HIGHLIGHTS

As part of the Valeant transaction in December 2016, the Company raised €104 million in new funding through a combination of a rights issue, a new senior loan and both ordinary and amortising convertible bond issues. The Company took the decision early in 2017 to refinance these bonds, which also meant refinancing the senior debt facility as well. This refinance was completed in May 2017 with Orbimed Advisors, on slightly better cash terms for the Company than the instruments it replaced. In early 2018, we were able to eliminate almost all of the remaining warrants and convertibles, so that at the year end our balance sheet and shareholding are clear of these complicating factors. This has also reduced the negative effects of IFRS fair value adjustments relating to those warrants and convertibles which were a significant feature of the 2017 financial statements.

The cash generation from revenues during the year enabled the Company to offer an option for cashless exercise of the outstanding warrants of the Company, to decrease the dilutive share overhang caused by the existence of these warrants. This resulted in the exercise of 14,802,056 warrants, saving the Company from issuing an additional 3,679,787 shares and equating to a reduction of the fullydiluted share capital by 0.6%. The remaining Ordinary Bonds converted into 2,746,476 shares, and these Ordinary Bonds were then eliminated and delisted from the Cayman Islands Exchange where they had been tradable.

These exercises, together with the exercise of employee options during the first open period for many quarters, resulted in a balance sheet which has only one debt facility, the loan from Orbimed Advisors. Repayments of this debt facility began in September 2018. Even with repayments of debt of over  $\leq 14.5$  million excluding exit fee in the third and fourth quarters, cash increased during the year by over  $\leq 21.5$ million to  $\leq 81.5$  million, from  $\leq 60.0$  million at the end of 2017.

Following a reassessment of the adjustments made at the end of 2017 under IFRS, we have decided to reclassify some charges and capital items, which gives a more accurate picture of the redemption of the Ordinary Convertible Bonds and exercise of related warrants. This has resulted in a net change to the net result for 2017 from an  $\in$ 80.0 million loss to a  $\notin$ 76.2 million loss, and a restatement of the year end equity position from  $\notin$ 18.8 million to  $\notin$ 16.1 million, with the balance ( $\notin$ 0.9 million) shown in loans and borrowings in liabilities on the balance sheet. The individual adjustments made form the subject of a detailed note (Note 4) in this annual report.

#### IN MARCH,

Pharming Group shares were included in the Euronext Amsterdam SmallCap index (AScX). On entry into the AScX, Pharming became one of the larger index members. Composition of the AScX is reviewed quarterly by Euronext. Entry eligibility into any of the Amsterdam indexes is evaluated by certain price criteria as well as criteria related to free float/market capitalisation and free float/velocity. Based on these evaluations, Euronext ranks the companies by size into one of the indexes of the Amsterdam stock exchange.

#### **OVERALL:**

Total annual revenues increased to €135.1 million (including €0.8 million of license revenue) in 2018 from €89.6 million in 2017 (including €0.9 million in license revenue). The remaining unamortised license revenue will be exhausted in 2020.

Operating results improved very strongly to a profit of €38.0 million in 2018 from €21.9 million in 2017, an increase of 74% in spite of considerable increases in marketing and sales and R&D activity, mainly due to the effect of strong sales growth and efficient production of RUCONEST® in major markets. The basic underlying unadjusted operating result (EBIT) was €40.6 million, but this was reduced by a one-off writeback of previously capitalised development costs of €2.6 million relating to a superseded version of the small vial now under development. Operating costs increased significantly, reflecting the increased activity preparing for new clinical studies for pre-eclampsia and acute kidney injury, as well as development work on new forms of RUCONEST® including the concentrated liquid vial format and intramuscular and subcutaneous routes of administration.

FFor the first time in its history, Pharming Group reported net profits in 2018. The net profit of €25.0 million represented a €101.2 million reversal of a loss of €76.2 million in 2017. The main point of difference was the very large adjustments to profit required in 2017 in connection with the amortising bonds and their subsequent refinance, together with a significant adjustment to fair value of derivative financial liabilities stemming from the large share price rise during 2017. The elimination of these instruments has resulted in simplification of the capitalisation table which has led to much smaller adjustments relating to fair value changes during

2018. Together with a stronger operating result from larger sales, this has enabled the Company to reach sustainable net profitability.

The strong sales performance was so much better than previous years that the Board of Management has increased the book value of the contingent consideration from €28.3 million in 2017 to €49.5 million (US\$56.6 million) in 2018. This is essentially a provision for potential future costs of contingent liabilities taken on in the context of the reacquisition of the commercial rights for RUCONEST® in North America in December 2016 (specifically the sales milestone payments to Bausch Health Companies Inc. (Bausch), formerly Valeant Pharmaceuticals International Inc.). This is a strong expression of confidence in the future sales performance in the USA for RUCONEST®, which we believe will continue growing for the time being despite increased competition in the HAE marketplace. As the first milestone amount was due and paid in the first quarter of 2019, the amount of this payment (\$20.0 million or €17.5 million) is shown in the current liabilities section of the balance sheet, with the remainder shown under long term liabilities. Release of part of this provision will have the effect of negating the effect of the milestone payment on the Company's income statement in the first quarter 2019.

At the same time, because we believe that we will continue to generate positive net quarterly results in 2019, we expect to be making taxable profits in the foreseeable future and so have recorded an increase in the deferred tax asset to €35.1 million (2017: €9.4 million) in respect of net operating losses which we expect to be able to use in future periods. The net effect of this change is an increase in the net result of €24.1 million. After many years of operating losses, this is a strong statement in support of our belief in the underlying sustainable performance of the Company.

The equity position improved from €16.1 million in December 2017 to €61.8 million in December 2018, mainly due to the changes in the net result achieved by the Company and the equity increases from exercise of warrants and options. The 2017 equity figure was restated to reflect a change for that year in the accounting treatment of some of the fees associated with the refinance in 2017 as detailed in Note 4 to the Financial Statements on page 102.

Inventories reduced slightly from €18.3 million in December 2017 to €17.3 million in December 2018, largely due to the

increase in sales above the effect of movement of inventory from lower value raw materials to higher value drug product. This level of inventory together with our increased capacity improvements should enable us to continue to meet the growing sales levels especially in the US and in Europe.

The cash position including restricted cash increased from €60.0 million at year-end 2017 to €81.5 million at year-end 2018. This was mainly due to the strong sales performance of RUCONEST® especially in the third and fourth quarters, and occurred despite considerable increases in marketing and R&D activities and the repayment of over €14.5 million (\$16.7 million) of the loan. Cash generation has been strong across all four quarters of 2018, as sales revenues grew and as faster credit collection was achieved. Please note that all of these results were obtained without any price increase for RUCONEST® in any major market.

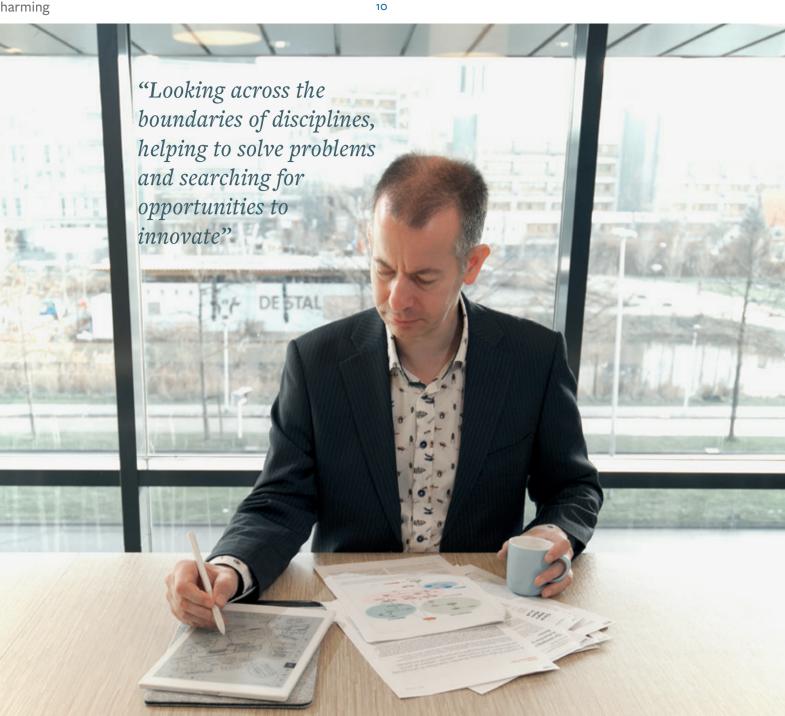
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# After the year end 2018

Since 31 December 2018, the following additional events have occurred:

• In March 2019, Pharming paid the first milestone due to Bausch Health Companies Inc. (formerly Valeant Pharmaceuticals International, Inc.) of €17.5 million (US\$20 million). This payment became due when cumulative net sales in the USA reached a certain undisclosed threshold level. Up to a total of an additional €39.3 million (\$45 million) of milestones may be due in future years if cumulative net sales in any one year reaches additional specific undisclosed higher levels.

◆ Also in March 2019, the Company provisionally committed to make a small €4.1 million investment in its fill and finish partner BioConnection B.V. ("BioConnection") composed of €1.6 million of cash and €2.5 million of debt converted to equity. This investment also involves the acceptance by Pharming of a corporate guarantee of up to €3 million in favour of ABN AMRO in respect of BioConnection. The entire transaction is intended to support BioConnection in taking out up to €12.1 million of new facilities to enable it to expand capacity almost four fold, to benefit specifically Pharming as well as other clients. BioConnection is a profitable company.



# **Testimonial Edwin**

By the time this report is published, I will have been with Pharming for close to ten years. I started in preclinical safety, acquiring further responsibilities in pharmacovigilance and regulatory affairs over the next couple of years. Long days, but I enjoyed the challenges and expanded my knowledge in a variety of fields. This flexibility is the main reason I have worked for Pharming for so long; you may get hired to do a certain job, but if you like other things, you will generally be allowed to further develop in other directions. In 2015, a year after the approval of RUCONEST® in the USA, my role changed.

Combining my scientific background, close to 20 years' experience in drug development and my never-ending curiosity, I can now do what I enjoy most: looking across the boundaries of disciplines, helping to solve problems and searching for opportunities to innovate. From that angle I participate in the project teams, but I also support business development, researching other companies and their projects or products. My ambition is to contribute to developing new therapeutics for diseases that badly need new treatments. This is what I hope to be doing with Pharming for many years to come.

# **About Pharming**

Pharming is a specialty pharmaceutical company innovative products for the safe, effective treatm diseases and unmet medical needs. Pharming's le RUCONEST® (conestat alfa) is a recombinant hum esterase inhibitor approved for the treatment of a attacks in patients in Europe, the US, Israel, Cold South Korea. The product is available on a named basis in other territories where it has not yet obta marketing authorsation.

The distribution of RUCONEST® in various market on page 13.

RUCONEST® is awaiting approval for the treatment of HAE in young children (2-13 years of age) and is also being evaluated for various additional follow-on indications.

An entirely new recombinant human alpha-glucosidase (rhaGLU) enzyme replacement therapy for Pompe disease is ready for clinical study, and this will be filed as soon as feedback from the regulatory authorities on the clinical study has been received and incorporated, and sufficient material from new processes has been manufactured and the files completed.

Pharming's technology platform includes a unique, GMP-compliant, validated process for the production of pure recombinant human proteins that has proven capable of producing industrial quantities of high quality recombinant human proteins in a more economical and less immunogenetic way compared with current cell-line or plasma fractionation-based methods. Leads for recombinant human alpha-galactosidase (rhaGAL) enzyme replacement therapy (ERT) for Fabry's disease are being optimised at present, with additional programs not involving ERT also being explored at an early stage.

Pharming has a long-term partnership with the China State Institute of Pharmaceutical Industry (CSIPI), a Sinopharm company, for joint global development of new products, starting with recombinant human Factor VIII for the treatment of Haemophilia A. Pre-clinical development and manufacturing will take place to global standards at CSIPI and will be funded by CSIPI. Clinical development will be shared between the partners with each partner taking the costs for their territories under the partnership.

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Pharming began to report financial results and related information in both euros and US dollars during 2018, beginning with the first quarter results statement in May 2018. This reflects the increasing importance of US dollars as a currency within Pharming, and the wider audience now seeking Pharming's published information. The presentation currency in 2019, from the first quarter results, will be US dollars first, with comparable data for the income statement and balance sheet given in euros afterward.

Additional information is available on the Pharming website: www.pharming.com

# Strategic Focus

Pharming is focused on improving treatment options for patients with life-altering conditions. The Company strategy is centred around three pillars of growth:

- Organic growth in HAE;
- Organic growth in other indications; and
- Expansion of the pipeline supplemented by external opportunities.

Activities to execute this growth strategy include:

- Commercialising our own products in the major markets, with RUCONEST® (a form of rhC1INH) as the lead product at present;
- Where the product is partnered, assisting the partner to obtain the best value for RUCONEST® and patients by pursuing additional regulatory approvals and additional indications for the product;
- Developing more convenient dosing forms of RUCONEST® (especially painfree or virtually painfree injection methods);
- Developing rhC1INH for additional large unmet indications, including acute kidney injury, pre-eclampsia and delayed graft function at present;
- Developing or acquiring external opportunites for new products which can be used by the same physicians who treat HAE patients, or can help those patients further, or can be commercialised using the same infrastructure; and
- Developing new protein replacement treatments for enzyme-deficiency disorders such as Pompe disease and Fabry's disease, as well as other possible rare disease approaches.

# Commitment

#### Pharming is committed to:

- Producing good value for all stakeholders through an entrepreneurial culture with appropriate recognition and efficient management of opportunities and risks; and
- Communicating openly, consistently, fairly and in a timely manner to all internal and external stakeholders; and
- Operating to the highest standards of ethics, environmental responsibility and animal welfare; and
- Continuing to maintain the highest levels of social and corporate responsibility as a pharmaceutical company, a research organisation, a manufacturer, an employer, a partner and a workplace.

# Distribution of RUCONEST®

#### RUCONEST®

is distributed by Pharming in Austria, France, Germany, Luxembourg, the Netherlands, the United Kingdom and the United States of America. Pharming holds commercialisation rights in Algeria, Andorra, Bahrain, Belgium, Ireland, Jordan, Kuwait, Lebanon, Morocco, Oman, Portugal, Qatar, Syria, Spain, Switzerland, Tunisia, United Arab Emirates and Yemen. In some of these countries this is done in association with the HAEi Global Access Program (GAP).

#### RUCONEST®

is distributed in Colombia, Costa Rica, the Dominican Republic, Panama, and Venezuela by Cytobioteck,

#### RUCONEST®

is distributed by Swedish Orphan Biovitrum AB (publ) (SS: SOBI) in the other EU countries, and also in Azerbaijan, Belarus, Georgia, Iceland, Kazakhstan, Liechtenstein, Norway, Russia, Serbia and Ukraine.

# RUCONEST is distributed in Israel by Kamada.

**RUCONEST**® is distributed in South Korea by HyupJin Corporation.

## CHIEF EXECUTIVE OFFICER'S STATEMENT

"2018 was the year in which we generated net profits for the first time in Pharming's history. We have now built a sufficiently reliable revenue base that we are able to launch new programs, invest in new indications and build new capacity projects to enable a great, sustainable future for Pharming."

#### **Clear differentiation within HAE**

In September we received a complete response letter from the FDA with respect to prophylaxis of HAE. The FDA encouraged early filing of this supplementary biologics license application (sBLA) because of the inability of competitors to supply plasma-derived C1 esterase inhibitor products during 2017, and they accepted the file at the start of the year. The data, although from only two small Phase II studies, was sufficient for approval, except for one small area of uncertainty. We will resolve that question in the next prophylaxis study with the new forms of RUCONEST®.

In December, however, an important investigator-sponsored real world observational study from the Charité Hospital study in Berlin, the first of its kind in HAE, showed clearly how very reliable RUCONEST® is when properly dosed in any attack. In the study, RUCONEST® showed 100% efficacy with first treatment at the recommended clinical dose. The main outcome of the study was that treatment with recombinant therapy RUCONEST® or with plasma-derived C1 treatments requires no re-dosing (or very occasional re-dosing for plasma-derived treatments) to resolve HAE attacks, whereas the main acute product offered at present, icatibant (Firazyr®), needed re-dosing in almost 50% of all applications, including repeat applications.

For patients with HAE, convenience is very important to compete successfully, but the most important thing is to

have a drug on which they can absolutely rely. The recent data showed again that when properly dosed, RUCONEST® will stop an HAE attack first time without re-dosing. It also showed that many attacks have prodromal phases (during which the patient knows an attack is imminent but has not yet experienced any symptoms) of up to nine hours. This means a typical patient, who will have one to two attacks a month, will benefit enormously from having RUCONEST® available to stop any attacks from developing, reliably and quickly. At the same time, the data for RUCONEST® shows that it is also very effective for patients who have a lot of attacks (eight or more a month), for the same reason – it can stop every attack very quickly with the first dose, often before any symptoms are experienced. The effect typically lasts for more than 72 hours.

#### Huge potential expansion for rhC1INH beyond HAE

In 2018, we took two further significant steps forward in clinical development for additional indications for rhC1INH (including RUCONEST®) outside of HAE. The first was the positive outcome with clinically and statistically significant results from a proof of concept study of RUCONEST® in contrast-induced nephropathy, and the other was the filing of a full clinical program for investigation of RUCONEST®

as a treatment for early-stage pre-eclampsia. We anticipate that final ethics committee approval will be received soon and that we will then be able to start recruiting and treating patients. Following the positive results from the investigator-sponsored study in contrast-induced nephropathy, we are designing and will seek feedback from the regulatory authorities on the subsequent clinical study in the subgroup of patients that experienced the biggest benefits in last year's study: patients undergoing percutaneous coronary interventions, such as stent insertions and balloon angioplasty operations.

#### Expansion of the pipeline beyond rhC1INH

Over the year, we have continued to make progress on our human recombinant  $\alpha$ -glucosidase for the treatment of Pompe disease, for which manufacturing is being upscaled to provide material for IND-enabling studies and to produce clinical trial material.



Sijmen de Vries, Chief Executive Officer and Chairman of the Board of Management

Our third program from our technology platform, human recombinant a-galactosidase for the treatment of Fabry's disease, is in lead optimisation stage to ensure commercial viability and will be undergoing process development and pre-clinical testing during 2019.

# "Patient convenience is very important to compete successfully"

#### Strong Resources

The strong sales performance, up 51.4% on a like-for-like basis over 2017, and the resulting profitability up 74% at the operating level year-on-year, have provided the Company with a strong cash generation to allow us both to launch these clinical studies and to repay our debt facility with Orbimed Advisors. Orbimed have been an excellent partner to Pharming, making much of this stability possible. We have also been able to progress to strong net profitability, and while this net profit is likely to fluctuate in size as we continue our clinical trial programs for new large indications, we believe that overall net profitability is sustainable on the current business.

Throughout the year, building on our infrastructure for RUCONEST® was our focus. The new sales level has driven further expansion of our raw materials production capacity, and we have now initiated a second expansion of that raw materials capacity along the same lines. The new indications, although they are still several years from approval, would require much larger volumes of rhC1INH than is possible using our current set-up, and so we have re-commenced development of a cattle version of rhC1INH. The cattle version of rhC1INH is even closer to natural human C1 esterase inhibitor than the current version, and so we do not anticipate any significant obstacles to that cattle version being approved in the future.

Despite the increased costs of these expansion activities and the clinical development activity mentioned above, the improvements in commercial performance and the financial restructuring enabled Pharming to become the first net profitable biotech company in Europe to have developed

and sold its own product on both sides of the Atlantic. While the share price had a rocky road through 2018, the overall trend in sales, costs and profits is still very good indeed and we anticipate building value for shareholders over the next few years.

"In 2018 we became the first net profitable biotech to have developed and sold our own product on both sides of the Atlantic"

During the year, our long-term Supervisory board member and former Chairman Jaap Blaak decided to step down from the Supervisory Board. Jaap has been a tireless, committed and effective ambassador for Pharming, and on behalf of all at Pharming and all shareholders over the last 12 years, I should like to offer our thanks here to Jaap for his enormous contribution to Pharming since 2008. He will be missed.

None of these achievements and development programs would be possible without the support, expertise and hard work of all our employees. I would like to take this opportunity once more to thank all Pharming employees as well as all of our investors, partners and debt providers for their support and commitment throughout 2018, which enabled us especially to execute on the commercial development of the Company to create the platform for very significant growth.

I look forward with confidence to continuing the upward story of Pharming in 2018, with sales increasing further, a new exciting pipeline and new opportunities for enhanced shareholder value.

Leiden, 28 March 2019

Sijmen de Vries Chief Executive Officer and Chairman of the Board of Management *"Each* RUCONEST® vial represents a patient in need and their lifesaving therapy"

# Testimonial Galina

I joined Pharming two years ago, I was excited to join su a well-known company. For the past two years I have been working in the Supply Chain department. My department plays an important role in the manufacturing process of RUCONEST®. Planning the production process together with the manufacturing site and staying in control of the manufacturing process is incredibly important and can be quite challenging. Each RUCONEST® vial represents

patient in need and their lifesaving thera mportant aspect of my job is to ensure w product to supply patients with what th need it. I am confident we will be able to in the time to come and I look forward to seeing what tl future holds for Pharming. I know for sure that this is the company for me and that I will be supplying patients for many years to come.

## MANAGEMENT REPORT

# Operating review 2018

#### Continued sales growth allows us to launch new clinical programs for new products

The excellent RUCONEST® sales effort in the USA and in the EU has continued to create momentum in the underlying patient numbers in both markets. This growth has required additional sales people in the US towards the end of the year. During the year, Pharming provided unconditional support for the HAEA (the US HAE patients' association), the HAEi (the international HAE patients'association) and their programs as well as other HAE centres of excellence in the USA and elsewhere.

Pharming remains committed to bringing several further improvements to enhance convenience for HAE patients to the clinic and market as soon as possible, including our new premixed small injection volume vial which will be tested for intramuscular delivery and later subcutaneous delivery, as well as enabling new routes of administration such as intradermal application designed to reduce pain. All of these new forms will increase convenience for patients.

# Regional market and product overview

#### USA

RUCONEST®, as the first and only recombinant C1-inhibitor in HAE, will be the only C1-inhibitor product which will (if approved for prophylaxis) be able both to treat HAE acute attacks and to deliver significant reduction in attacks if used prophylactically. Recombinant C1 esterase inhibitor addresses the root cause of HAE with very reliable and consistent results and an excellent safety and tolerability profile. In addition, it is not susceptible to attenuation of effects or failure of therapy due to having effect on only one of several potential pathways. Due to its easily scaleable production, RUCONEST® supplies are not dependent on availability of (commercially-obtained) blood donations. Lastly, there is no exposure to known or presently-unknown viral infections that could be derived from the significant usage of human blood plasma-derived products.

Following supply shortages of competitor products in 2017, when one company ran out of their plasma-derived C1-inhibitor product and another did not have sufficient plasma-derived C1-inhibitor product to meet all the demands on launch of that product and to make its other product, we began increasing our supply capacity to allow greater safety stock for patients in case a similar shortage occurs in the future, and to allow for increasing sales.

The development of our commercial infrastructure and activity in the USA in 2017 and 2018 has led to a significant growth in sales, with US product sales reaching a record €126.7 million.

The US market for acute and prophylactic treatment of HAE continued to expand in 2017, and is now estimated by most observers as between US\$1.7 billion and US\$1.8 billion. All currently-approved products except one (ecallantide, which has a black box FDA label warning for a risk of anaphylaxis and must be administered in a clinic setting) are self-administered by injection at home. New products for prophylaxis were introduced in 2017 and 2018, including a twice-monthly injection of a kallikrein-inhibitor antibody. Like the bradykinin inhibitor approach, this approach seeks to prevent attacks caused by a lack of one protein by causing a lack of a second protein, and it remains to be seen if this approach of continuous blocking of this pathway works for the long term without complications, as it only addresses attacks arising on one of the four known pathways in HAE attacks.

The market leader in the US\$800 million prophylaxis market was a plasma-derived C1-inhibitor (pdC1INH), which is only approved for prophylactic use as it failed in clinical trials for acute treatment. This is now being replaced by a new, higher dosed pdC1INH drug as well as gradually by the new kallikrein-inhibitor antibody. Although not yet approved, RUCONEST® has shown positive data in a Phase 2 clinical study: RUCONEST® taken twice a week reduced attacks by 72% on average with a 96% response rate.

The acute segment is estimated at approximately US\$950 million, led by the icatibant and another plasma-derived C1-inhibitor product only approved for acute use. Icatibant is identified as a bradykinin inhibitor, and blocks the Bradykinin B2 receptor, one of the mechanisms responsible for HAE symptoms.

#### EUROPE

The continuing expansion by Pharming of commercialisation of RUCONEST® in Western Europe and other countries is proceeding very well, with sales growing by over 55% outside the USA in 2018 compared to 2017. Sales growth has also been positive in Eastern Europe, but the entrenched positions and historical commercial arrangements of certain competing products in Western Europe continues to be the main obstacle to realise the full potential. These obstacles are gradually being overcome, however, as the power and reliability of RUCONEST® in both therapeutic effect and supply leads to greater adoption by national medicines agencies and important clinics across the region.

#### CHINA

Our collaboration with China State Institute of Pharmaceutical Industry, a Sinopharm company, continues to progress well.

This collaboration includes full development and commercialisation rights for RUCONEST® in China. The full RUCONEST® manufacturing process and quality system has been transferred to Sinopharm, enabling manufacture for China but also allowing Sinopharm to supply Pharming with RUCONEST® in the future. This will help to improve our margins further.

In 2018 we assisted CSIPI and CDIP, the biologicals manufacturing subsidiary of Sinopharm, who are now expecting that approval of RUCONEST® in China may be brought forward considerably because of new regulations there. As a result they are now concentrating their efforts on being able to manufacture RUCONEST® in a brand new facility for their own commercialisation, but also to be able to supply Pharming in the future for the US and EU/ ROW markets.

#### **OTHER MARKETS**

RUCONEST® continues to be commercialised in Colombia through our partner there, Cytobioteck. Sales activity has also begun in additional countries agreed with Cytobioteck in 2016: Costa Rica, the Dominican Republic and Panama.

#### HAEI GLOBAL ACCESS PROGRAMME ("HAEI GAP")

Following a request from the international HAE patient organisation (HAEi), we entered into an agreement to make RUCONEST® the first therapy available under the "HAEi Global Access Program" (HAEi GAP). This program seeks to ensure that in countries where no adequate HAE therapies are approved or otherwise avail- able, all eligible HAE patients can, through their treating physicians, have access to safe and effective treatment for their HAE. As part of this program, several requests have been received and the initial treatments were started. In September, in association with HAEi, Pharming announced the appointment of Inceptua Medicines Access as the new distribution partner for HAEi GAP, enabling patients in all countries where Pharming's product RUCONEST® is not commercially available to gain access to the drug through an ethical and regulatorycompliant mechanism. It is the only known program of this type which has been initiated through a patient group.

Pharming is fully confident in the ability of its partners to commercialise RUCONEST® successfully in all their territories, but it should be noted that Pharming depends on the success of its commercial partners to market its product in those territories. Pharming is therefore exposed indirectly to risks suffered by its chosen partners. We continue to believe that RUCONEST® is the best option for most HAE patients and we continue to support all our commercialisation partners wherever possible.

# Development of RUCONEST®

## RUCONEST<sup>®</sup> FOR HEREDITARY ANGIOEDEMA (HAE)

RUCONEST® was originally developed for the treatment of acute attacks of HAE. HAE is a rare genetic disorder in which the patient's body is unable to manufacture sufficient amounts of a fully-functioning version of C1 esterase inhibitor, a protein which is responsible for stopping inflammatory attacks and associated swelling in the body at an appropriate point in disease cycles. Abdominal attacks cause abdominal swelling and vomiting, potentially leading to misdiagnosis and unnecessary surgery, and swelling of the skin can lead to disfigurement, disability and pain. Untreated, attacks can last between 48 and 120 hours and can be fatal, especially if the swelling starts at or reaches the throat area. Estimates of the prevalence of the disease vary between 1 in 10,000 to 1 in 50,000, depending on the genetic diversity of the population. Acute attacks usually begin to be noticed in childhood or adolescence, but due to the disorder's rarity, the condition is often not correctly diagnosed for several years. The frequency of HAE attacks varies between patients, from extreme cases with two to three attacks per week to milder cases with a few attacks per year. A typical patient has around 18-24 treated attacks per year.

Additional information about the condition can be found on the international HAE patient's association website at www.haei.org.

# TREATMENT OF ACUTE AND BREAKTHROUGH ATTACKS OF HAE

In December, Pharming announced presentation of the initial results from an investigator-initiated, observational, "real-world" comparative study of therapies in acute attacks of hereditary angioedema ("HAE"). The study examined and compared re-dosing rates *inter alia* for human C1 esterase inhibitor in recombinant form (RUCONEST®) and plasmaderived forms (such as Berinert®, Cinryze®) to icatibant (Firazyr®) in seven individual patients at risk of HAE attacks. A total of 69 attacks were recorded. The study was led by Professor Dr Marcus Magerl of the Department of Dermatology and Allergy at the Charité Universitätsmedizin Berlin, Berlin, Germany. The main outcome of the study was that treatment with recombinant therapy RUCONEST® and plasmaderived C1 treatments required significantly less redosing than icatibant to resolve HAE attacks. The full results of the study will be published by the investigators in due course. These results corroborate with other recent published studies which confirm that around 30% or more of the attacks treated with icatibant need (multiple) re-dosing.

#### **PROPHYLAXIS OF HAE**

In the treatment sector of acute HAE (without prophylaxis), each individual HAE attack is treated. In prophylaxis, the patient is given the drug on a regular basis with the aim of preventing attacks or reducing the frequency of breakthrough attacks. In the US, the size of the prophylactic indication is significant, with three drugs approved specifically for that indication: two pdC1INH versions, with worldwide sales of more than US\$800 million\* between them in 2018, and a long acting monoclonal antibody, which is aimed at blocking the bradykinin/kallikrein pathway and was approved in September 2018.

#### \*Sources for market figures: Company quarterly and annual reports, IMS and Symphony data.

In its own prophylaxis studies, RUCONEST® achieved positive results in two independent clinical trials with very high responder rates and reduction of frequency of attacks in high-need patients. Following discussions with the FDA, Pharming filed for a supplementary Biologics License Approval (sBLA) for RUCONEST® in December 2017, and the file was accepted for review by the FDA with a response date of 21 September 2018. In September 2018, Pharming received a Complete Response Letter from the FDA, from which it was clear that for the final question, the burden of evidence could not achieve the statistical hurdle required, as result of the relatively small size and short duration of treatment of the Phase II study. We plan to resolve this question in the next prophylaxis study with the new forms of RUCONEST®.

#### HAE IN CHILDREN

Pharming announced positive results from an open-label Phase II study evaluating RUCONEST® for the treatment of acute attacks of HAE in paediatric patients. This study involved 20 patients aged 2 up to 13. If successful and approved by regulatory agencies, this extension would broaden the label for RUCONEST® in Europe and would extend the regulatory exclusivity period, which are both valuable benefits. Currently, RUCONEST® has regulatory exclusivity in Europe until 2025.

The open-label, single arm, Phase II clinical trial was designed in agreement with the European Medicines Agency (EMA) as part of a Paediatric Investigation Plan (PIP) to assess the pharmacokinetic, safety and efficacy profiles of RUCONEST® at a dose of 50 IU/kg in paediatric HAE patients aged 2-13 years in support of a paediatric indication for treatment of HAE attacks.

A total of 20 children with HAE were treated for 73 HAE attacks at a dose of 50 IU/kg (up to a maximum of 4200 IU). The study reported clinically meaningful relief of symptoms assessed using a visual analogue scale (VAS) completed by the patient (assisted by their parent). The median time to onset of relief was 60 minutes (95% confidence interval: 60-63), and the median time to minimal symptoms was 122 minutes (95% confidence interval: 120-126). Only 3/73 (4%) attacks were treated with a second dose of RUCONEST®.

RUCONEST® was generally safe and well-tolerated in the study. No patients withdrew from the study due to adverse events. There were no related serious adverse events, hypersensitivity reactions or neutralising antibodies detected.

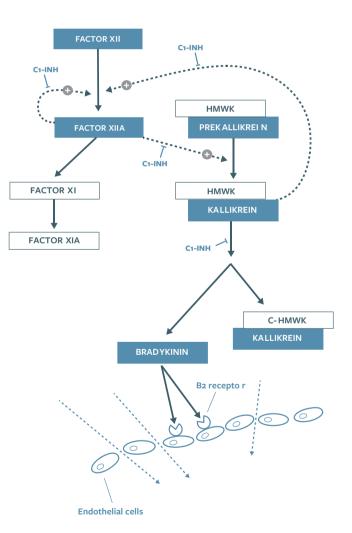
#### BIOCHEMICAL PATHWAYS FOR DEVELOPMENT OF HAE ATTACKS

Hereditary angioedema is caused by a deficiency of the protein C1 esterase inhibitor (C1-inhibitor). This deficiency leads to the uncontrolled activation of the contact system pathway resulting in the over-production of some mediators including bradykinin. Bradykinin is necessary to enable tissues to swell in certain shock situations or other circumstances, and acts on two receptors, B1 and B2. This has the effect of opening channels in the vascular wall, leading to the leaking of fluid from blood vessels to the tissue space. The most common symptoms of an HAE attack are caused by over-production of the bradykinin initiator protein kallikrein, and thus excessive leakage of fluid into tissue spaces (edema or swelling).

At a dose of 50 U/kg, RUCONEST® normalises C1-inhibitor effects in virtually all HAE patients (Source: "Target levels of functional C1-inhibitor in Hereditary Angioedema". C. E. Hack, A. Relan, E. S. van Amersfoort & M. Cicardi, Allergy, 2012 Jan;67(1):123-30.). Returning C1-inhibitor activity levels to normal has been shown to be clinically relevant in HAE attack treatment and prevention.

After administration, RUCONEST® irreversibly binds to several target molecules, including importantly the coagulation factor FXII and the protease kallikrein, which cleaves a plasma protein into bradykinin and other products. By binding to and chemically deactivating these molecules, RUCONEST® stops the production of bradykinin and thereby stops or aborts the HAE attack on the relevant pathway.

**C1 INHIBITOR** 



# "RUCONEST® WAS GENERALLY SAFE AND WELL-TOLERATED IN THE STUDY"

Other therapies are available or are being developed which do not deal with all pathways to HAE, but instead focus on kallikrein or bradykinin themselves to reduce or stop the symptoms, but often the attack continues in the background, causing a relapse or worsening effect necessitating a second or further doses. RUCONEST® deals with all pathways (including the lectin pathway that is also able to activate the release of bradykinin; not shown on this illustration) by restoring the normal concentration of C1 esterase inhibitor, thereby stopping essentially all attacks with no observed relapse or worsening effects for nearly all patients. In addition, because RUCONEST® is a protein replacement therapy, whereby the missing protein that the patient cannot effectively produce themselves is replaced by injection with RUCONEST<sup>®</sup>, it does not carry any risks which may be associated with stopping any other pathway completely. The long term risks of prophylaxis using the blocking of bradykinin or kallikrein pathways, effectively causing a deficiency in one or both of those proteins, have not been elucidated, and so it is not known whether it is safe in the long term to manage one protein deficiency by creating a second chronic protein deficiency. The kallikrein and bradykinin pathways serve a useful purpose in other situations than HAE. It remains to be proven, therefore, whether this will be a reliable approach to the problem.

# INTRAMUSCULAR, SUBCUTANEOUS AND OTHER FORMS OF RUCONEST®

In the absence of any other factors, some patients prefer a subcutaneous injectable product or an intramuscular injection to an intravenous injectable product, because of the lower level of training and care needed to make the injection safely and effectively. C1-inhibitors can be administered during the prodromal phase of an attack, which in this case is the period when the attack has started and the patient is aware of it, but no symptoms have appeared yet. This period can be more than two hours, and if a C1-inhibitor, adequately dosed, is taken during that time, normally the symptoms do not develop and the patient usually does not progress to the painful stage of an attack.

The Company is developing a new concentrated low-volume injection version of the full dose of RUCONEST® which can be used for intravenous, intramuscular or subcutaneous delivery to enable patients to benefit from its power and efficacy in whichever form they find most convenient.

Subject to approval, the new form of RUCONEST® will be tested in appropriate clinical settings for intramuscular, intradermal and subcutaneous delivery. The program is currently progressing slower than previously planned for technical reasons, mainly because we were unable to divert the necessary rhC1INH drug substance needed to validate the new form manufacturing processes and for production of clinical trial materials away from the RUCONEST® production because of high sales demand. This delay allowed us to restore inventories after substantial amounts of RUCONEST® were delivered to patients as (free-of-charge) emergency treatments, both in the US and in the EU, to provide them with medicine during periods of acute shortfalls of competitor plasma-derived C1INH products in late 2017 and early 2018.

# Additional indications for RUCONEST®

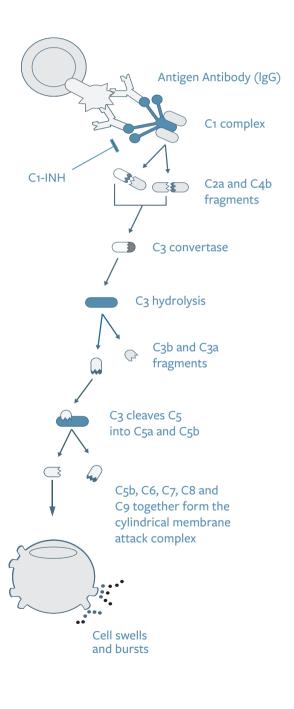
RUCONEST® is a recombinant version of a very important human protein called C1 esterase inhibitor (C1INH). It is called recombinant because it is made outside the human body, using Pharming's proprietary technology platform which enables a very close version of the natural human protein to be made. Inside the body, C1INH works by inhibiting the formation of the most important complex at the top of the complement system. The complement system, sometimes known as the complement cascade, is a major part of the immune system, responsible for certain immune-mediated inflammation reactions, including most reactions that cause vascular edema (swelling). The complement cascade enhances (i.e. complements) the ability of antibodies and phagocytic cells (a type of white blood cells) to clear microbes and damaged cells from our bodies, promotes inflammation, and attacks the pathogen's cell membrane. It is part of the innate immune system, which is not adaptable and does not change over the course of an individual's lifetime. The complement system can be recruited and brought into action by antibodies and other challenge triggers generated by the adaptive (i.e. the changeable) immune system.

The complement system consists of a number of complex proteins found in the blood, in general synthesized by the liver, and normally circulating as inactive precursors (pro-proteins). When stimulated by one of several triggers, enzymes called proteases produced for the purpose in the system cleave specific proteins to release active fragments called cytokines and initiate an amplifying cascade of further cleavages. The end result of this complement activation or complement fixation cascade is stimulation of the phagocytes to clear foreign and damaged material, inflammation to attract and enable the movement of additional phagocytes, and activation of the cell-killing membrane attack complex. Over 30 proteins and protein fragments make up the complement system, including serum proteins and specific cell membrane receptors.

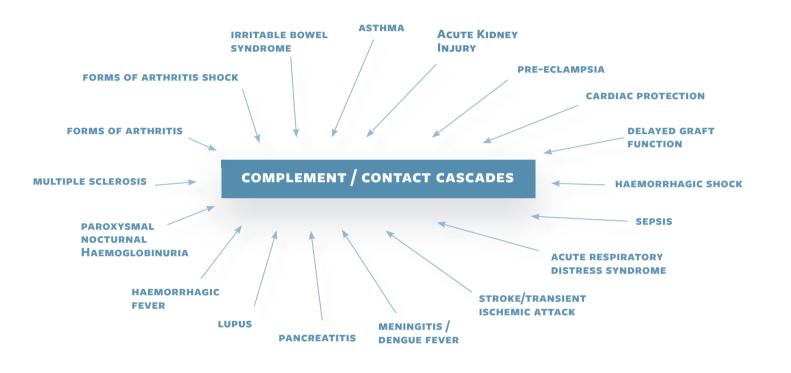
Once the complement cascade has been triggered, the body also produces a counter-protein, C1 esterase inhibitor or C1INH to start to slow the reaction down, and the rate at which the reaction can be slowed down is constant as the body can only produce a low maximum level of C1INH. This means that serious trigger events can take much longer to resolve than minor ones, because the level of C1INH production catches up to the level of minor releases of cytokines more quickly than it can to major releases of cytokines. The most powerful releases of cytokines, sometimes known as 'cytokine storms', can occur so fast that a fatal 'shock' reaction occurs before the C1INH can bring the release under control.

This system is thought to be playing an important part in many disease conditions and injury situations, where inflammation or vascular leakage running out of control are responsible for the symptoms of those conditions. In others, hypoxic conditions can result, where blood has not been able to circulate properly to bring oxygen to various tissues. The detrimental effects of such hypoxia can be exacerbated upon reperfusion with blood by local activation of the complement cascade. In some of those conditions, therefore, there may be a role to play for externally-administered C1INH which could act to normalise that situation more quickly, allowing the body to have a less dangerous or more measured response, or to prevent the symptoms entirely. While C1INH is unlikely to 'cure' the underlying problem, this extra supply might allow for the damage caused or even the risk of death to be reduced and/or delayed long enough for the problem to be resolved either naturally or through the intervention of the patient's physician team.

#### CLASSICAL PATHWAY OF COMPLEMENT ACTIVATION



The following diagram shows the most important indications in this area. Many of these conditions are entirely unmet medical needs, often with no approved therapy. Sometimes this is because they cause death very quickly, or because they lead to other more serious morbidities. A few do have approved treatments, largely because other mechanisms are also involved or are more important, such as for asthma.



This has led the Company to explore a number of new indications for RUCONEST® as indicated below:

#### ACUTE KIDNEY INJURY (AKI)

AKI, and its more dangerous analogue contrast-induced nephropathy (CIN) is a form of kidney damage which occurs in stress situations such as when a patient is injected with contrast medium as part of a contrast-enhanced examination, for example a Computed Tomography (CT) scan. In patients who have impairment of the kidneys prior to such examinations, the difficulty in clearing the injected contrast medium can result in further kidney damage which might be reversible, or which is irreversible and requires permanent dialysis or renal transplantation. It can also result in death in some cases. AKI is a serious and expensive complication in the contrast-enhanced examination setting, where patients are often compromised following minor or major cardiac events. When AKI occurs, it usually requires dialysis and often leads to prolonged hospitalisation, which results in poor long term outcomes for patients.

In October the Company announced positive results from a Phase II investigator-initiated study of RUCONEST® (recombinant human C1 esterase inhibitor, or "rhC1INH") in a double-blind, placebo-controlled clinical trial in patients at risk of nephropathy resulting from contrast-enhanced examinations. The study was led by Dr. Michael Osthoff at the University Hospital Basel, Basel, Switzerland.

In the study, 75 eligible patients with known moderate-tosevere renal function impairment were given either 50 units per kg (up to 4200 units) of RUCONEST® (n=37) or placebo (n=38) immediately prior to treatment with standard-of care contrast medium as part of an elective coronary angiography with or without a percutaneous coronary intervention ("PCI"), and then a second identical treatment four hours after the examination or intervention.

In the overall study, RUCONEST® showed a statisticallysignificant effect (p= 0.038) in reducing the rise in urinary Neutrophil Gelatinase-Associated Lipocalin (NGAL), the primary endpoint for the study and a generally recognised early marker of acute renal injury, in patients undergoing investigations enhanced with standard contrast media, such as for PCIs.

The results were especially clear in the sub-group of patients (n=30) undergoing actual PCI. The intent-to-treat analysis in this group showed that patients on RUCONEST® had a median increase in peak urinary NGAL concentration within 48 hours of 1.8 ng/ml, compared with an increase of 26.2 ng/ml in the placebo arm (p=0.04). This corresponds to a clear difference in the median percentage change in the peak urinary NGAL level within 48 hours of 11.3% in the RUCONEST® arm and 205.2% in the placebo arm (p=0.001).

Following this positive outcome, the Company is preparing a new Phase IIb study of the effects of RUCONEST® in patients with severe kidney impairment undergoing percutaneous coronary intervention operations.

#### PRE-ECLAMPSIA (PE)

Pre-eclampsia is a life-threatening multisystem disorder in pregnancies leading to maternal and neonatal mortality and morbidity, usually first detected by hypertension. Proteinuria is a common symptom. Abnormal or impaired spiral artery development between the mother and the fetus may be responsible, causing complement cascade triggering when these spiral arteries come under stress, especially oxidative stress because of poor blood flow. Emerging evidence has shown that activation of the complement system following such poor placentation is implicated in the pathological processes of PE.

The outcome for both mother and baby can be severe. 50,000 maternal deaths a year are recorded for patients who proceed to full-blown eclampsia, while many more are caused by long-term irreversible damage to organs caused by PE while the mother carries her child before birth. Treatments include termination of the fetus or very premature birth, which is often associated with very high rates of mortality. Palliative care of the PE-damaged mother and neonatal care of premature babies can drive the costs of PE patients very high. Even if they can be born safely, consequences for the child can be severe, with growth restrictions, learning difficulties and moderate to severe disabilities affecting over half of such newborns. Almost 2.5 million cases are reported annually, with rates running at between 3% and 10% of all pregnancies in developed countries.

Pharming is currently finalising ethics committee reviews in the EU and Australia, and we anticipate obtaining approval shortly to begin recruiting in a proof of concept study in symptomatic pre-eclampsia, in which women developing symptoms after 25 weeks will receive RUCONEST® from that point. Details will be published once approval is obtained to start the study.

#### ISCHAEMIC REPERFUSION INJURY (IRI)

IRI is a complication arising from tissue damage caused by lack of oxygen during an interruption of blood supply (ischaemia) until the tissue is supplied with blood again (reperfusion).

This can occur in traumatic injury involving haemorrhagic shock, in organs prior to and during transplantation, in the brain as a result of stroke and in the heart as a result of myocardial infarction (a main type of 'heart attack'). It has been shown in various preclinical models that C1 esterase inhibitor can reduce the extent and effects of IRI in such cases. In hypovolemic shock, for example, after a severe injury where the body is losing fluid, having a certain inhibitory effect on the mechanism causing or accelerating such complications can be very valuable for the patient.

These indications, although they are all large unmet medical needs, are extremely difficult to study in a clinical setting, and so Pharming is working with different potential partners to find a way to explore the use of RUCONEST® to help patients with these problems. These include an ongoing preclinical study with the US Army Institute of Surgical Research into the use of RUCONEST® for some of these indications.

## **PIPELINE DEVELOPMENT**

#### DELAYED GRAFT FUNCTION (DGF)

DGF, a form of IRI, is a serious and costly complication in the clinical transplantation setting. When DGF occurs, it necessitates the use of dialysis and leads to prolonged hospitalisation, which results in adverse long term outcomes and significantly higher costs. Current interventions focus on activities that occur after the organ is harvested from the donor (e.g. cold storage or machine perfusion of the organ). As demonstrated with a preclinical model, donor pre-treatment with RUCONEST® prior to transplantation represents a novel approach to addressing some of the limitations of current strategies to reduce the impact of DGF. This study was conducted by Dr Luis Fernandez of the University of Wisconsin, who showed that RUCONEST® pre-treatment of harvested organs significantly reduced the incidence of DGF in transplant operations. The mechanism of action was the inhibition of the complement cascade inflammatory response pathway. A clinical study is now underway at the University of Wisconsin to prove this concept.

Pharming's clinical and research teams are also continuing on two major projects, in Pompe disease and Fabry's disease.

#### **ALPHA-GLUCOSIDASE, FOR THE TREATMENT OF POMPE DISEASE**

Pompe disease (also known as Acid Maltase Deficiency or Glycogen Storage Disease type II) is an inherited muscular myopathy disorder caused by the build-up of a complex sugar called glycogen in the body's cells. It affects around 1 in 40,000 people in general, varying within different ethnic groups. Pompe disease is a rare multisystem genetic disorder that is characterised by absence or deficiency of the lysosomal enzyme alpha-glucosidase (GAA). This enzyme is required to break down (metabolise) the complex carbohydrate glycogen and convert it into the simple sugar glucose. Glycogen is a thick, sticky substance and failure to achieve proper breakdown results in massive accumulation of lysosomal glycogen in cells, particularly in cardiac, smooth, and skeletal muscle cells. Pompe disease is a single-disease continuum with variable rates of disease progression and different ages of onset. The infantile form is characterised by severe muscle weakness and abnormally diminished muscle tone (hypotonia) without muscle wasting, and usually manifests within the first few months of life

Additional abnormalities may include enlargement of the heart (cardiomegaly), the liver (hepatomegaly), and/or the tongue (macroglossia). Without treatment, progressive cardiac failure usually causes life-threatening complications by the age of 12 to 18 months. Pompe disease can also present in childhood, adolescence or adulthood, collectively known as late-onset Pompe disease. The extent of organ involvement may vary among affected individuals, but skeletal muscle weakness is usually present with minimal cardiac involvement. Initial symptoms of late-onset Pompe disease may be subtle and may go unrecognised for years. Pompe disease is caused by mutations of the GAA gene and is inherited as an autosomal recessive trait. The only approved therapy to date is Enzyme Replacement Therapy (ERT) using recombinant human alpha-glucosidase, produced by Chinese Hamster Ovary (CHO) cells. This method of producing large, complicated and heavily glycosylated proteins often results in versions of the basic protein amino-acid sequence that do not have proper glycosylation patterns (i.e. are not very close versions of the natural human version) and which can therefore be very immunogenic (i.e. they provoke an immune system response upon administration) or cause

off-target effects, due partly to the limitations on the original cell molecular biochemistry and partly to genetic drift (mutations of the producer cells causing variants of the protein to be made as the original cell is multiplied billions of times to produce commercial quantities of the protein).

Pharming's platform, however, allows for full mammalian biochemistry to be brought into play with almost no risk of genetic drift. This produces commercial quantities of more accurate enzymes which are far closer to the natural human analogue and which are often far less immunogenic as a result. This can be seen in RUCONEST®, which has not shown any significant immunogenicity in over 75,000 applications, whereas most cell-line-based attempts to manufacture the same human protein have shown acute immunogenicity or other off-target effects. Patients receiving ERT for conditions such as HAE or Pompe usually need treatment during their entire life. All of the approved therapies for Pompe have so-called boxed warnings for immunogenicity, the general term for this kind of toxicity. The main reason for it seems to be the body's response to the inaccurate artificial molecule or the variants and the difficulty of getting the artificial molecule into the relevant cells, which means larger doses of drug are required leading to large immunogenic effects.

Human recombinant  $\alpha$ -glucosidase produced using Pharming's platform technology is intended to have much better immunogenicity, safety and potentially efficacy profiles than existing and forthcoming products, largely due to the advantages identified above including improvements in glycosylation patterns. The product will not be considered a 'biosimilar' to existing therapies by the regulatory authorities as it is produced on a totally different production platform. The approach by Pharming (if successful) may therefore result in a so-called 'Biobetter'. In 2018, sales of Pompe therapies were €819 million.

Most other therapies involve trying to improve delivery of currently available recombinant CHO-cell alpha-glucosidase versions, whereas we believe the problem lies in the way this molecule itself is produced.

In addition, however, at present all current therapies show significant antibody formation in the patients, which reduces the efficacy of the drug therapy and eventually stops the patients benefitting from the drug. Estimates of this effect vary between 60% and 80% in Pompe disease and around

50% in Fabry disease. A therapy which did not provoke an immune response of this kind might therefore be much more effective in such refractory patients, increasing the size of the addressable market.

#### **ALPHA-GALACTOSIDASE FOR THE TREATMENT OF FABRY'S DISEASE**

Fabry's disease (also known as Anderson-Fabry disease, angiokeratoma corporis diffusum, and alpha-galactosidase A deficiency) is another rare genetic lysosomal storage disease resulting from the deficient activity of a different enzyme, alpha-galactosidase A (aGalA), caused by an X-chromosome mutation of the GLA gene. Fabry's disease can cause a wide range of systemic symptoms. It is a form of sphingolipidosis, as it involves dysfunctional metabolism of sphingolipids. Fabry's disease affects around 1 in 40,000 men and 1 in 60,000 women and is less dependent on ethnicity than Pompe Disease. This disorder belongs to the same group of diseases known as lysosomal storage disorders.

Lysosomes function as the primary digestive units within cells. Enzymes within lysosomes break down or digest particular compounds and intracellular structures. **a**GalA functions to break down specific complex sugar-lipid molecules called glycolipids, by removing the terminal galactose sugar from the end of these glycolipid molecules. The enzyme deficiency causes a continuous build-up of the glycolipids in the body's cells, resulting in cell abnormalities and organ dysfunction that particularly affect the heart and kidneys. The GLA gene is located on the X-chromosome and therefore, Fabry's disease is inherited as an X-linked disorder. Males are typically more severely affected than females. Females have a more variable course and may be asymptomatic or as severely affected as males (see Genetics section below).

There are two major disease phenotypes: the type 1 "classic" and type 2 "later-onset" subtypes. Both lead to renal failure, and/or cardiac disease, and early death.

As for Pompe disease, the approved treatments at present use a recombinant form of the human enzymeaGalA produced in cell lines. As for a-glucosidase, Pharming believes that its own platform technology can produce a pure, less immunogenetic a GalA that will compare favourably with existing therapies on safety, efficacy and immunogenicity. In 2018, sales of Fabry disease therapies were over €1.0 billion. Again as for  $\alpha$ -glucosidase, proper therapy for patients who are refractory on existing medications may increase the overall market size significantly.

# FACTOR VIII FOR THE TREATMENT OF HAEMOPHILIA-A

Factor VIII (FVIII) is an essential blood-clotting protein, also known as anti-haemophilic factor (AHF). In humans, factor VIII is encoded by the F8 gene. Defects in this gene result in haemophilia A, a recessive X-linked coagulation disorder. Factor VIII is produced in liver sinusoidal cells and endothelial cells outside the liver throughout the body. This protein circulates in the bloodstream in an inactive form, bound to another molecule called von Willebrand factor, until an injury that damages blood vessels occurs. In response to injury, coagulation factor VIII is activated and separates from von Willebrand factor. The active protein (sometimes written as coagulation factor VIIIa) interacts with another coagulation factor called factor IX. This interaction sets off a chain of additional chemical reactions that form a blood clot. In individuals with Haemophilia-A bleedings do not occur faster or more profusely than in healthy individuals, but, because their blood clots poorly, the flow of blood from a wound doesn't stop easily.

Haemophilia-A can be mild, moderate or severe, depending on the baseline level of factor VIII made by that individual. The approximate size of the global market for recombinant versions of clotting factor VIII in 2018 was US\$3.5 billion. As for the liposomal storages diseases, the recognised standard of care for Haemophilia-A is replacement of the missing factor, in this case factor VIII. Replacement of this protein may be obtained through recombinant factor VIII, which is artificially created in a laboratory manufacturing practice. Many physicians and voluntary health organisations favour the use of recombinant factor VIII because it does not contain components derived from human blood. Factor VIII can also be obtained from plasma (i.e., blood donations). Human blood donations do carry a risk of transmitting viral infections such as hepatitis.

While Pharming does not have in-house expertise in hematological disorders, we are assisting our Chinese partner CSIPI in developing a recombinant Factor VIII which would be suitable as a drug both for Chinese markets and globally. CSIPI is leading development on this program.

#### PROPRIETARY TRANSGENIC TECHNOLOGY PLATFORM

Pharming's main technology platform is the development of human recombinant proteins with excellent therapeutic properties and good safety profiles through the generation of transgenic animals which only express the human protein in their milk. This enables the safe, pure production of the protein without the animal suffering or being biologically affected. Pharming is open to discussion regarding use of its transgenic platform to make high purity, low or nonimmunogenic, scalable versions of human proteins, peptides, antibodies and other biological molecules for use (including exclusive use) by its new partners. It is also possible to make similar molecules for veterinary uses.

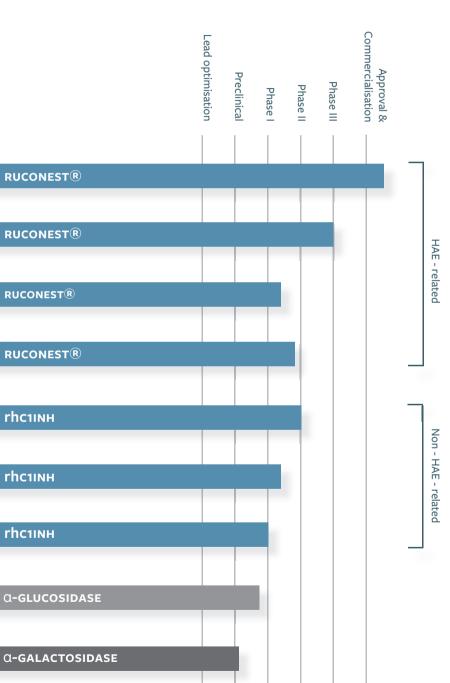
During the year, we made significant progress in developing the platform technically so that in the future greater quantities of target substances can be generated from far fewer animals, again ensuring no distress to the animals, reducing the number of animals involved even further and allowing for better costs of production in the future. This included a project with a view to regenerating our cattle herd to enable us to produce recombinant human C1INH on a larger scale.

#### PIPELINE

The Pharming pipeline at the date of this annual report therefore appears as follows:

Acute Hereditary Angioedema (HAE) RUCONEST® HAE Prophylaxis (IV) RUCONEST® HAE Prophylaxis (SC and ID) RUCONEST® RUCONEST® HAE Acute (IM) rhс1імн Pre-Eclampsia rhс1імн Acute Kidney Injury (AKI) rhс11NH Delayed Graft Function Pompe Disease a-glucosidase Fabry Disease

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The financial objectives for 2018 were:

- Ensuring that sales of RUCONEST® in all markets is optimised so that the maximum potential for the product can be achieved
- Ensuring that the pace of research and development costs continues in line with the development of sales of RUCONEST® so that profitability is achieved at both the operating and eventually the net level, so that cash resources can be sufficient for the Company's future needs excluding potential new opportunities; and
- Ensuring that any opportunities for acquisitions or new development projects or products are captured on a financial basis that is optimised for shareholders.

All of these objectives were achieved in 2018. For 2019, the main financial objectives are very similar:

- Ensuring that sales of RUCONEST® in all markets is optimised for HAE so that the maximum potential for the product can be achieved in that indication;
- Ensuring that the development of new forms of RUCONEST® for HAE; new indications for rhC1INH in other larger indications; and of recombinant enzymes for Pompe and Fabry diseases proceeds smoothly and positively
- Ensuring that the pace of research and development costs continues in line with the development of sales of RUCONEST®, so that profitability is as far as possible maintained at the net level, so that existing or available non-dilutive cash resources are sufficient for the Company's future needs excluding potential new opportunities; and
- Ensuring that any opportunities for acquisitions, licenses or new products are captured on a financial basis that is optimised for shareholders.

#### Financial summary

		Restated **	% CHANGE
Total revenue	135.1	89.6	51%
Gross profit	113.0	77.2	46%
Operating result	38.0	21.9	74%
Financial income, expenses and adjustments	(37.1)	(107.6)	(66%)
Tax credit/(expense)	24.1	9.4	n/a*
NET RESULT	25.0	(76.2)	
BALANCE SHEET			
Cash & marketable securities	81.5	60.0	36%
SHARE INFORMATION			
Earnings per share before dilution (€)	0.041	(0.152)	126%

\* The tax credit is principally a one-off credit reflecting the balance of the Company's net operating losses taken on the balance sheet, and is therefore not directly comparable year on year.

\*\* Prior year's financial statement have been restated as detailed below in Note 4 to the Financial Statements.

#### **REVENUES AND GROSS PROFIT**

Revenues increased to €135.1 million in 2018 from €89.6 million in 2017. Both years include amounts of deferred license revenue released, reflecting a portion of earlier license fee payments from partners including SOBI and SIPI which have been allocated across a number of financial years in accordance with accounting guidelines. These amounts were €0.8 million in 2018 and €0.9 million in 2017.

Revenues from product sales by Pharming and its partners increased to €134.3 million (2017: €88.7 million) reflecting a very good year overall for RUCONEST® sales in the US (€126.6 million (US\$149.3 million), up from €83.7 million (\$98.9 million) in 2017). This shows the continuing growth in patient numbers and usage of RUCONEST® as patients become aware of its reliability and efficacy compared with other available therapies. During the year, we also increased our sales force in the US slightly to enable additional growth in future years

Product sales for RUCONEST® in Europe and the Rest of World ("RoW") were €7.6 million (2017: €5.0 million), reflecting sales by SOBI in Europe coupled with strong growth in direct sales by Pharming in the countries recovered from SOBI in 2016.

Costs of product sales during the year amounted to €22.2 million, up from €12.4 million in 2017, reflecting the strongly increased sales volume and savings obtained by better inventory management, plus the cost of contributing free vials for emergency treatments to patients during the stock limitations at competitors particularly in the first quarter.

Gross profit increased from €77.2 million in 2018 to €113.0 million in 2017, an increase of 46%. The main reasons for this increase were growing sales in the USA and EU, tempered by the need to supply free RUCONEST® to ensure patients did not suffer from lack of therapy during the stock shortages by competitors early in the year in the US and later in the year in Europe.

#### **OPERATING COSTS**

Operating costs increased 35% from €56.1 million in 2017 to €75.6 million in 2018. This increase was substantially due to the increased sales and marketing activities both in the US and in the EU together with increased clinical development activity in connection with the new indications of pre-eclampsia and acute kidney injury. Further costs were incurred in connection with development of the new forms

of administration for RUCONEST® and increased preclinical activity relating to the second product alpha-clucosidase for Pompe disease treatment.

Research and Development (R&D) costs within these figures increased from €18.7 million in 2017 to €28.9 million in 2018. In 2018, the costs have mainly been incurred in developing the two new major indication programs for RUCONEST®, continued development of the programs for Pompe and Fabry's disease, the new routes of administration and opportunities for RUCONEST® including the regeneration of a cattle version of C1 esterase inhibitor and further improvements in the technology platform to enable better versions of new products. These costs were further increased by the taking of €2.6 million of previously capitalised development costs to the income statement in respect of a previous version of the new form of concentrated small-volume vial of RUCONEST® which has been superseded.

General and administrative costs increased to €12.2 million from €6.0 million in 2017. The increase is mainly related to the addition of core management in the US and Europe, and costs incurred in connection with management of the larger and more internationally-active Company in 2018, as well as increases in provision for share-based compensation reflecting the larger workforce and the depreciation on the intangible assets.

Marketing and sales costs of €34.5 million (2017: €31.4 million) reflect the full year effect of Pharming's commercialisation activities in the USA and Europe. We do not expect significant increases in this level of expenditure until new products become available for Pharming to commercialise. The infrastructure we have built will enable us to add several new products for relatively low incremental costs.

#### **OPERATING RESULT**

Operating results improved very strongly to a profit of €38.0 million in 2018 from €21.9 million in 2017, an increase of 74% in spite of considerable increases in marketing and sales and R&D activity, mainly due to the effect of strong sales growth and efficient production of RUCONEST® in major markets. The basic underlying adjusted operating result was €40.6 million, but this was reduced by a one-off writeback of previously capitalised development costs of €2.6 million relating to a superseded version of the small vial now

under development. Operating costs increased significantly, reflecting the increased activity preparing for new clinical studies for pre-eclampsia and acute kidney injury, as well as development work on new forms of RUCONEST® including the concentrated liquid vial format and intramuscular and subcutaneous routes of administration. The principal elements of this operating success are strong sales performance coupled to tight cost control.

#### FINANCIAL INCOME AND EXPENSES

The 2018 net loss on financial income and expenses was €37.1million, mostly from non-cash items, compared with a loss of €107.6 million a year earlier. This is mainly due to two items: (i) the interest on loans and borrowings and non-cash adjustments thereto, totalling approximately €14.3 million; and (ii) the increase in the non-cash provision for contingent consideration (i.e. the milestones due to Bausch Health Companies Inc. upon reaching certain sales targets) of €21.2 million. A loss was also recorded on the change of value of the loans and borrowings as a result of exchange rates during the year, although this was balanced by the corresponding gains on amounts of cash held in US dollars.

#### **TAXATION**

As a result of the growth in sales, it is now very likely that the Company will be able to use its net operating (taxable) losses from previous years against taxable profits going forward. The Board of Management has therefore elected to report a deferred tax asset in accordance with IFRS, reflecting the timing differences between the tax value of those losses and the time when they can be exercised. This has led to an additional credit to the income tax charge (i.e. a positive movement) of €24.1 million in 2018 (2017: €9.4 million).

#### **NET RESULT**

With the elimination from our balance sheet of the complex financial instruments which all resulted in large non-cash adjustments when marked to fair value under IFRS, the net loss of €76.2 million in 2017 (after restatement) was reversed in 2018 into a net profit of €25.0 million. The first sales milestone due to Bausch Health Companies Inc. (formerly Valeant) was triggered in 2018 but was not payable until February 2019 - this does not have any net impact on the net profit for the first quarter because the amount has already been provided for under contingent consideration within 'Other Financial Liabilities' on the balance sheet.

#### **INVENTORIES**

Inventories decreased slightly from €18.3 million in 2017 to €17.3 million in 2018, due to the improving sales level in the USA including the need to make RUCONEST® available to patients who were left without adequate therapy by stock limitations of competitor products. This sales level was approximately equal to the production level during the year. The inventory was also adjusted by a provision for impairment of €1.5 million related to batches of raw material which needed to be destroyed owing to out-of-specification analysis results. During 2018 Pharming completed work on a second production facility enabling us to double capacity for raw material production, and this facility is expected to come on-stream during 2019 once inspected and if approved by regulatory authorities. Preparations to initiate the construction of a third facility were started at year end.

#### **CASH AND CASH EQUIVALENTS**

The total cash and cash equivalent position (including restricted cash) increased from €60.0 million at year-end 2017 to €81.5 million at year-end 2018.

The principal elements of cash flow were the positive operating cash flow (before changes in working capital as shown in that statement) of €47.0 million (2017: €27.1 million), balanced by an increase in working capital of  $\notin$ 4.1 million (2017: reduction of €11.1 million); capital expenditure on new assets of €3.8 million (2017: €6.0 million), and the net cash used for repayments and interest on loans and bond settlements (net of option and warrant exercise proceeds) of €18.0 million (2017: €3.3 million). This reflects mainly the fact that the Company started to repay its debt obligations to Orbimed Advisors on schedule in the third quarter of 2018.

As the Company's sales are largely in US dollars and the Company's debt is largely in US dollars, a natural hedge exists which means that any decline in the US dollar exchange rate over the year to reduce sales reported in euros has a balancing effect of reducing the size of the debt liability when reported in euros. The effect of the exchange rate movements on amounts held in cash had a total effect of a gain of €2.9 million (2017: loss of €1.1 million).

#### EQUITY

The equity position increased strongly from €16.1 million in 2017 to €61.8 million in 2018, mainly due to the net profit for the year together with the redemption effects of conversion of the ordinary bonds and exercise of options and warrants.

#### PERFORMANCE OF PHARMING SHARES

During 2018, the Pharming stock price fluctuated around an average price of €1.15 per share. The year-end price was €0.76 (2017:  $\notin$ 1.13), with a high of  $\notin$ 1.57 in both January and June 2018 and a low of €0.68 in December 2018.

The closing number of shares as at the reporting date was 621,501,238 (2017: 579,014,891). New issues of stock representing a total of 42,486,347 shares were made to investors during the year related to the conversion of the remaining Ordinary Bonds due 2021, exercise of warrants, and exercise of employee options. As at the date of this report, the number of shares in issue is 621,501,238 and the fully diluted number of shares is 663,472,726.

More information on the current share capital of the company can be found in Note 33 to the Financial Statements.

## NO ANTI-TAKEOVER MEASURES IN PLACE

The Board of Management believes that Pharming shareholders are the best persons to judge whether a takeover bid for the company is fair for them at the time of offer, after receiving an informed opinion from the Board of Management regarding the advantages and disadvantages of such bid.

At present, therefore, there are no anti-takeover measures in place which would restrict the shareholders from receiving information about, or from accepting or rejecting, a genuine bid for their shares.

# Outlook 2019

#### For the remainder of 2019, the company expects

- Continued growth in revenues from sales of RUCONEST®, mainly driven by the USA and European operations.
- Maintenance of positive guarterly net earnings during the year.
- Continued investment in the expansion of production of RUCONEST<sup>®</sup> in order to ensure continuity of supply to the growing markets in the US, Europe, China and the Rest of the World.
- Investment in further clinical trial programs for RUCONEST® in acute treatment and prophylaxis of HAE, the development of a small intravenous liquid version and new intramuscular, subcutaneous and intradermal versions of RUCONEST® as well as research into other routes of administration.
- Investment in clinical trials for pre-eclampsia and acute kidney injury, and support for investigators wishing to explore additional indications for RUCONEST®
- Investment in development of the new pipeline programs in Pompe disease and Fabry's disease, and other new development opportunities and assets as these occur.
- Increasing marketing activity where this can be profitenhancing for Pharming.
- 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, as we continue to believe that RUCONEST® represents arguably the most effective and reliable safe therapy option to treat acute angioedema attacks in patients with HAE.

No further financial guidance for 2019 is provided.

Throughout 2019, starting with the quarterly report for the first quarter to be published on 16 May 2019, Pharming will report all financial figures in US dollars, with reference figures in euros. This decision reflects the growing importance of US dollars as a functional currency within the group, as the appetite for Pharming information from a much wider audience as the Company continues to grow. A decision as to the presentation of euros alongside US dollars for 2020 will be taken later in the year once we can see how the business is developing.

# Going concern

Pharming's 2018 financial statements have been drawn up on the basis of a going concern assumption.

The 2018 year-end cash balance of €81.5 million is expected to fund the Company for more than eighteen months from the date of this report. The receipts from commercial supply of product to our partners in Europe, the Middle East, Latin America, South Korea and Israel and proceeds from direct sales in the USA, Austria, France, Germany, Luxembourg, the Netherlands and the United Kingdom currently generate more cash than the Company requires for day to day expenses or to supply those sales, and thus the surplus cash generated will support our financial reserves further.

Pharming has a previous history prior to 2017 of operating losses. The Board of Management anticipates that during 2019 such quantities of RUCONEST® will continue to be sold (directly or by our partners) that the proceeds to Pharming from such sales are more than sufficient to meet our operating costs, finance costs and all other cash requirements, including debt repayment and capital expenditure, as was the case in 2018.

Presently, no further assurance can be given both on the timing and size of future profits and whether consistent net profitability can be maintained on this basis. We remain confident that the development of RUCONEST® and its successor products will enable this situation to continue.

In addition, in the event that the Company needs to raise capital by issuing additional shares, shareholders' equity interests may be diluted as to voting power, and their interests as to value will depend on the price at which such issues are made. The Company sees no need to raise capital to support its current operations, but may take an opportunity to do so in either equity issue or debt to support future expansion or costs if appropriate terms can be obtained that are in the best interests of shareholders.

# STATEMENT OF THE BOARD OF MANAGEMENT

On the basis of the above and in accordance with best practice 1.4.3 of the Dutch Corporate Governance Code effective as of 8 December 2016, and Article 5:25c of the Financial Markets Supervision Act, the Board of Management confirms that: This report provides sufficient insight into the nature of the Company's risk management and control systems and confirms that the control systems functioned properly in the year under review; • The report also provides sufficient insights into any failings in the effectiveness of the internal risk management and control systems; • The control systems provide reasonable assurance that the financial reporting does not contain any material inaccuracies: • Based on the current state of affairs, it is entirely appropriate that the financial reporting is prepared on a going concern basis; and • The report identifies those material risks and uncertainties that are relevant to the expectation of the company's continuity for the period of at least twelve months after the preparation of the report. The Board of Management declares that to the best of its knowledge and in accordance with applicable reporting principles, the consolidated financial statements give a true and fair view of the assets, liabilities, financial position and profit of the Group, and the Management Report incorporated in this Annual Report includes a fair review of the development and performance of the business and the position of the Group, together with a description of the principal opportunities and risks associated with the expected development of the Group. For a detailed description of the risk factors, we refer to the 'Corporate governance and risk management' chapter in this report."

The Board of Management Leiden, 28 March 2019,

## MANAGEMENT STRUCTURE

Pharming has a two-tier board structure, consisting of a Board of Management (in Dutch: Raad van Bestuur) and a Board of Supervisory Directors (in Dutch: Raad van Commissarissen). In addition, an Executive Committee sits immediately below the Board of Management and is responsible to the Board of Management for day to day operations in certain key functions.

#### **MANAGEMENT POWERS AND FUNCTION**

The Board of Management is entrusted with the management of the Company and is responsible for the policy and the central management of the Company under the supervision of the Board of Supervisory Directors. The Board of Management is authorised to commit the Company in contractual obligations to third parties. The Board of Management has adopted the Board of Management Regulations, which provide for certain duties, composition, procedures and decision-making of the Board of Management.

The Board of Supervisory Directors is charged with supervising the policy of the Board of Management and execution of that policy in the general course of the Company's affairs and the enterprise connected therewith. The Board of Supervisory Directors assists the Board of Management by rendering advice. In performing their duties, the members of the Board of Management are obliged to act in the best interests of the Company and the enterprise connected therewith. The Board of Supervisory Directors has adopted the Board of Supervisory Directors Regulations, which provide for certain duties, composition, procedures and decision-making of the Board of Supervisory Directors.

The members of the Board of Management and the members of the Board of Supervisory Directors are appointed at General Meetings of Shareholders from nominations made by the Board of Supervisory Directors. If the nomination comprises two or more persons for each vacancy, the nomination shall be binding. In addition, the Board of Supervisory Directors is authorised to make a non-binding nomination for a vacancy, consisting of one person. If the Board of Supervisory Directors fails to submit the nominations in time, the General Meeting of Shareholders has the authority to appoint any person it chooses. Notwithstanding the foregoing, the General Meeting of Shareholders may at all times, by a resolution adopted by a majority of the votes cast representing more than one

third of the Company's issued share capital, deprive the nominations of their binding effect. The General Meeting of Shareholders may adopt or reject a non-binding nomination by a resolution adopted with a majority of the votes cast. The members of the Board of Management and the members of the Board of Supervisory Directors may at any time be suspended or dismissed by a resolution adopted by a majority of the votes cast representing more than one third of the Company's issued share capital. The members of the Board of Management may also be suspended by a resolution of the Board of Supervisory Directors. If in the aforementioned cases, the quorum of one third of the Company's issued share capital is not met, a new meeting will be convened in which a nomination can be rejected or a dismissal or suspension can be resolved by a majority of the votes cast.

#### **EXECUTIVE COMMITTEE**

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The Company also has a senior management group which supports the Board of Management in its work, which it calls its Executive Committee. This is not an executive committee in the sense implicit in the Dutch Corporate Governance Code and is included here for reference only. The Board of Management retains all executive decision-making authority for the Company under the supervision of the Board of Supervisory Directors

DURING 2018, THE BOARD OF MANAGEMENT WAS COMPOSED OF THE FOLLOWING MEMBERS				
NAME	POSITION	MEMBER SINCE	TERM	
Mr. Sijmen de Vries	Chief Executive Officer	13 October 2008	Up to AGM in 2021	
Mr. Bruno Giannetti	Chief Operations Officer	01 December 2006	Up to AGM in 2019	
Mr. Robin Wright	Chief Financial Officer	28 October 2015	Up to AGM in 2020	

#### EXECUTIVE COMMITTEE

BOARD OF MANAGEMENT

DURING 2018, THE EXECUTIVE COMMITTEE WAS COMPOSED OF THE BOARD OF MANAGEMENT PLUS THE FOLLOWING MEMBERS:

NAME	POSITION	MEMBER SINCE
Mrs Anne-Marie de Groot	SVP, Organisational Development	o1 January 2014
Dr Erica Kerkvliet	Head of Research & Development	o1 January 2017
Dr Esther van Stralen	Head of Technical Operations	o1 January 2017
Mr Stephen Toor	General Manager, Pharming Americas	o1 January 2017
Mr James Cornicelli	VP, Global Business Development	23 July 2018

#### BOARD OF SUPERVISORY DIRECTORS

NAME	POSITION	MEMBER SINCE	TERM
Mr Paul Sekhri	Chairman	30 April 2015	Up to AGM in 2019
Mr Juergen Ernst	Vice Chairman	15 April 2009	Up to AGM in 2021
Dr Barrie Ward	Member	23 May 2007	Up to AGM in 2019
Mr Aad de Winter	Member	15 April 2009	Up to AGM in 2021
Dr Jan Egberts	Member	30 April 2015	Up to AGM in 2019
Mr Jaap Blaak	Member	23 May 2007	Resigned 23 May 2018

## **BOARD OF MANAGEMENT**



## Sijmen de Vries, MD MBA (1959)

TITLE Chairman of the Board of Management and Chief Executive Officer NATIONALITY Dutch DATE OF INITIAL APPOINTMENT 13 October 2008 OTHER CURRENT BOARD POSITIONS Other current board positions: Mr. De Vries holds a non-executive directorship in Midatech Pharma plc.

During 2018, Mr. De Vries was responsible for the overall management of the Company, including specifically commercial activities, quality assurance, business development and animal welfare. Mr. De Vries has extensive senior level experience in both the pharmaceutical and biotechnology industry. He joined Pharming from Switzerland-based 4-Antibody where he was CEO. Mr. De Vries has also been CEO of Morphochem AG and prior to this he worked at Novartis Pharma and Novartis Ophthalmics and at SmithKline Beecham Pharmaceuticals plc where he held senior business and commercial positions. Mr. De Vries holds an MD degree from the University of Amsterdam and a MBA in General Management from Ashridge Management College (UK).



## Bruno M.L. Giannetti, MD PhD (1952) TITLE Member of the Board of Management and Chief Operations Officer NATIONALITY Italian DATE OF INITIAL APPOINTMENT 1 December 2006 OTHER CURRENT BOARD POSITIONS

Mr. Giannetti holds no other board positions.

During 2018, Mr. Giannetti was responsible for the Company's operations including research and development and manufacturing activities as well as medical governance and non-clinical and clinical development, regulatory affairs, drug safety, and medical information teams. He has more than 25 years of experience in the pharmaceutical and biotech industry. Previously, he was the President and founder of CRM Clinical Trials GmbH (now Topcro GmbH), CEO of AM-Pharma B.V. and President and CEO of Verigen AG. He has served as senior management consultant for pharmaceutical R&D projects at Coopers & Lybrand (in Switzerland and the UK). Mr. Giannetti was also worldwide Vice-President Marketing and Medical Information at Immuno, Austria and Head of Clinical Research at Madaus AG. Mr. Giannetti holds a PhD in Chemistry and a MD PhD degree in Medicine from the University of Bonn and has been appointed visiting Professor at the Pharmaceutical Faculty of the University of Seville (Spain).



## Robin Wright, BA FCA (1964) TITLE: Member of the Board of Management and Chief Financial Officer NATIONALITY: British DATE OF INITIAL APPOINTMENT 28 October 2015 OTHER CURRENT BOARD POSITIONS

Other current board positions: Mr. Wright holds the position of non-executive Chair of the UK company Vaccitech Ltd.

Mr. Wright is responsible for the financial and capital management, accounting and investor relations activities of the Company within the CFO role, and for legal and other support functions beyond this. He has extensive senior level experience as a CFO of public companies in both the pharmaceutical and biotechnology industries. He is a qualified accountant and joined Pharming from Sweden-based Karolinska Development AB (publ.) (KDEV: SS), where he was CFO and Head of Business Development. Mr. Wright was prior to this CFO and Head of Business Development at Orexo AB (publ.) (ORX: SS) in Sweden. Before going to Sweden, he worked in private equity and corporate finance advisory roles, including long periods at Citibank Salomon Smith Barney and Barclays de Zoete Wedd. He has completed over 170 global license and M&A transactions as well as several hundred financing transactions within the pharma/ biotech sector. Mr. Wright holds a BA degree in Chemistry from Oxford University and is a Fellow of the Institute of Chartered Accountants in England and Wales in the UK.

## **EXECUTIVE COMMITTEE**

#### Anne-Marie de Groot (1981)



TITLE Senior Vice President Organisational Development NATIONALITY Dutch DATE OF INITIAL APPOINTMENT 1 January 2014

Mrs. De Groot is responsible for developing and executing internal strategic development within the Company to drive performance and identify and implement best business practices, including continuous education and alignment of the organisation to be prepared to deliver on new challenges. She has extensive and hands-on experience leading the Human Resources, Corporate Communications, Information Technologies and Support Services groups and plays a key role in aligning talent to business strategy, cultivating an environment of high employee engagement and in developing the organisational design. Mrs. De Groot has over 12 years of experience crossing the full spectrum of the HR discipline including leadership and talent development, talent acquisition, corporate culture development, organisation design and restructuring, mergers and acquisitions, compensation and benefits, payroll and performance management. She held various Human Resources and Talent Acquisition positions at Randstad, Janssen Pharmaceuticals (the pharmaceutical companies of Johnson and Johnson) and Pharming. She holds a Bachelor in Social Work and a Bachelor in Human Resources Management from Hogeschool Leiden.

## Erica Kerkvliet (1968)



TITLE Senior Director of Research & Development. NATIONALITY Dutch DATE OF INITIAL APPOINTMENT 1 January 2017

Mrs. Kerkvliet is responsible for Pharming's Research and Development (R&D). She leads the research team, the development teams (process development, analytical development and non-clinical development) and the R&D production team. In this role she is responsible for developing new products through R&D, and for enabling new programs to be developed to produce those new products in manufacture. Furthermore, R&D plays a key role in bringing new products to Technical Operations and supports improvements in the production of the current product RUCONEST®. Mrs. Kerkvliet has been working at R&D departments of various pharmaceutical and biotechnological companies for more than 18 years and has more than 10 years of experience in leading various development departments. As a result, she has extensive experience in developing therapeutic proteins and vaccines for treating various diseases. She studied Biology at the University of Leiden and holds a PhD in Cell biology from the University of Amsterdam.

## Stephen Toor (1971)



TITLE Senior Vice President and General Manager US NATIONALITY American DATE OF INITIAL APPOINTMENT 1 January 2017

Mr. Toor is responsible for Pharming's US subsidiary, Pharming Healthcare Inc (PHI). In this role he oversees all aspects of PHI's US operations including the commercialisation of RUCONEST® for patients with hereditary angioedema. Mr. Toor has over 23 years' experience leading commercial operations, brand launches and portfolios (rare disease, biologics and small molecule) in Europe, globally and in the US. His former companies include Pharmacia/Pfizer, Schering-Plough/Merck and Bausch Health. He holds a BA (Hons) in European and American History from Manchester Metropolitan University.

#### Esther van Stralen (1974)



TITLE Head of Technical Operations. NATIONALITY Dutch DATE OF INITIAL APPOINTMENT 1 January 2017

Ms. van Stralen is responsible for the manufacture and release of all Phase 3 and commercial products according to the required quality systems. In this role, Ms. van Stralen is responsible for leading the manufacturing facilities, downstream processing and quality control departments. Ms. van Stralen, has over 19 years' experience including more than 7 years in biopharmaceuticals. Her experience encompasses the management of products, from early development up to and including commercialisation and project management. Her leadership skills include communication, change management, and collaboration with cross-functional groups and external vendors. She holds a PhD in Immunology from the University of Utrecht and a Bachelor degree in Biotechnology from the Hogeschool in Amsterdam.

## James t. Cornicelli (1970)

TITLE



Vice President, Global Business Development NATIONALITY American DATE OF INITIAL APPOINTMENT 23 July 2018

Mr. Cornicelli is responsible for Pharming's global business development which includes the search and evaluation of external sourced compounds, execution of strategic transactions that broaden the product portfolio, and the expansion of Pharming global reach through the establishment of development and commercial partnerships. Mr. Cornicelli has 18 years' experience in the pharmaceutical industry contributing the growth of a wide range of companies. He started his career at TAP Pharmaceuticals before spending 12 years contributing to the success Salix Pharmaceuticals in various commercial leadership roles as well as executing strategic transactions in business development. Mr. Cornicelli spent 5 years based in Europe working for UCB Biopharma where he led global business development for the UCB immunology business unit. Before joining Pharming, he spent a year leading corporate strategy at a venture-backed healthcare IT company based in Boston, MA. He graduated from Nazareth College of Rochester with a BS in Business Administration and studied at the Kenan- Flagler Business School at the University of North Carolina at Chapel Hill where he earned a Master of Business Administration.

# BOARD OF SUPERVISORY DIRECTORS

## Paul Sekhri (1958)



TITLE Chairmanof the Board of Supervisory Directors NATIONALITY American DATE OF INITIAL APPOINTMENT 30 April 2015 **OTHER CURRENT BOARD POSITIONS:** Mr. Sekhri is President and CEO of eGenesis.

Mr. Sekhri has 30 years of operational experience in life sciences with in-depth knowledge of multinational pharmaceutical and biotechnology markets and products. Mr. Sekhri is Chairman of Compugen Ltd, a company specialising in predictive discovery of new therapies for unmet medical need. During 2018, Mr Sekhri was President and Chief Executive Officer of Lycera Corp., a biopharmaceutical company developing breakthrough medicines to treat cancer and autoimmune disease. Prior to joining Lycera, Mr. Sekhri was Senior Vice President, Integrated Care at Sanofi, where he led the creation of innovative solutions and business models to meet patient needs. Previously, he served as Group Executive Vice President, Global Business Development and Chief Strategy Officer at Teva Pharmaceutical Industries Ltd. Mr. Sekhri has held positions in small biopharmaceutical companies, large and small pharmaceutical companies, and venture capital/private equity firms, including TPG, Cerimon Pharmaceuticals, Ariad Pharmaceuticals and Novartis AG. Mr. Sekhri completed postgraduate studies in clinical anatomy and neuroscience at the University of Maryland, School of Medicine and received his BSc degree from the University of Maryland. In addition to his board position at eGenesis, he currently serves on several public and private boards including Alpine Immune Sciences, Petra Pharma Corporation, Topas Therapeutics GmbH and Veeva Systems, Inc.; as well as several non-profit boards including The English Concert in America, The Orchestra of St. Lukes, The Knights and the Metropolitan Opera.

### Juergen H.L. Ernst, MBA (1939)



TITLE: Vice Chairman, member of the Audit, Corporate Governance and **Remuneration Committees** NATIONALITY: German DATE OF INITIAL APPOINTMENT: 15 April 2009 **OTHER CURRENT BOARD POSITIONS:** Mr. Ernst is board member of the supervisory board of Aeterna Zentaris Incnc.

Mr. Ernst has extensive senior level experience in the field of pharmaceutical development and marketing. From 1969 until 1989 he held several positions at Kali-Chemie AG (subsidiary of Solvay SA), including Head of Pharmaceutical Marketing and Head of Pharmaceutical Division. In 1989, Mr. Ernst continued his career at Solvay and held several positions until he retired in 2004. Amongst others, Mr. Ernst was chairman of the supervisory board of Aeterna Zentaris Inc., member of the board of Pharmaceutical Division, CEO of Health Divisions, General Manager Pharmaceutical Sector and supervisory director and member of the Executive Committee. Mr. Ernst holds an ISMP Degree from Harvard University and an MBA from the University of Cologne.

#### Barrie Ward, PhD (1938)



TITLE: Member and Chairman of the Corporate Governance and Remuneration Committees NATIONALITY: British DATE OF INITIAL APPOINTMENT: 23 May 2007 **OPTHER CURRENT BOARD** POSITIONS: Mr. Ward is a board member of ADC Therapeutics SARL.

Mr. Ward has a broad international network and experience in managing and financing biopharmaceutical companies. He has held senior management positions in the UK, US and Singapore at several pharmaceutical and biotechnology companies, including Glaxo Group Research Ltd, Virus Research Institute Inc., Avant Immunotherapeutics Inc. and KuDOS Pharmaceuticals Ltd. and board positions at Cancer Research Technology Ltd., Spirogen SARL, CellCenteric Ltd. and BergenBio AS. His most recent senior management position was CEO of KuDOS Pharmaceuticals Ltd, which was sold to Astra-Zeneca in 2006. Mr. Ward holds a PhD in microbiology from the University of Bath, UK.

#### Jan Egberts, MD, MBA (1958)



TITLE: Member and member of the Audit Committee NATIONALITY: dutch DATE OF INITIAL APPOINTMENT: 30 April 2015 **OTHER CURRENT BOARD POSITIONS:** Mr. Egberts is a board member of Agendia Inc. and supervisory board member of CHDR, Implanet SA and Lead Pharma.

Mr. Egberts has over 25 years of executive experience in the pharmaceutical and medical device sectors, most recently as Chief Executive Officer at Agendia Inc., a molecular diagnostics company. Prior to this, Mr. Egberts was Chief Executive Officer of Octoplus N.V., a specialty pharmaceutical company, which was acquired by Dr. Reddy's Laboratories Ltd. In 2013, Mr. Egberts also served as a senior healthcare advisor for 3i Group plc, a private equity firm, and as President, Chairman and Chief Executive Officer of Novadel Pharmaceuticals Inc., where he developed a portfolio of pre-clinical and clinical compounds, gaining FDA approval for two compounds. In addition, Mr. Egberts has held multiple business development and general management positions at Johnson & Johnson, Merck & co. and Molnlycke Health Care. Mr. Egberts graduated from Erasmus University Medical School in the Netherlands and he obtained his MBA from Stanford after which he worked as a management consultant for McKinsey & Co. Mr. Egberts continues to serve on the supervisory board of CHDR (Center for Human Drug Research) and Implanet SA.

#### Aad de Winter, LLM (1953)



TITLE: Member, Chairman of the Audit Committee and member of the Corporate Governance Committee NATIONALITY: Dutch

DATE OF INITIAL APPOINTMENT: 15 April 2009 **OTHER CURRENT BOARD POSITIONS:** Mr. De Winter holds no other board positions.

Mr. De Winter has extensive financial experience. He started his career at AMRO Bank in 1980. He worked in the areas of capital markets, investment banking and institutional investor relationship management. In 1990, Mr. De Winter became senior Advisor Corporate and Institutional Finance at NIBC (formerly 'De Nationale Investerings Bank'). As of 1998, Mr. De Winter was at NYSE Euronext (now Euronext), Amsterdam responsible for advising and admitting companies to the stock exchange in Amsterdam as Director Listing & Issuer Relations. As of January 2009, until July 2015, Mr. De Winter was an Associate Partner at First Dutch Capital, Amsterdam and from 2008 to end of 2013, he was a member of the China and India working group at the Holland Financial Centre which was, inter alia, focused on attracting Chinese and Indian companies to a (cross) listing on the Euronext Amsterdam. Since 2010 he is an Associate Partner at Nederlandsche Participatie Exchange (NPEX), an innovative online financing and trading platform for securities of SME companies. Mr. De Winter has more than three decades of experience in assisting companies with stock exchange listings for various capital markets instruments. He holds a law degree from Erasmus University, Rotterdam, specialising in corporate law.

## Jaap Blaak, MSc (1941)



TITLE: Member and member of the Remuneration Committee NATIONALITY: Dutch DATE OF INITIAL APPOINTMENT: 23 May 2007 DATE OF RESIGNATION: 23 May 2018 **OTHER CURRENT BOARD POSITIONS:** n/a

Mr Blaak was previously Chairman of the Supervisory Board of Pharming and remained a director until May 2018, when he stepped down from the board of Supervisory Directors. Mr. Blaak has held executive positions with Hoogovens, Indivers N.V. and Interturbine Holding B.V. in the Netherlands, U.S. Germany and Singapore. In 1983, he got involved with the foundation of the MIP Equity Fund, one of the largest venture capital groups in Europe, and was appointed CEO in 1986. MIP made several investments in Life Science companies and was the driving force behind the BioScience Park in Leiden. Later on MIP merged with the ABN AMRO Venture Capital Group to form Alpinvest. Mr. Blaak has been an advisor to the Dutch Ministry of Economic Affairs for the Biopartner and Technopartner Program and other innovative projects related to Entrepreneurship and Innovation. Mr. Blaak holds an MSc in Physics and Business Economics from the Free University in Amsterdam and followed the Advanced Management Program of the Harvard Business School (AMP' 81).

# Board of Supervisory **Directors:** Committees

The Board of Supervisory Directors has appointed from among its members an Audit Committee, a Remuneration Committee and a Corporate Governance Committee.

#### THE AUDIT COMMITTEE

The Audit Committee consists of Mr. De Winter (Chairman), Mr. Ernst, and Mr. Egberts. The tasks performed by the Audit Committee include reviewing the scope of internal controls and reviewing the implementation by the Board of Management of recommendations made by the independent external auditor of Pharming.

#### THE REMUNERATION COMMITTEE

The Remuneration Committee consists of Mr. Ward (Chairman) and Mr. Ernst. Mr. Blaak was released from this committee when he left the Supervisory Board on 23 May 2018. A successor for his position in the remuneration committee will be appointed by the Board of Supervisory Directors following the AGM 2019. The Remuneration Committee advises the Board of Supervisory Directors with regard to salaries, grants and awards under incentive plans, benefits and overall compensation for the individual members of the Board of Management.

The Board of Supervisory Directors decides upon remuneration of the Board of Management. The remuneration of each of the members of the Board of Supervisory Directors is determined by the General Meeting of Shareholders.

#### THE CORPORATE GOVERNANCE COMMITTEE

The Corporate Governance Committee consists of Mr. Ward (Chairman), Mr. Ernst and Mr. De Winter. The Corporate Governance Committee is responsible for monitoring compliance with the Dutch Corporate Governance Code.

# CORPORATE GOVERNANCE AND RISK MANAGEMENT

#### **CORPORATE GOVERNANCE**

Pharming has a two-tier governance structure, as is common among listed companies in the Netherlands. The management, general affairs, direction, performance and long-term success of Pharming is entrusted to the Board of Management under the supervision of the Board of Supervisory Directors. A list of our current Board of Management and Supervisory Board members, their roles, dates of appointment, and their other major appointments is set out on page 37-44 of this Annual Report.

Pharming's compliance with Corporate Governance Codes and details of Pharming's Corporate Governance Statement, as required by Dutch law, can be found on our website: https://www.pharming.com/about-us/corporate-governance

#### **RISK MANAGEMENT AND CONTROL**

Risk management is integral to Pharming's strategy and to the achievement of Pharming's long-term goals. Pharming's Board of Management is responsible for designing, implementing, and operating the Company's internal risk management and control systems. The Board takes a comprehensive approach to risk management and has developed an internal risk management and control system, incorporating Pharming's strategy and the Five Components Cube of the Committee of Sponsoring Organisations of the Treadway Commission (COSO). The system is tailored to the COSO risk factors that are relevant to the Company, allowing for its small size.

This approach provides reasonable assurance that strategic, operational, financial and compliance objectives can be met and the risks facing the business are being assessed and mitigated.

Pharming's risk management and internal control framework has been in place for the duration of the financial year covered by, and to the date of the approval of, this Annual Report. A summary of the risks that could prevent Pharming from achieving its objectives is included in the section 'Risk factors' of this report.

## Our internal risk management and control systems make use of various measures including:

• Annual evaluation by the Board of Supervisory Directors of the objectives reached;

- Periodical updates to the Board of Supervisory Directors reviewing developments relating to operations, finance, research and development, business development, clinical development, and investor relations;
- Quarterly reporting and review of the financial position and projections by the Board of Management to the Board of Supervisory Directors;
- Periodic review meetings by the Board of Management with departmental managers;
- Annual, quarterly and monthly agendas, incorporating financial and operational objectives, cash flow forecasts and evaluation of progress objectives;
- A whistle-blower's procedure, communicated with all employees and published on the Company's website;
- Regular meetings to discuss the financial results, controls and procedures between the Audit Committee, the Board of Management and the Independent Auditor;
- Periodical evaluation of the company's Risk Management Plan Risk Assessment by an internal Risk Assessment Team.

## The Company maintains records and procedures designed to:

- Accurately and fairly reflect the transactions and disposition of the assets of the Company;
- Provide reasonable assurance that transactions, receipts, and expenditure is recorded and made by authorised employees and permits the preparation of financial statements in accordance with generally accepted accounting principles;
- Provide reasonable assurance of the prevention or timely detection of unauthorised acquisition, use or disposition of the Company's assets that could have a material effect on the financial statements.

The internal risk management and control systems of the Company are undertaken by the Audit Committee and the Corporate Governance Committee and regularly discussed between the Board of Management and the Board of Supervisory Directors. These Committees regularly review the significant risks and decisions that could have a material impact on Pharming alongside the Board of Management. These reviews consider the level of risk that Pharming is prepared to take in pursuit of the business strategy and the effectiveness of the management controls in place to mitigate the risk exposure.

Our risk management and control systems cannot provide absolute assurance that Pharming will achieve its objectives and we may not be successful in deploying some or all our mitigating actions. If the circumstances in these risks occur or are not successfully mitigated, our cashflow, operating results, financial position, business and reputation could be materially adversely affected. Risks and uncertainties could also cause actual results that vary from those described, which may include forward looking statements, or could impact on our ability to meet our targets or be detrimental to our profitability or reputation.

With respect to the financial reporting risks, reference is made to the 'Statements of the Board of Management' in this report. Refer to the note 32 'Financial risk management' on page 133.

# **Risk Factors**

The following risk factors have been identified by the Board of Management as the main risk areas challenging Pharming in achieving its objectives. Included are the risk-mitigating actions we have taken.

## Our risk appetite and approach to risk management differs by risk type:

- Strategic risks: we aim to deliver on our strategic ambitions and priorities, and are willing to accept reasonable risks to achieve these. The following Strategic Risks are assessed in more detail in this Annual Report:
- Commercial Risks; and
- Macroeconomic Risks.
- Operational risks: we face operational challenges that may require management attention. Our objective is to avoid risks that could negatively impact on our goal to achieve operational efficiency, while ensuring our quality standards are unaffected. The following key Operational Risks are assessed in more detail in this Report:
- Risks related to CMC/pre-clinical research and development
- Risks related to clinical research and development
- Risks related to regulatory procedures
- Risks related to production procedures
- Risks related to quality control procedures
- Personnel Risks

- Financial Risks: our financial strategy is focused on a strong financial position and creating long-term value to our shareholders. Our objective is to avoid risks which could negatively impact on this long-term value.
- Legal, IT, IP and Corporate Compliance Risks: we strive to be fully compliant with our code of conduct and national and international laws and regulations of the countries in which we operate.

To determine if a risk is acceptable, the Board of Management conducts a risk assessment to identify the level of risk the Company deems acceptable. The risk assessment is based upon our strategic goals, our business principals, our policies and procedures, and taking into consideration the highly-regulated markets we operate in.

# Strategic Risks

The two main strategic risks are Commercial **Risk and Macroeconomic Risk.** 

## **COMMERCIAL RISK**

Pharming's future success may depend upon its ability to enter into partnerships with third parties.

Pharming currently has a product portfolio which focuses on the commercialisation and further development of RUCONEST® as a treatment for an indication of Hereditary Angioedema (HAE).

Pharming's strategy for the commercialisation of other products, in particular, those for larger indications, is to partner or out-license such products to third parties. The process of establishing partnerships, however, is difficult, time consuming and involves uncertainty.

If Pharming is unable to commercialise a new product itself due to financial or strategic factors, we may have difficulty in locating and entering into favourable agreements with suitable third parties to bring the sales of the relevant product to the level necessary to ensure profitability. Pharming's ability to predict the success of any partnership is limited due to the complexity and uncertainty of thirdparty negotiations. There are currently no partnerships on

the development or commercialisation of any of Pharming's products, other than for RUCONEST® and Factor VIII. Other products being developed by Pharming have entered the clinical stage.

#### What are we doing to manage the risks?

In order to mitigate this risk of dependency, Pharming has established partnerships in potentially lucrative geographical areas with partners capable of commercialising RUCONEST® in their local markets.

North American Market: In the North-American market, which was re-acquired from Valeant in 2016, Pharming is engaged in the direct US commercialisation of Ruconest®.

Eastern European Market: To gain market acceptance in Eastern Europe, Pharming has partnered with SOBI. SOBI has a specialised sales team working in Eastern European countries with physicians that treat HAE patients.

Central European Market: Pharming initiated commercialisation in Austria, Germany and the Netherlands in 2014. In 2016, Pharming amended the license agreement with SOBI thereby taking back licenses for 21 countries, and sales rights in the largest of those markets, the UK and France. These markets are now yielding positive results.

Maintaining strong commercial relationships with third parties such as SOBI mitigate the above risks and will make entering into future partnerships with third parties easier. Pharming faces intense competition in the various markets for its products

Although Pharming is the sole provider of a recombinant therapy (either on the market or in development) for the treatment of HAE attacks, the Company faces intense competition from other products used to treat HAE. Two other non-recombinant C1-inhibitor products and one product using another mechanism of action have been approved by the European Medicines Agency (EMA), each for the treatment of acute HAE attacks. One recombinant kallikrein antibody has been approved for the preventive treatment of acute HAE attacks.

In the United States, two human blood plasma-derived C1-inhibitor product and two products with alternative mechanisms of action have been approved for the treatment of acute HAE attacks. Two blood plasma-derived C1-inhibitor products and a monoclonal kallikrein antibody for the preventive treatment of HAE attacks have also been approved (All of the above-mentioned products are applied parenterally, either by intravenous or subcutaneously. Oral products for the prevention of acute HAE attacks are also being developed.) Consequently, Pharming may not obtain sufficient market penetration with RUCONEST® or a sufficient level of sales of the product to allow it to become or remain profitable. For products under development, Pharming is also exposed to the risk that a competitor may bring a product with similar effects to the market faster than the Company does, which may result in Pharming's sales of its products to fall short of the level needed to reach profitability.

New technologies from competitors may make RUCONEST® or any other products under development and Pharming's technology obsolete. Several competitors are active in the market for therapeutic products with more resources and significantly greater experience in the industry, such as, obtaining regulatory approvals. The above events may have a material adverse effect on Pharming's financial position and operational performance

#### What are we doing to mitigate the risk?

Pharming is working towards developing new application forms for RUCONEST® (i.e. intramuscular, intradermal) for the prophylaxis and the treatment of acute HAE attacks. Furthermore, it is developing C1INH preparation to treat several new indications like pre-eclampsia or acute kidney injury after PCI. If successful, Pharming expects to have a significant competitive advantage over plasma-derived products due to their supply limitations.

Pharming sets clear long-term commitments in research and development of its Products. In addition to Pharming commercialising its own products in the major markets, where ruconest<sup>®</sup> is partnered, Pharming is assisting:

- 1 the partner to obtain the best value for RUCONEST®; and
- **2** the patients by pursuing additional regulatory ap provals and additional indications for the product.

Alongside these initiatives, Pharming is also focused on the following activities to mitigate the risk of competition:

- Evaluating external opportunities to enhance the product range and pipeline to enable better value from Pharming's resources;
- Developing or acquiring new products which can be used by the same physicians who treat HAE patients, can help those patients further, or can be commercialised using the same infrastructure;
- Developing new protein replacement treatments for enzyme-deficiency disorders such as Pompe disease and Fabry's disease, among other possible approaches;
- Developing new products through collaboration with CSIPI, such as recombinant human Factor VIII for the treatment of Haemophilia A.

## Pharming's products may not gain market acceptance

Sales of medical products depend on physicians' willingness to prescribe the treatment. This is based on a determination by physicians that the products are safe and effective for the patient. The relative cost may also be a factor when physicians compare Pharming products with competing treatments. Even if Pharming's products achieve market acceptance, the market may fluctuate resulting in Pharming being unable to generate sufficient revenue.

#### What are we doing to manage the risk?

Pharming is committed to producing cost-effective, safe and efficacious products. Our research and development team actively search for ways to improve existing products and produce new products that are both cost-effective and considers factors important to physicians.

The success of Pharming is dependent on public, market and governmental acceptance of its transgenic technology, development methods and products.

Pharming uses genetic transfer technology and genetic modification in the development of our products. These and other activities are a common subject of debate and negative publicity. Activist organisations and individuals have tried to stop various industries from using genetic modification, usually employing media smear campaigns. These actions may have a material adverse effect on Pharming's reputation financial position.

Furthermore, the Company is dependent on the market accepting our products to enable commercialisation. Market acceptance is dependent on the opinions formed

by the medical community, partners and competitors and are affected by evidence of safety and efficacy of the relevant products. Failure to obtain market acceptance of our products may also have a material adverse effect on Pharming's financial position, operational performance and financial market standing.

#### What are we doing to manage the risk?

The efficiency and high quality of our products mean that this risk is mitigated by the high demand for our products, which has been proven to save lives. Pharming also provides a less toxic and damaging product to treat patients with lifethreatening conditions.

#### Unsatisfactory reimbursements paid by third parties and unsatisfactory cost-effectiveness of Pharming's products once approved for marketing

Pharming's financial success is dependent on the reimbursement of our products by third parties such as government health administration authorities, private health insurers and other organisations. There is an increasing tendency of health insurers to reduce health- care costs by limiting both the coverage and the level of reimbursement for new therapeutic products and in some cases by refusing to provide coverage altogether. Not obtaining reimbursements, or obtaining insufficient reimbursements, from these third parties may have an adverse effect on Pharming's, financial position.

In addition to reimbursements from third parties, if the Company succeeds in bringing a product to market, it also faces uncertainties about the profitability of the product. The value of the product, acceptable to Pharming, may differ from that of health care insurers and/or consumers. This will prove the product uncompetitive and may adversely affect Pharming's financial position and financial market performance.

#### What are we doing to manage the risk?

The issue of reimbursement affects both the European market and the USA. Pharming's partner, SOBI originally addressed this on a country-by-country basis, and reimbursement has been obtained in most of the EU countries.

In the US, the product, once approved, needs to be covered under the various reimbursement programs that are applicable for various groups of US citizens. The coverage

under the reimbursement programs is a legal requirement for certain federal government funded special interest groups such as Medicare patients or armed forces veterans. These discounts can take some time to be applied. Pharming reports net sales to the market, meaning that an amount out of the funds received for sale of the product (Gross Sales) is deducted from the Gross Sales to allow payment (Allowances) for such discount claims and other discounts such as fast payment and listing discounts. These allowance funds are held by Pharming until claims for the relevant discounts have been received and become payable. In case of an unexpected increase in eligible patients, it is sometimes necessary to make additional provisions over and above the original allowances for these discounts to be claimed. The result is usually an adjustment to sales.

Information on sales progression, marketing, sales planning and execution will be exchanged on a regular basis with our commercial partners through Joint Steering Committees. To mitigate risks in these areas, Pharming continuously evaluates and implements improvements in both up-stream and down-stream manufacturing processes which will reduce the COGS and the margin pressure.

## MACROECONOMIC RISKS

#### The Macroeconomic environment is volatile

The volatility of the macroeconomic environment impacts on Pharming's objectives. In particular, the limited availability of funds in the market affects Pharming's ability to operate. The US and EU biotech markets have been slowly recovering since the year 2014.

#### What are we doing to manage the risk?

To mitigate the risks of the macroeconomic environment, Pharming plans financial activities in advance to ensure sufficient cash flow. In order to do so, Pharming maintains strong relationships with international banks and investors.

#### The cycle of biotechnology investment

Biotech investment tends to occur in cycles. The market is reasonably volatile, with the sector generally being seen as reliable for positive performances during a downturn.

#### What are we doing to manage the risk?

Pharming is aware of the money flows into biotech funds and the geographical differences between the Netherlands/ Benelux/Europe and the US. Pharming is also aware of the risk assessment of investors at any point in the investment cycle.

Pharming recognises improvements and deteriorations of the biotech investment climate and acts to ensure that if funding is required from external sources, it raises funds when these are available at acceptable terms. To do so, Pharming maintains relationships/contact with a spread of international banks and investors (both equity and debt). The financing completed to achieve the reacquisition of commercial rights of RUCONEST® in the US and its subsequent refinancing has left Pharming with a solid, dependable balance sheet with no immediate need of funding. Pharming continues to monitor the biotech investment sentiment by following (financial and operational) sector news, keeping in close contact with banks both in the US and Europe and actively discussing funding and shareholder opportunities with these banks. The Company will continue to visit selected investor conferences and organise non-deal road shows in order to inform (potential) investors.

#### Cost of funding varies with the macroeconomic environment

Global economic changes impact the cost of funding for all companies worldwide. Although the biotech sector has its own dynamics, it is expected that its development will ultimately be linked to future global economic trends. At present, restrictions on new investment funding in economic downturns tend to increase the cost of all forms of raised capital, with upturns having the opposite effect.

#### What are we doing to manage the risks?

The Company cannot influence the global changes that are taking place; however, we can strive to beat the trends by:

- Changing the investor base towards more institutional shareholders:
- Informing our existing shareholders base to create a better understanding of the fundamentals of biotech development and pharmaceutical sales markets; and
- Ensuring that we have, or have access to, sufficient capital to carry out our plans.

#### High Profile failures of biotech companies alter the investment environment

Next to economic behaviour, investors in biotechnology are also driven by sentiment and news flow. Performance of other biotech companies can have an impact on the investment environment. This could also have an impact on Pharming's stock price development and availability of funding.

#### What are we doing to manage the risks?

While Pharming cannot control other companies management, in order to mitigate reputational damage, Pharming identifies different audiences, determines their relative importance for the Company's immediate future and assess the information necessary. We do this in part by contracting professional PR consultants to advise on our communication methods and attending selected investor conferences both in Europe and the US to meet interested investors. Pharming communicates important developments in press releases on their website and in the Annual Report.

# **Operational Risks**

Operational or operating risk in this case refers to research and development risks, manufacturing risks, clinical risk and personnel risk. There are other areas of operating risk which are assessed and managed, such as documentary error risk, but they are not considered material for this report.

## **RISKS RELATED TO CMC/PRE-CLINICAL RESEARCH AND** DEVELOPMENT

The Company's development pipeline has been dependent on the RUCONEST® franchise

Pharming's operational development is dependent on the RUCONEST® franchise. Any negative finding on the properties, efficacy or safety of the source of the recombinant protein may have a significant impact on the Company's existence.

What are we doing to manage the risk? A set of activities to expand the pipeline are ongoing including:

- Development of recombinant human alpha-glucosidase (rhaGLU) for the treatment of Pompe disease;
- Development of recombinant human alpha-galactosidase (rhaGAL) for the treatment of Fabry's disease;
- Collaboration with Chinese company CSIPI to produce recombinant Factor VIII; and
- Platform improvement by Pharming R&D at Evry in France to develop new platforms with in- creased protein expression and/or improved glycosylation profiles.

In addition to these activities for new molecule projects, Pharming is also pursuing new indications for RUCONEST® and other forms of rhC1INH and supporting independent investigators to do so.

New ad hoc activities are sometimes introduced, and ongoing activities are continued as much as possible while the data is promising. Progress of the projects is discussed each quarter with the Board of Supervisory Directors.

#### The development pipeline is at an early stage

Pharming's recent focus has been on identifying potential projects with a relatively short development time. This assumes that the main advantages of a potential new product, compared to existing alternatives on the market, should be effective and safe. This assumption relies on the advantages provided by the Company's proprietary platform including a significant commercial upside due to lower cost of goods.

Since 2015, significant effort has been applied to identifying suitable pipeline candidates, resources and infrastructure to mitigate the risk associated with focusing on a single product. At present, our R&D department is structuring different subdivisions to accommodate the work necessary for our new product development. However, our pipeline products are still in the early stages of development and exposed to the product failure during development.

#### What are we doing to manage the risk?

• Potential products such as rhaGLU and rhaGAL have been selected, recommended by the Pharming Pipeline Team. It is expected that these potential products will have a relatively short development time based on the assumption that the main advantage of a potential new product as compared to existing alternatives on the market at this stage should be safety, and these are essentially human proteins.

• Project teams have been set up for each project which will work to bring the projects to the next stage.

Pharming is looking to reduce the development timelines further by searching for new projects in areas where core competence and knowledge that are already available in the Company. A professional project structure has been developed so that projects are properly monitored, and needs are met.

#### The development of Pharming's early stage products involves a long product development cycle

The development of a therapeutic drug to marketing approval is a lengthy process. During this time a research project must proceed through preclinical and several clinical stages of development, as well as the regulatory approval process. Due to this lengthy process and the inherent uncertainty of research and development of pharmaceuticals, only a small fraction of initial product candidates receive regulatory approval.

#### What are we doing to manage the risk?

In addition to RUCONEST® and other Pharming products in development, Pharming seeks to discover products in several long-term research projects for which clinical trials have not vet been initiated.

A failure to develop additional products successfully and within a reasonable time frame could have significant detrimental consequences for Pharming's, financial position operational performance and business prospects.

#### Quality and flexibility of outsourced development activities are harder to control that in-house activities

Outsourced activities performed for process development do not give the quality we are used to obtaining when processes are developed in house. In addition, outsourcing of these activities is costly and often inefficient. A delay may occur in process development due to the Contract Research Organisation (CRO) or Contract Manufacturing Organisation (CMO) involved may not be able to deliver in time.

#### What are we doing to manage the risk?

• The Pharming process development team closely monitors the progress and sometimes repeats process steps; Analytical Development colleagues are also closely involved and repeat tests regularly.

• In order to maintain control and management of the outsourced processes, we hold periodic meetings with the CROs/CMOs involved.

## **RISKS RELATED TO CLINICAL RESEARCH AND DEVELOPMENT**

#### Pharming relies on third parties to conduct preclinical and clinical trials

Pharming does not have the ability to conduct preclinical and clinical trials for product candidates in its own facilities and must rely on agreements with third parties to undertake these activities (i.e. contract research organisations, medical institutions, clinical investigators and contract laboratories). Pharming remains responsible that each of the preclinical and clinical trials are conducted in accordance with its general investigation plan and protocol. Moreover, the European Medicines Agency (EMA) and the US Food and Drug Administration (FDA) require Pharming to comply with regulations and standards, commonly referred to as Good Clinical Practices, for conducting, re- cording and reporting the results of preclinical and clinical trials. This is to ensure that data and reported results are credible and accurate and that trial participants are adequately protected.

#### Pre-clinical or clinical trials may be extended, delayed, suspended or terminated if third parties:

- do not successfully carry out their contractual duties or regulatory obligations;
- meet expected deadlines;
- need to be replaced;
- fail to adhere to Pharming's preclinical and clinical protocols or regulatory requirements (thereby compromising the quantity or accuracy of the data); or
- for any other related reasons.

In the above circumstances, Pharming may not be able to obtain regulatory approval for, or successfully commercialise, product candidates. This may have a material adverse effect on Pharming's financial position, or operating performance.

#### What are we doing to manage the risk?

Pharming's legal, regulatory and clinical departments focus on initiating and maintaining good relationships with competent third parties. Penalties for contractual defaults are carefully considered and third parties are selected with importance placed upon past performance and reputation.

#### Clinical trials in new indications fail

Pharming is currently developing new routes of administration for RUCONEST® in several indications, independently or in co-development with various partners. Furthermore, several additional indications are being pursued as Investigator Initiated Trials

Clinical trials are expensive and risky. General Clinical Practice rules have recently become stricter, which will cause a further increase in clinical development costs. The likelihood of a drug in clinical phase to get approved by the FDA has decreased in the last decade from 23% to 11.8%, and overall from concept to approval the probability of success is 1.5% for small molecules and 2% for biologic drugs (drugs based on existing human molecules). "Rushed development" and "cutting corners" have been named as the most common reasons for failure of proof of concept, dose finding and confirmatory studies.

#### What are we doing to manage the risk?

RUCONEST® provides patients with an indication of acute HAE with an active protein enzyme known to be missing or defective in the patient, for new indications, it is challenging to find a biochemical rationale for a postulated efficacy in indications other than HAE. The success of the treatment is more uncertain. Nevertheless, the evidence for the importance of the biochemical processes on which RUCONEST® acts in new indications is robust, mitigating the risk of failure.

Alongside the strong evidential position, all project plans are evaluated by the Executive Committee (EC) and planning and Implementation of any clinical study is subject to Board of Management (BOM) approval. Development programs at Pharming may be partnered and sometimes co-funded, and therefore also may be subject to the review processes of the partner or funding entity.

#### Cost of trials overrun

Clinical trials are expensive and costly protocol amendments are regularly required. The costs of clinical trials have increased significantly in recent years mainly due to increased regulatory requirements.

#### Additional reasons for cost overruns include:

- a lengthy recruitment period for test patients;
- the addition of centres to gather patients and test results; and
- a decision to have an interim analysis for efficacy.

#### What we are doing to manage the risk?

To mitigate risk structurally, we work to implement the following processes:

- Clinical studies are managed by the Project Team;
- Special attention is paid to planning and conducting each clinical trial, adding scientific monitoring activities by a separate team of experts to the standard GCP conform monitoring plan.
- Deviations from the budget are flagged with the Executive Committee and proposals for protocol changes with significant budget impact require Board of Management approval;
- Development of formal processes for Project Management;
- Development of formal processes for Budgeting and Forecasting; and
- Negotiating contract research organisation contracts with clear conditions and limited capacity for budget expansions.

#### **Risks related to Regulatory Procedures**

The process of undertaking and completing preclinical studies and clinical trials, and obtaining regulatory approvals, may take several years and require substantial expenditure. There can be no assurance that applicable regulatory approvals for the Company's products will be granted in a timely manner, or at all. Any failure or delay in commencing or completing clinical trials for Pharming's products may have an adverse effect on the business.

The regulatory approval process is costly and lengthy and Pharming may not be able to successfully obtain all required regulatory approvals. Negative or inconclusive study results (either preclinical or clinical) could result in Pharming stopping the development of a product or technology or requiring additional clinical trials or other testing. This could have significant detrimental consequences for Pharming's financial position and operational development.

#### Pharming may not obtain all regulatory approvals for its products

Once a product receives regulatory approval, the approval may be subject to limitations or conditions (i.e. limitations on the indications for which the product is marketed or additional proof being required of the product's effectiveness and safety). Even after approval is granted, the product, its manufacturer and the manufacturing facilities are subject

to ongoing scrutiny and regular inspections by the relevant agencies. If previously unknown problems are discovered in connection with the product, the manufacturer or the manufacturing facilities, restrictions may be imposed on use and withdrawal of the product from the market. This would adversely affect Pharming's operational efficiency and financial position.

#### What are we doing to manage the risk?

Compliance with regulations is an essential part of Pharming's business operation. Pharming has strengthened its in-house team in regulatory affairs for both the US and EU and continues to do so. Our regulatory specialists are heavily involved in monitoring and reviewing our practices to provide reasonable assurance that we remain aware of and in line with all relevant legal obligations.

**Regulatory standards are constantly** developing and failure to comply with applicable regulatory requirements could have serious consequences for the Company The industry in which Pharming operates is highly regulated and the applicable regulatory requirements vary considerably between the different markets in which Pharming operates. These regulations are subject to development and future regulatory standards relating to, for instance, biotechnologyderived products, may be imposed that are distinct from those currently employed. Pharming cannot guarantee it will be able to meet such standards as they evolve and are implemented.

In addition to changing regulatory requirements, the failure of Pharming to comply with applicable regulatory requirements could result in, among other things, injunctions, product recalls, product seizures, fines and criminal prosecution.

#### What are we doing to manage the risk?

As noted above, compliance with regulations is an essential part of Pharming's business operation. Pharming has strengthened its in-house team in regulatory affairs for both the US and EU and continues to do so. Our regulatory specialists are heavily involved in monitoring and reviewing our practices to provide reasonable assurance that we remain aware of and in line with all relevant regulatory obligations. At the same time, Pharming has also strengthened and continues to strengthen its pharmacovigilance team, to ensure downstream compliance and fast response to issues arising for patients.

#### **Risks related to Production Procedures** Pharming uses living mammals as the source for its program

of recombinant product

The unique platform used by Pharming to produce its recombinant products bears the risk of failure due to contamination of the produced milk, due to diseases of the producing livestock or due to a breakdown of the facilities.

#### What are we doing to manage the risk?

Our production, operating and facility specialists are heavily involved in monitoring and reviewing our practices to provide reasonable assurance that we remain aware of and in line with all relevant obligations in relation to Pharming's production.

#### Pharming relies on single source suppliers for the provision of essential processes or materials incorporated in certain products and product candidates

Pharming relies on a single supplier for certain essential materials incorporated into products and product candidates. Any disruption in the supply of these materials could adversely affect our ability to deliver product or complete clinical trials. Other studies of product candidates, regulatory applications or commercialising product candidates in a timely and commercially-valuable manner, may be adversely affected, should supply by disrupted.

#### What are we doing to manage the risk?

Pharming has contingency plans designed to deal with any supply chain issues. Pharming continuously evaluates and implements improvements in both up-stream and downstream manufacturing processes. Pharming has begun to gradually insource manufacturing activities and engage other partners to create alternatives or additional capacity to existing suppliers.

#### Pharming's future supplies of RUCONEST® are dependent on third parties

Pharming has entered into (downstream) manufacturing and supply agreements for the production of rhC1INH, the drug substance of RUCONEST®, namely with Sanofi and BioConnection. Pharming may have to develop and/or contract additional (upstream or downstream) manufacturing capabilities and may have to develop or contract additional (downstream) purification capacity. It is uncertain whether and to what extent Pharming will be able

to develop such capabilities or enter into such partnerships or agreements on a timely basis and on acceptable terms. Even if a partnership or agreement has been concluded, the possibility exists that these partners fail to live up to the agreements made with them or that Pharming is unable to maintain such agreements. A failure to develop and/or sufficiently contract additional manufacturing capacity on a timely basis could have significant detrimental consequences for Pharming's business, financial position, results of operations, prospects and market price of the shares.

#### What are we doing to manage the risk?

Pharming has actively engaged in expanding its milk production capabilities in independent, geographically separated sites, thereby minimising the risk of a complete production stop caused by contaminations, diseases or catastrophe in one site.

Pharming is planning to build a downstream facility to become independent from third party suppliers. Furthermore, Pharming is planning to acquire a significant stake in the supplier of the finished product. At the end of these processes Pharming will have almost full control over the whole production chain for RUCONEST®.

#### **Risks related to quality control procedures**

The release of product to the market is dependent on a set of quality control procedures. Some of these procedures, although validated, are very sensitive and complex with the risk of false results wrongly impairing the release.

#### All guality control procedures essential for the release are performed by third parties.

Pharming does not have a GLP certified analytical lab capable of performing the quality control procedures needed for the release of product. Presently third parties fulfil this task, but in some cases the diligence, timely delivery and accuracy of the selected Contract Laboratory Organisations does meet the expected quality standards.

#### What are we doing to manage the risk?

Pharming has started activities to build its own certified quality control laboratory, capable of performing most of the required analytical procedures. Furthermore, Pharming has started a scientific program to challenge and reassess all currently used quality control procedures with the aim to improve/replace those by modern, more robust and easier to perform analyses, where possible.

## **PERSONNEL RISKS**

Pharming is dependent on its ability to recruit and retain its management and key employees Pharming's success is dependent on the performance and expertise of its management, sales and technical personnel. Competition for qualified employees is intense in the fields in which Pharming is engaged and there is no guarantee that qualified employees will not leave Pharming. The loss of one or more of these employees could lead to significant delays in product development and thus negatively influence Pharming's business activities. Pharming's continued success depends on recruiting and retaining highly qualified employees, especially in management, product sales and R&D. The loss of individual employees or a failure to attract new highly qualified employees could have a significant detrimental consequence on Pharming's financial position and operating performance.

#### What we are doing to manage the risk?

Pharming strives to be an employer of excellence. The Company provides our employees with the opportunity to enjoy their work, learn and grow by providing internal and external training programs and development opportunities. Together with offering competitive remuneration packages Pharming can minimise employee turnover, attract higher quality talent and provide accountability to stakeholders.

Management and employee development, succession planning, company culture and branding are focal points in the organisational development activities.

## LEGAL, IT, IP AND **COMPLIANCE RISKS**

A material change in the laws and regulations to which Pharming is subject, or in their interpretation or enforcement could adversely affect Pharming's business, results of operations and financial condition

Pharming must comply with a variety of laws and regulations, including regulatory, health and safety, license requirements, tax and Corporate Governance Regulations. Pharming may be required to pay penalties for noncompliance with the laws and regulations of local, regional, national, US and EU authorities to which it is subject. A material change in the applicable laws and regulations, or in their interpretation or enforcement, could force Pharming to alter its business strategy or operations, leading to additional costs or loss of revenue, which may adversely affect its business.

#### What are we doing to manage the risk?

Pharming has developed a system with external parties to signal and inform changes in any law or regulation. The Company has also recently enabled a successful challenge to the legality of freedom of information activities from parties wanting to interfere with Pharming's technology platform, thereby putting our employees at risk, as well as putting the lives of patients who depend on our products at risk.

Pharming's success is dependent on our ability to obtain and protect rights to proprietary technology and to develop Pharming's technology and products without infringing the proprietary rights of third parties Patents, trade secrets and other proprietary rights are important to the success of Pharming's business. Pharming uses patents and licensing to protect our products and technology and is careful to develop products that don't infringe on the proprietary rights of third parties. Currently, Pharming has several patent applications granted and pending in countries including the US, Europe and Japan. The patent positions of pharmaceutical companies can be uncertain and may involve complex legal and factual questions.

It is uncertain whether pending patent applications will be successful, that these patents will afford adequate protection or that the existing patents will not be challenged. Failure to obtain patents may result in expensive and protracted proceedings to defend Pharming's proprietary rights.

The success of Pharming also depends, in part, on the ability of its licensors to obtain, maintain and enforce their intellectual property rights to the extent required for Pharming to develop and commercialise our products.

#### What are we doing to manage the risk?

Our legal, compliance and regulatory specialists are heavily involved in monitoring and reviewing our intellectual property and proprietary rights to ensure that we remain aware of an in line with all relevant laws and legal obligations concerning this area of law.

Furthermore, Pharming seeks to protect its other proprietary rights through confidentiality and non-disclosure agreements with employees and third parties. These agreements, while reducing the risk of infringing on Pharming's proprietary rights, cannot provide absolute protection from superior capability or independently developed products.

#### Pharming operates in a litigious industry sector

Pharming participates in an industry subject to significant product liability and intellectual property claims, among other litigation. While Pharming operates in good faith, it is not certain that the subject matter of Pharming's patents and patent applications are original, or that we were the first to apply for such a patent. There is also a risk that existing patents may be challenged, invalidated or unenforceable. Moreover, Pharming's technologies and products may infringe on third party intellectual property rights.

As a result, Pharming may face litigation or other legal proceedings concerning its intellectual property. These processes can be time-consuming and costly. In the event of an unfavourable ruling in patent or intellectual property litigation, Pharming could be subject to significant liabilities to third parties, or be required to cease developing, manufacturing or selling the affected products or technology. Each of these outcomes may adversely affect Pharming's financial position

Pharming may also be confronted with claims which are raised with the main aim of exploiting the nuisance value of publicly raised claims. In order to prevent the infringement of third-party intellectual property rights, Pharming may need to acquire licenses for patents held by third parties to re-establish or maintain its freedom to operate, possibly on unfavourable terms. A failure to obtain licenses for patents held by third parties, or failure to obtain them on favourable terms, may have a material adverse effect on Pharming's financial and operational position

Pharming is not aware of any pending litigation however may face such claims in the future. Such claims, although not considered material, may impose considerable costs or may consume significant management resources.

#### What are we doing to manage this risk?

Pharming is committed to complying with the laws and regulations of the countries in which we operate. In specialist areas, relevant teams are responsible for setting

detailed standards and ensuring that all employees are aware of and comply with regulations and laws specific to their roles.

As noted above, our legal, compliance and regulatory specialists are heavily involved in monitoring and reviewing our practices to provide reasonable assurance that we remain aware of and in line with all relevant laws and legal obligations.

Pharming is not aware of any pending litigation and does not believe that there is any material litigation or other proceedings pending or threatened.

## **CORPORATE COMPLIANCE RISKS**

Pharming is a data controller of personal data as well as special categories of personal data The General Data Protection Regulation was implemented on 25 May 2018 and governs how Pharming collects and processes personal data. Under the regulation Pharming is considered a Controller of data processing and is subject to several legal obligations. Importance is placed on the collection and processing of special categories of personal data which, for Pharming's purposes, is data that reveals genetic data or data concerning health.

What are we doing to manage the risk?

Compliance with the GDPR is a vital part of Pharming's corporate compliance program. Pharming has strengthened its compliance team in both the US and EU and continues to do so. Pharming's compliance specialists are heavily involved in monitoring and reviewing our practices and providing trainings to all employees to create awareness of Pharming's obligations. Moreover, a companywide review of all personal data held is currently being undertaken to assess our level of protection.

# **Financial Risks**

Pharming generates insufficient cash from commercial activities to meet all our potential future anticipated requirements. Pharming does not exclude the possibility that we may incur losses in future periods and could be dependent, at that stage, on financing arrangements with third parties, as has been the case since its incorporation

Pharming currently generates insufficient cash from commercial activities to meet all its potential future anticipated requirements and is dependent on financing arrangements with third parties, as has been the case since its incorporation. The available net cash (cash and cash equivalents) as at the date of this Annual Report is not expected to deplete before the end of March 2020.

Product sales are currently exclusively related to RUCONEST<sup>®</sup> and are realised directly by the Company and through Pharming's commercialisation partners. The ability of Pharming to attract external funding is (inter alia) dependent on the external market conditions (equity and/ or debt).

Pharming had incurred losses in each year since incorporation until this financial year ended December 2018. These losses have arisen mainly from costs incurred in R&D of Pharming's products and general and administrative expenses. The acquisition by Pharming of all commercialisation rights to RUCONEST® in North America (USA, Canada and Mexico) from Valeant Pharmaceuticals International Inc. (Valeant, NYSE/TSX: VRX), has enabled Pharming to achieve enough revenues now and in the future to continue to generate profits.

The amount and timing of any expenditure required to implement Pharming's business strategy and continue the development of its products will depend on many factors, some of which are out of Pharming's control, including but not limited to:

- Scope, rate of progress, results and cost of Pharming's preclinical and clinical trials and other R&D activities;
- Terms and timing of any collaborative, licensing and other arrangements that Pharming may establish; Higher cost,

slower progress than expected to develop products and delays in obtaining regulatory approvals; Number and characteristics of products that Pharming pursues;

- Cost and timing of establishing sales, marketing and distribution capabilities;
- Timing, receipt and amount of sales or royalties, if any, from Pharming's potential products, or any upfront or milestone payments during their development phase;
- The cost of preparing, filing, prosecuting, defending and enforcing any intellectual property rights; and
- The extent to which Pharming acquires or invests in businesses, products or technologies.

No assurance can be given that Pharming will remain profitable in the future. Furthermore, if Pharming's products fail in clinical trials or do not gain regulatory approval, or if Pharming's products do not achieve market acceptance, Pharming may not remain profitable on a sustainable basis.

Pharming does not exclude the possibility that we may need additional funding in the future, which may not be available to Pharming on acceptable terms or at all, which could force Pharming to delay or impair its ability to develop or commercialise its products. There can be no assurance that additional funds will be available on a timely basis, on favourable terms, or at all, or that such funds, if raised, would be sufficient to enable Pharming to continue to implement its long-term business strategy. If Pharming is unable to raise such additional funds through equity or debt financing, it may need to delay, scale back or cease expenditures for some of its longer-term research, development and commercialisation programs, or grant rights to develop and market products that Pharming would otherwise prefer to develop and market itself, thereby reducing their ultimate value to Pharming. Pharming's inability to obtain additional funds necessary to operate the business could materially and adversely affect the market price of the shares and all or part of an investment in the shares could be lost. In addition, to the extent Pharming raises capital by issuing additional shares, Shareholders' equity interests may be diluted.

#### Exchange rate fluctuations could negatively affect Pharming's financial condition

Pharming is based in the Netherlands, but sources materials, products and services from several countries outside the EUterritory which are paid in local currencies. As a result of the commercialisation of RUCONEST® in the USA and in other countries outside the EU and the USA, Pharming will also

receive payments or generate costs in US dollars or possibly in other currencies.

At present, the total of Pharming's gross profit on its net sales in the USA of US\$149.3 million approximately balances the Company's outstanding loan of US\$100 million, thereby providing a natural hedge to movements in the euro: US dollar exchange rate. Any change in the exchange rate means an increase in the euro value of sales and hence an increase in the loan balance in euros, or a decrease in the euro value of sales balanced by a reduction in the loan balance in euros. As sales grow, of course, it will be necessary to make more conservative assumptions and to begin proper external hedging policies by buying dollars and/or euros at forward rates in an integrated treasury policy.

Pharming's policy for the management of foreign currency risks is aimed at protecting the operating results and positions held in foreign currencies, in particular, of the US dollar. Certain payments and sales of RUCONEST® in the USA are being made and will be received in US dollars.

Repayments and interest payments of the loan will be made in US\$. Some direct payments of US activities are carried in US\$ through the Dutch entities. At 31 December 2018, the Company's cash and cash equivalents, including restricted cash, amounted to €81.5 million. This balance consisted of cash assets denominated in euros for a total amount of €8.9 million and cash assets denominated in US dollars for a total amount of US\$83.0 million or €72.6 million (applying an exchange rate of €1=\$1.1439 at 31 December 2018). The US\$ cash balances are currently mainly used for the repayment of the loans and US costs in US dollars, and are otherwise converted to euros for payment of non-US obligations.

The Company performed a sensitivity analysis by applying an adjustment to the spot rate at year-end. A 10 percent strengthening of the euro versus the US dollar has a hypothetical result of respectively a loss or gain of approximately.

€2.2 million on sales and a similar amount in reduction of the holding value of debt. As a result, Pharming's business and Share price may be affected by fluctuations in foreign exchange rates between the euro and these foreign currencies, including the US dollar, which may have a significant impact on Pharming's reported results of operations and cash flows from year to year.

In addition, the Company has provided its major financial statements in both euros and US dollars, starting with the first quarter of 2018, and will make a decision as to whether to change the functional and reporting currency to the US dollar for years after 2018 later in the year 2019.

#### Interest rate fluctuations could negatively affect Pharming's financial position

Pharming's interest rate risk policy is aimed at minimising the interest rate risks associated with the financing of the Group. This policy translates into a certain desired profile of fixed-interest and floating interest positions, including those generated by cash and cash equivalents and those paid on finance lease liabilities.

The Company performed sensitivity analyses regarding the effect of a 1% interest increase or a 1% interest decrease on the carrying value of the financial instruments at year-end 2016. Pharming concluded that the total effect taking place on the carrying value of these items in either case would have been approximately €0.81 million at year-end 2017.

However, a rise in the interest rates on its liabilities may cause Pharming to pay more interest than anticipated, negatively impacting the profitability and liquidity position of the Group, which could have a significant impact on Pharming's reported results of operations and cash flows from year to year.

## Risks relating to the dilution relating to the warrants, options and the convertible bonds

Dilutive effects may reduce future potential earnings per share and subsequently the market price of the shares. Full exercise of all the remaining warrants would result in a dilution of shareholders in their proportionate ownership and voting rights of 3.0%. All of the convertible bonds (both ordinary and amortising convertible bonds) have been redeemed, and so will have no effect on the shareholding from the date of this report. Full conversion of all outstanding employee and management options would result in a dilution to shareholders in their proportionate ownership and voting rights of 6.7%.

The effects of dilution may reduce earnings per share and independently the market price of the shares. The impact of dilution will also impact the amount that each individual share will be worth in terms of proportionate ownership and voting rights.

Future sales, or the possibility or expectation of future sales, of a substantial number of shares may temporarily depress the price of the shares.

Future sales of shares, or the perception that such sales will occur, could cause a decline in the market price of the shares. Pharming cannot predict whether substantial numbers of shares will be sold in the open market.

Future sales of shares could be made by shareholders or through a capital increase undertaken by the Company for additional working capital, to fund an acquisition or for another purpose. A sale of a substantial number of shares, or the perception that such sale could occur, could materially affect the market price of the shares and could also impede Pharming's ability to raise capital through the issue of equity securities in the future.

## The market price of the shares may be volatile, and investors may not be able to sell shares at or above the price paid for by them.

The market price of the shares is subject to many factors, including the liquidity of the market for the shares, the public opinion about general economic and market conditions and the public sentiment about the Company and the biotech industry. In addition, the market price of the shares could fluctuate substantially due to any of the risks described herein materialising or the sale of large blocks of shares. Moreover, stocks of life science companies which are currently not profitable, such as Pharming, and stock markets in general, have from time to time experienced extreme price and volume fluctuations that may be unrelated or disproportional to the operational performance of particular companies. Because of all these different factors, the market price of the shares has been, and may be in the future, highly volatile.

## Pharming does not intend to pay dividends for the foreseeable future.

Pharming does not intend to pay any dividends for the foreseeable future. Payment of future dividends to Shareholders will effectively be at the discretion of the Management Board, subject to the approval of the Supervisory Board, after considering various factors including Pharming's business prospects, cash requirements, financial performance and new product development. In addition, payment of future dividends may be made only in so far as Pharming's shareholders' equity exceeds the amount

of its paid-up and called in capital increased by the reserves which are required to be maintained pursuant to Dutch law. Accordingly, investors cannot rely on dividend income from the shares and any returns on an investment in the shares will likely depend entirely upon any future appreciation in the price of the shares.

If securities or industry analysts do not publish research or reports about Pharming's business, or if they change their recommendations regarding the shares adversely, the price and/or trading volume of the shares could be affected.

The trading market for the shares may be influenced by the research and reports that industry or securities analysts publish about Pharming or Pharming's business. Currently there are several institutions which publish independent research reports on the Company, including Oppenheimer, Stifel, HC Wainwright, Roth and First Berlin Equity Research GmbH. Other institutions have made enquiries about beginning such research activities.

If one or more of the analysts who cover Pharming or Pharming's industry downgrade the shares in a research report, the market price of the shares would probably decline. If one or more of these analysts ceases coverage of Pharming or fails to publish reports on Pharming regularly, the Company could lose visibility in the financial markets, which could cause the market price and/or trading volume of the shares to decline.

#### **Risk-mitigation actions – Financial risks.**

We may need additional funding in the future, which may not be available to us on acceptable terms, or at all, which could force us to delay plans or profitability or impair our ability to develop or commercialise our products. There can be no assurance that additional funds will be available on a timely basis, on favourable terms, or at all, or that such funds, if raised, would be sufficient to enable us to continue to implement our long-term business strategy. If we are unable to raise such additional funds through equity or debt financing, we may need to delay, scale back or cease expenditures for some of our longer-term research, development and commercialisation programs, or grant rights to develop and market products that we would otherwise prefer to develop and market ourselves, thereby reducing their ultimate value to us.

In addition, to the extent we raise capital by issuing additional ordinary shares, existing shareholders' equity interests may be diluted as to voting power and may also be diluted (or enhanced) as to value, depending on the terms of such additional share issues and the reasons for the issue. The Finance team monitors market developments, including the position of the banks. All cash in EUR has been placed at ABN Amro, which is a Dutch government owned bank, or at Silicon Valley Bank, a very highly accredited US bank with a high credit rating, which has been a lender to the Company before now.

The Dutch government has an excellent credit rating. The cash is denominated in euros and US dollars and is kept in flexible deposits.

# **Testimonial Yolanda**

"At Pharming, the

special attention"

small groups of patients

we work with have our

as senior scientist is to provide understanding and educate my fellow colleagues and the scientific community regarding our preclinical development projects. By learning about the specific mechanics of a disease and revealing the mechanism of action as well as potential side effects of our medications in development, we can create and improve therapy options for patients. Our existing product and pipeline projects are related

to rare and devastating diseases; at Pharming, the small groups of patients we work with have our special attention. Ever day I realise what patients go through their entire lives; the can't switch off their computer and go home as their disease is 24/7. Therefore, I don't mind working long hours, it's my passion to help the patients that drives me every day; to push a further the development of life changing therapies.

## **REPORT OF THE BOARD OF SUPERVISORY DIRECTORS**

The Board of Supervisory Directors, in general, supervises the Board of Management in its duty to manage the Company. It performs its duties and activities in accordance with the Articles of Association of the Company, its regulations, which are posted on the Company's website, the applicable law and the Dutch Corporate Governance Code applicable as of 8 December 2016 (the "Code"), as adopted into law in the Netherlands on 7 September 2017.

#### The supervision of the Board of Management by the Board of Supervisory Directors includes: The achievement of the Company's objectives;

- The corporate strategy and the risks inherent in the business activities:
- The structure and operation of the internal risk management and control systems;
- The financial reporting process;
- Compliance with primary and secondary regulations;
- The Company-shareholder relationship; and
- Corporate social responsibility issues that are relevant to the Company.

The Board of Supervisory Directors determines, together with the Board of Management, the corporate governance structure of the Company and ensures compliance with the Code and other (foreign) applicable rules and regulations, assisted by its Corporate Governance Committee. Through the Audit Committee, it supervises the financial reporting process and assisted by its Remuneration Committee, it determines the remuneration of the individual Board of Management members within the remuneration policy adopted by the Annual General Meeting of Shareholders. The report of the Remuneration Committee is presented separately in this report.

# Composition and remuneration

In 2018, the composition of the Board of Supervisory Directors was as follows: Mr. Sekhri (Chair), Mr. Ernst (Vice-Chair), Mr Blaak, Mr. Ward, Mr. De Winter, Mr. Egberts. Mr Blaak stepped down from the Board at the AGM on 23 May, 2018.

The remuneration of the members of the Board of Supervisory Directors is determined by the General Meeting of Shareholders. The annual remuneration is based on the position an individual has in the Board of Supervisory Directors, the Audit Committee and the Remuneration Committee, no additional remuneration was agreed for members of the Corporate Governance Committee.

#### For 2018, the annual compensation was as follows:

- Board of Supervisory Directors: Chairman €50,000 and Member €36,000;
- ◆ Audit Committee: Chairman €9,000 and Member €3,000;
- ◆ Remuneration Committee: Chairman €6,000 and Member €3,000; and
- ◆ An additional compensation of €1,000 per day is paid in case of extraordinary activities.

As result of a 80% pay-out of the Long Term Incentive Plan (LTIP) 2016, in March 2019, Mr Sekhri, Mr. Ernst, Mr. Ward, Mr Egberts and Mr. de Winter received shares in the Company (details of Supervisory Directors' shareholdings can be found in note 26.

The members of the Board of Supervisory Directors do participate in the Company's LTIP. No loans or other financial commitments were made to any member of the Board of Supervisory Directors on behalf of the Company.

In the opinion of the Board of Supervisory Directors, the independence requirements referred to in best practice provisions [2.1.7 to 2.1.9] inclusive have been fulfilled and all members regard themselves and their colleagues on the Board of Supervisory Directors as independent. Pharming does not require its Board of Supervisory Directors members to disclose any holdings in other listed and/or unlisted companies.

# Activities

The Board of Supervisory Directors met 9 times in 2018. The individual presence of the Supervisory Directors is reflected in the following schedule:

Date	5/6 March	23 March	28 March	16 May	23 May
EXTRA PARTICIPANTS	CEO/COO/ MR. M RIZZO, MR. B WEBBER (ORBIMED)	ceo/coo/ mr. m rizzo, mr. b webber (orbimed)	ceo*/coo*/ mr. m rizzo*, mr. b webber* (orbimed)	CEO*/COO*/ MR. M RIZZO*, MR. B WEBBER* (ORBIMED)	ceo/coo/ mr. m rizzo, mr. b webber (orbimed)
Mr. Ernst	Р	Р	<b>P</b> *	<b>P</b> *	Р
Mr. Ward	Р	Р	<b>P</b> *	<b>P</b> *	Р
Mr. De Winter	Р	Р	<b>P</b> *	<b>P</b> *	Р
Mr. Egberts	Р	Р	<b>P</b> *	<b>P</b> *	Р
Mr. Sekhri	Р	Р	<b>P</b> *	P*	р
Date	24/25 July	21 September	23/24 October	20 December	
Date EXTRA PARTICIPANTS	24/25 July ceo/coo/ mr. m rizzo, mr. b webber (orbimed)	21 September CEO*/COO*	23/24 October CEO/COO/ MR. M RIZZO, MR. B WEBBER (ORBIMED)	20 December CEO/COO/ MR. M RIZZO, MR. B WEBBER (ORBIMED	
EXTRA	CEO/COO/ MR. M RIZZO, MR. B WEBBER		CEO/COO/ MR. M RIZZO, MR. B WEBBER	CEO/COO/ MR. M RIZZO, MR. B WEBBER	
EXTRA PARTICIPANTS	ceo/coo/ mr. m rizzo, mr. b webber (orbimed)	сео*/соо*	ceo/coo/ mr. m rizzo, mr. b webber (orbimed)	ceo/coo/ mr. m rizzo, mr. b webber (orbimed	
extra participants Mr. Ernst	ceo/coo/ mr. m rizzo, mr. b webber (orbimed) P	сео*/соо* Р*	ceo/coo/ mr. m rizzo, mr. b webber (orbimed) P	ceo/coo/ mr. m rizzo, mr. b webber (orbimed P	
<b>EXTRA</b> <b>PARTICIPANTS</b> Mr. Ernst Mr. Ward	CEO/COO/ MR. M RIZZO, MR. B WEBBER (ORBIMED) P P	сео*/соо* Р* Р*	ceo/coo/ mr. m rizzo, mr. b webber (orbimed) P P	CEO/COO/ MR. M RIZZO, MR. B WEBBER (ORBIMED P P	

#### \* Joined by teleconference call

The Board of Management attended these meetings except when the composition, performance, remuneration of the Board of Management and the self-evaluation of the members of the Board of Supervisory Directors and its committees were discussed and voting took place.

As part of good governance, the Board of Supervisory Directors conducts a self-evaluation annually. These evaluations generally cover two parts; one part is the work of the Board of Supervisory Directors in relation to key objectives of the Company and the second part is the structure of the Board of Supervisory Directors to ensure that the members bring the correct skills and background knowledge for the benefit of the Company. The annual self-evaluation took place after the BOSD meeting of 20

December 2018 in the light of the changing emphasis of the activities of the company and the composition of the board as from 2019. The conclusions reached were that the balance of skills and experience in the Board of Supervisory Directors and in the Board of Management were appropriate and suitable to the needs of the Company at this time and the levels of information sharing and supervision were effective.

At the meetings of the Board of Supervisory Directors, the Company's financial and operational targets, strategy and accompanying risks, the latter always formulated in an appropriated Risk Assessment document, were extensively discussed. Amongst other topics, a considerable amount of time was spent on RUCONEST® discussing commercialisation, with a significant emphasis on the position in the US, and regulatory issues with regard to RUCONEST®, the competitive landscape, partnerships, licensing opportunities, refinancing of the Company, succession planning, corporate governance, the financial performance and structure of the Company, the targets for 2019 and the operational and financial risks to which the Company is exposed.

#### During its meetings, the Board of Supervisory Directors paid special attention to the following risks:

- The Company's progress on the achievement of objectives. There is no certainty that these objectives will actually be achieved:
- The Company is largely dependent on the success of one key product; RUCONEST® in one market, the US. In other markets, the execution of its commercialisation strategies and outcome of any registration process is uncertain and may be influenced by unpredictable events;
- The Company is active on a niche market for an orphan drug product with at least four competitors and with potentially another competitive entry within the coming 18 months;
- The timely development of the Company's products is dependent on the ability to attract and retain experienced commercial staff, particularly for its US operations and capital under attractive conditions.
- Pipeline development of other indications, products and production locations.

All these risks have been thoroughly discussed with the Board of Management and, where possible, actions have been undertaken to minimise the Company's exposure. Financial risks are actively monitored by the finance department, whose findings are discussed with the Board of Management on a monthly basis or more often if deemed necessary. The finance department also maintains a close working relationship with the company secretary to monitor other corporate and contractual risks. The risks are further described in the 'Corporate governance and risk management' chapter in this report. Due to the current size of the Company, there is no internal auditor function within the organisation.

# Audit Committee

The Audit Committee in 2018 consisted of Mr. De Winter (Chairman), Mr. Ernst, and Mr. Egberts.

During the four Audit Committee meetings held in 2018, the financial statements were discussed with a special emphasis on progress on sales revenues in the face of increased competition in some areas, as well as the impact of IFRS-related issues and a reorganisation of the Finance function in Europe and the USA. In addition, the external Auditor's audit plan 2018, its management letter and board report for the audit of the 2017 year end numbers were discussed. The main topics discussed related to revenue recognition, the valuation of inventories, and the impact of increased profitability both on timing differences leading to deferred tax assets or liabilities and on the likelihood of paying milestones to Bausch Health Companies Inc. and the effect on the contingent consideration. The audit committee also took a leading role in selecting a replacement auditor for Pricewaterhouse Coopers, who are obliged to resign as auditors after 10 years in office due to Dutch independence regulations. The new auditors will be Deloitte, who will be proposed at the Annual General Meeting in May 2019 for the approval of shareholders. Lastly, but importantly, the audit committee is satisfied that the internal controls and external audit processes are effective in managing risks across the company, and has made additional recommendations for alterations related to the changing nature of the organisation to improve the control environment further.

The quarterly financial statements, draft annual report and draft auditors Board Report and Management letter are circulated to the full Board of Supervisory Directors in advance of every relevant Audit Committee meeting.

The Board of Supervisory Directors, after a recommendation to that effect from the Audit Committee, has concluded that the Company does not yet require the establishment of an internal auditor function. The Board has assessed whether adequate alternative measures have been taken and will consider each year whether it is necessary to establish an internal audit department. In arriving at this conclusion, the Board took the following into consideration:

- Due to the size of the Company, Pharming has it created a specific position for an internal auditor but it has provided for the assessment and testing of the risk management and control systems to be supported by the Chief Financial Officer and external auditors.
- As a result of the Company operating in the highly regulated field of development and worldwide commercialisation of human medicines, the Company has a fully staffed Quality Assurance department which is responsible for, inter alia, maintaining, auditing and testing an extensive system of Standard Operating Procedures throughout the Company and for the execution of audits on all (major) suppliers, subcontractors, licensees and internal departments of the Company including the Finance department, although this is not exactly the same as an internal auditor function.
- The audit committee has reviewed the need for an internal auditor as at March 28, 2019. Based on this review, the Board of Supervisory Directors has recommended to the Management Board that due to the size of the company no internal auditor is needed at this point in time.
- The audit committee will reconsider this position annually and make recommendations to the Board of Supervisory Directors accordingly.
- The fast rate of growth of the Company at present may cause a different determination at some point in the foreseeable future.

Date	6 March	16 May	26 July	25 October
EXTRA PARTICIPANTS	CEO/COO/CFO/ STAFF/PWC/ MR.WARD/ MR.SEKHRI	CEO/COO/CFO/ STAFF/PWCPWC/ MR.WARD/ MR.SEKHRI	CEO/COO/CFO/ STAFF/PWCPWC/ MR.WARD/ MR.SEKHRI	CEO/COO/CFO/ STAFF/PWC*/ MR.WARD/ MR.SEKHRI
Mr. Ernst	Р	Р	Р	Р
Mr. De Winter	Р	Р	Р	Р
Mr. Egberts	р	Р	р	Р

PwC = PricewaterhouseCoopers Accountants N.V. \* Joined by teleconference call

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# Corporate Governance Committee

The Corporate Governance Committee consisted of Mr. Ward (Chairman), Mr. Ernst and Mr. De Winter. During 2014, it was decided to include Corporate Governance as a mandatory and separate topic during every meeting of the Board of Supervisory Directors, and this was continued during 2018. The Corporate Governance Committee did not meet outside the Board of Supervisory Directors meetings during 2018. The principal focus of meetings during 2018 was the ramifications of the Dutch Corporate Governance Code, revised 8 December 2016 and passed into law on 7 September 2017 into Pharming's company practices.

# Remuneration committee

A report of the Remuneration Committee can be found on pages 68-74 of this annual report

# **Financial Statements**

The Financial statements of Pharming Group N.V. for 2018, as presented by the Board of Management, have been audited by PricewaterhouseCoopers Accountants N.V. Their report is included in this Annual Report on pages 150-158.

The Financial statements were unanimously approved by the Board of Supervisory Directors and the Board of Management has signed these Statements.

The Board of Supervisory Directors recommends the Annual General Meeting of shareholders to adopt the 2018 Financial statements and to discharge the Board of Management and the Board of Supervisory Directors from liability for their management and supervisory activities on behalf of the Company.

Leiden, 28 March 2019 The Board of Supervisory Directors *"There needs to be more than just a scientific challenge*"

# Testimonial: Chantal

I joined Pharming four years ago and am currently Director of Analytical Development in the Research and Development department. I'm responsible for the development of new analytical assays for our pipeline products, I also assist our Quality Control department in assay trouble shooting and assay improvements to maintain the highest level of quality and safety of Ruconest. The technology platform we use requires not only skilled people and state of the art equipment, but also creativity to develop the assays and characterisation of the product we need. It's a team effort



within our R&D department but also beyond. Pharming offers me a dynamic environment with the possibility to develop myself. Although the company has grown substantially since the moment I joined, it still feels like a place where I'm considered as an individual and not a number.

What is most important to me is that my work has a purpose. There needs to be more than just a scientific challenge. I am grateful to be able to contribute to improve patients' quality of life.

# **REPORT OF THE REMUNERATION COMMITTEE**

The Remuneration Committee proposes the remuneration policy to the Board of Supervisory Directors as well as the remuneration of the individual members of the Board of Management. The policy includes the remuneration structure, defining the amount of fixed remuneration, shares and/or options to be granted and the variable benefits, pension rights, severance pay and other forms of compensation.

The Remuneration Committee also prepares the remuneration report that accounts for the implementation of the remuneration policy over the past financial year. It includes an overview of the remuneration policy for the next financial year and subsequent years, both in accordance with the Company's current Board of Supervisory Directors Regulations and Remuneration Committee Regulations.

The objectives of the remuneration policy are to attract, motivate and retain good management by means of a competitive policy linked to the Company objectives and the overall performance of the Board of Management and to create a long-term relationship with the Company. The Remuneration Committee recognises that the Company is increasingly competing in an international environment. The policy and its implementation are reviewed by the Remuneration Committee at least annually.

# 2018 Remuneration policy and structure

The remuneration policy for 2018 was a continuation of the 2017, 2016, 2015 and 2014 policy and was approved in the Annual General Meeting of June 2014. Scenarios were tested during the year to ensure that the policy remains competitive and fair, and further benchmarking was performed in the foruth quarter as described below.

#### The main items of this policy are:

The remuneration of each member of the Board of Management consists of a fixed salary, an annual bonus as a percentage of the fixed component, short- or long-term incentives by way of shares and/or options to shares in the Company and benefits in kind such as health insurance and participation in a pension plan, as further specified in note

24 to the Financial Statements. In general, employment contracts or management contracts, with members of the Board of Management, provide for annual bonuses based on personal and/or extraordinary performance and/or the achievement of predetermined objectives. These contracts have included provisions for an individual target bonus in cash or shares of 60% (for the CEO) and 50% for the other member(s) of the gross annual salary (including holiday allowance). Other benefits, such as health insurance and pension schemes are in accordance with the applicable staff manual of the Company. Severance pay cannot exceed the member's gross annual salary. The notice period for each member is two months;

 Members of the Board of Management as well as other key individuals are eligible to participate in the Company's Long Term Incentive Plan (LTIP). Under the plan, participants receive shares in the Company, the number of which is dependent upon the performance of the Company share price, during a three-year period, compared to a peer group of European biotech companies (see page 73-74).

# Meetings and composition

During the 2018 financial year the Remuneration Committee consisted of Mr. Ward (Chairman), Mr. Blaak (until his resignation at the AGM in May 2018) and Mr. Ernst. Following the resignation of Mr. Blaak, the committee was, towards yearend, extended with Mr. Jan Egberts and subject to the election to the Supervisory Board of Ms. Deb Jorn, it was decided that Ms. Jorn will take the Chair of the committee from the May 2019 AGM onwards. The Remuneration Committee met twice in 2018. The individual presence of its Members is reflected in the following schedule:

During 2018, the Remuneration Committee comprised of the following members:				
Date of Meeting	January 09	December 20		
Mr Jaap Blaak	Р			
Mr Jurgen Ernst	Р	Р		
Mr Barrie Ward	Р	Р		
Mr Jan Egberts		Р		
Other participants	CEO/Mr de Winter	CEO/Mr de Winter, Mr Sehkri		

During these meetings the performance of the Board of Management in general and its individual members in particular were reviewed and discussed relative to pre-agreed targets and to define targets for the coming year. The remuneration packages, the commissioning of two benchmark studies by independent third parties to design a new long-term incentive plan and an assessment of achievements against the 2018 objectives were also discussed and agreed in the last meeting.

# Remuneration report 2018

In 2014, following the recommendations of the Remuneration Committee, the Board of Supervisory Directors decided to grant 19,200,000 share options to the Board of Management; (12,000,000 options to Mr. de Vries and 7,200,000 options to Mr. Giannetti). These options vest in five equal tranches on 31 January of 2015 2016, 2017, 2018 and 2019, as outlined below under the terms and conditions of the Board of Management Option Plan (as approved by the AGM on 18 June 2014), in line with the achievement of targets for the Board of Management.

The exercise price of these options, on a tranche by tranche basis, shall be equal to the VWAP measured over the 20 trading days prior to the date of the Annual General Meeting. For the fifth tranche of 3,840,000 (2,400,000 options for Mr. de Vries and 1,440,000 options for Mr. Giannetti) and also for the third tranche of 1,000,000 options for Mr. Wright, this resulted in a strike price of €1.382; being the VWAP measured over the 20 trading days prior to 23 May 2018. The share options will expire on 17 June 2019 for Mr. de Vries and Mr. Giannetti and on 25 May 2021 for Mr. Wright.

The Remuneration Committee carefully reviewed the performance of the Board of Management against both the corporate and personal objectives that had been set for 2018. In addition, the Remuneration Committee considered the pay ratios within the company and how these compare with the peer group companies.

For 2018, the pay ratio between the compensation of the CEO and the mean compensation of employees (excluding the CEO) was 7.49 to 1 (2017: 8.63 to 1). Compensation in each case comprises all salary, bonus, share-based compensation in cash or in kind and pension contributions.

The Remuneration Committee recommended and the Board of Supervisory Directors agreed that the Board of Management had met their pre-set corporate and personal objectives set for 2018 to a great extent and contributed to positioning the Company solidly for the future in particular by the following accomplishments.

- Achievement of the agreed Operating Profit and year-end cash balance by a combination of cost control and timing of implementation of R&D investments, balanced by strong revenue growth
- De-risking of the Company by broadening the territorial and indication revenue base for RUCONEST® and/ or acquisition of new assets for development and/ or leveraging of US/EU commercialisation infrastructure.
- Expansion of manufacturing capacity to meet future demands
- Driving shareholders' long-term returns by limiting (future) dilution, improving shareholder base and increase investor awareness

During 2018, the continued execution of direct commercialisation in the US, initiated in December 2016 and planned extension of EU commercialisation led to consistently increasing operational profitability and to the Company achieving net profitability for the first time in its history. In addition, the commercialisation generated significant amounts of excess cash, despite investments in increasing R&D activities and contractual amortisation payments of \$16.7 million on the \$100 million Orbimed loan.

These achievements, in combination with also meeting some of the other corporate objectives, led the Remuneration Committee to conclude that the Corporate Objectives were achieved to a considerable extent. The Remuneration Committee therefore recommended a pay-out percentage of 73% of the maximum for the 2018 bonus for all members of the Board of Management, which was confirmed by the Board of Supervisory Directors.

Following the recommendations of the Remuneration Committee, the Board of Supervisory Directors decided to pay out all of the bonus in cash.

A detailed overview of the compensation of the members of the Board of Management can be found in note 25 of this Annual Report.

The individual remuneration of the members of the Board of Management was reviewed and it was decided that, taking into account their individual performance and market developments and the timing of the previous review (06 Jan 2018), the Committee recommended and the Board of Supervisory Directors agreed, to increase the base salaries of all three members of the Board of Management by 3.5% from 01 January 2019.

# Remuneration policy 2019 and the future

To continue to be able to attract and retain top talent in a competitive and global environment and to focus management and staff on creation of sustainable added value, total compensation continues to be significantly driven by variable performance dependent income components and continues to be maintained in line with industry standards of companies at a comparable stage of development.

For 2019, the Remuneration Committee will continue to implement the compensation policy as approved at the 2014 AGM. All remuneration elements described below are consistent with and covered by the current compensation policy.

- Fixed salary determined by the Board of Supervisory Directors.
- Target bonus in cash and/ or shares percentage to be adopted

In accordance with the compensation policy approved at the 2014 AGM, with the development of the Company now having achieved net profitability, the basis for the annual cash bonus for 2019 and going forward shall remain unchanged:

- CEO: to a target of 60% of annual salary.
- Other Board of Management members: to a target of 50% of annual salary.

The issuance of any share-based bonus component for the cash bonus 2019 shall be valued at the VWAP measured over the 20 trading days prior to 31 January 2020. Payment of the bonus remains dependent on the achievement of pre-defined milestones, which are a combination of corporate and personal milestones.

Proposals on the potential award of a bonus, achievement of milestones and an increase of fixed salary is made by the Remuneration Committee towards the end of the year and formally approved by the Board of Supervisory Directors in the first meeting of the next year but in any case prior to or on the date of approval of the Annual Report.

The Board of Supervisory Directors has defined a mix of corporate and personal milestones that will be used to measure performance and potential award of bonus payments for 2019.

The main corporate objectives for 2019 for the Board of Management can be summarised as follows:

- Achievement of the agreed Operating Results targets and year-end cash balance targets by a combination of cost control and timing of implementation of R&D investments, balanced by actual revenue growth.
- De-risking of the Company by broadening the territorial and indication revenue base for RUCONEST® and/ or acquisition of new assets for development and/ or leveraging of US/EU commercialisation infrastructure
- Build the C1 inhibitor franchise by progressing the development of C1 inhibitor in indications beyond acute HAE attacks;
- Developing the current pipeline projects according to rational plans aimed at providing the best chance of apprial and comercial success;
- Driving shareholders' long-term returns, increase investor awareness and improving the shareholder base.

For competitive reasons further details of these milestones and the personal milestones are not publicly disclosed.

#### SHARE OPTIONS DEPENDENT ON **DEFINED PARAMETERS.**

Since 2014, the Board of Management has been of the belief that, following a considerable period up to that date of significant dilution of the share capital necessary to maintain the operations, such highly dilutive financings for the purpose of ordinary spending should be avoided wherever possible going forward.

In the light of these expectations and in order to improve the longer-term alignment of interests of the shareholders and Board of Management, it was decided and approved by the Annual General Meeting at 18 June 2014, that share options should no longer be given annually but to grant share options in 2014 onwards to the Board of Management that will vest in equal tranches over a five-year period going forward. This implied that the approved 2014 option grants for the Board of Management are covering the period 2014-2018, with annual vesting of tranches as outlined below.

	Number of options Grant 2014 for period 2014-2018	
Mr.Sijmen de Vries	12,000,000	
	Annual vesting tranches	Status
	2,4000,00	Vested (strike price €0,505)
	2,400,000	Vested (strike price €0,341)
	2,400,000	Vested (strike price €0,209)
	2,400,000	Vested (strike price €0,335)
	2,400,000	Vested (strike price €1.382)
	Number of options Grant 2014 for period 2014-2018	
Mr.Bruno Giannetti	7,200,000	
	Annual vesting tranches	Status
	1,4400,00	Vested (strike price €0,505)
	1,4400,00	Vested (strike price €0,341)
	1,4400,00	Vested (strike price €0,209)
	1,4400,00	Vested (strike price €0,335)
	1,4400,00	Vested (strike price €1.382)
	Number of options Grant 2015 for period 2015	
	Award	Status
Ir.Robin Wright	1,000,0000	Vested (strike price €0.355)
	Grant 2016 for period 2020	
Mr.Robin Wright	4,000,000	
	Annual vesting tranches	Status
	1,0000,00	Vested (strike price €0,209)
	1,000,000	Vested (strike price €0,335)
	1,000,000	Vested (strike price €1.382)
	1,000,000	In service at 31 January 2020

	Number of options Grant 2014 for period 2014-2018	
Mr.Sijmen de Vries	12,000,000	
	Annual vesting tranches	Status
	2,4000,00	Vested (strike price €0,505)
	2,400,000	Vested (strike price €0,341)
	2,400,000	Vested (strike price €0,209)
	2,400,000	Vested (strike price €0,335)
	2,400,000	Vested (strike price €1.382)
	Number of options	
	Number of options Grant 2014 for period 2014-2018	
Mr.Bruno Giannetti	7,200,000	
	Annual vesting tranches	Status
	1,4400,00	Vested (strike price €0,505)
	1,4400,00	Vested (strike price €0,341)
	1,4400,00	Vested (strike price €0,209)
	1,4400,00	Vested (strike price €0,335)
	1,4400,00	Vested (strike price €1.382)
	Number of options Grant 2015 for period 2015	
	Award	Status
Mr.Robin Wright	1,000,0000	Vested (strike price €0.355)
	Grant 2016 for period 2020	
Mr.Robin Wright	4,000,000	
	Annual vesting tranches	Status
	1,0000,00	Vested (strike price €0,209)
	1,000,000	Vested (strike price €0,335)
	1,000,000	Vested (strike price €1.382)
	1,000,000	In service at 31 January 2020

	Number of options Grant 2014 for period 2014-2018	
Mr.Sijmen de Vries	12,000,000	
	Annual vesting tranches	Status
	2,4000,00	Vested (strike price €0,505)
	2,400,000	Vested (strike price €0,341)
	2,400,000	Vested (strike price €0,209)
	2,400,000	Vested (strike price €0,335)
	2,400,000	Vested (strike price €1.382)
	Number of options Grant 2014 for period 2014-2018	
Mr.Bruno Giannetti	7,200,000	
	Annual vesting tranches	Status
	1,4400,00	Vested (strike price €0,505)
	1,4400,00	Vested (strike price €0,341)
	1,4400,00	Vested (strike price €0,209)
	1,4400,00	Vested (strike price €0,335)
	1,4400,00	Vested (strike price €1.382)
	Number of options Grant 2015 for period 2015	
	Award	Status
Mr.Robin Wright	1,000,0000	Vested (strike price €0.355)
	Grant 2016 for period 2020	
Mr.Robin Wright	4,000,000	
	Annual vesting tranches	Status
	1,0000,00	Vested (strike price €0,209)
	1,000,000	Vested (strike price €0,335)
	1,000,000	Vested (strike price €1.382)
	1,000,000	In service at 31 January 2020

With the election of Mr. Robin Wright to the Board of Management at the EGM held on 28 October 2015, 1,000,000 options were granted to Mr. Wright with a strike price of €0.355 (being the 20 day VWAP prior to 28 October 2015). In addition, a further 4,000,000 options were granted to Mr. Wright by the Annual General Meeting at 25 May 2016.

Description of the approved option grants and awards, covering the financial years 2014-2018 and the division of the annually vesting tranches to the Board of Management:

# **BOARD OF MANAGEMENT GRANTED SHARE OPTIONS**

All options granted in 2014 to Mr Bruno Giannetti and Mr. Sijmen de Vries have now vested on 31 January 2019. The strike price of the 2019 remaining share option grant for Mr. Robin Wright, being the fourth tranche of 1,000,000 options for Mr Robin Wright) and new options to be granted to Mr. Sijmen de Vries and Mr. Bruno Giannetti, subject to approval of the Annual General Meeting of Shareholders shall be equal to the VWAP measured over the 20 trading days prior to the date of the Annual General Meeting of Shareholders (22 May 2019).

# **BENCHMARK STUDIES TO DETERMINE** FORMAT AND AGGREGATE SIZE OF **EMPLOYEE OPTION GRANTS AND SIZE OF BOARD OF MANAGEMENT OPTION GRANTS** Following the issuing of the 2018 option grants to staff, the Company had no significant head-room available to issue future stock option grants, as the stock option pool of 10% of the Company's fully diluted equity which was granted at the AGM in 2006 is almost depleted.

Therefore, towards the end of 2018, the Company commissioned two benchmark studies with independent third parties specialised in the field of remuneration practices in the pharmaceutical and biotech industry to be able to decide what would constitute (i) an appropriate amount of equity to have (annually) available for granting stock options to staff and (ii) how to best structure such vehicle and (iii) determine appropriate stock option grant levels for the Board of Management. All of this, taking into consideration, the Company's size and (multinational) complexity, including the fact that a majority of staff eligible for options are employed in the Company's US subsidiary, and the Company's stage of (commercial) development.

Following results from the two above-mentioned independent benchmark studies, it was recommended by the Remuneration Committee and approved by the Supervisory Board, that no request for the approval of a new fixed staff option pool would be submitted to the AGM.

Instead, a specific amount of equity that can be used for granting staff options in that year will be proposed for approval each year by the AGM. This practice is consistent with industry standards and appropriate for the Company's complexity and (commercial) stage of development and will allow the Company to offer its eligible staff a competitive annual equity incentive.

In accordance with this decision of the Supervisory Board, the Company will seek approval from shareholders at the Annual General Meeting on 22 May 2019 for authority to grant up to 2.8% of its outstanding share capital, equating to 17,400,000 stock options in total, during 2019 to its staff.

# **BOARD OF MANAGEMENT 2019 OPTION** GRANTS

With regards to new share option grants for Mr. Bruno Giannetti and Mr. Sijmen de Vries, following recommendations by the Remuneration Committee, the Supervisory Board determined that, for 2019, the Company will return to its previous practice of annual stock option grants which vest when the respective Directors continue to be in service on 31 January of the year following the grant.

For 2019, the following grants will be proposed for approval by the Annual General Meeting of Shareholders on 22 May 2019.

Mr. Sijmen de Vries; 2,800,000 options and Mr. Bruno Giannetti; 1,600,000 options.

In line with Dutch Corporate Code, Mr. de Vries and Mr. Giannetti will commit not to exercise any of the options within 36 months of granting.

In the event of a change of control of the Company becoming irrevocable all granted but unvested options will vest immediately. In case of an event resulting in a change of control or in case of the announcement of a (contemplated) public offer the share in the Company, The Board of Supervisory Directors can decide that the Company shall settle the options for the Board of Management in cash.

# The Long Term Incentive Plan (LTIP)

Under this LTIP, restricted shares are granted conditionally to the Board of Management and certain eligible managers each year with a target value of 30% of annual salary.

These shares will vest after three years provided that the share price has increased above certain thresholds (i.e. increased total shareholder value). The number of shares vested will be based on the relative performance of the share price compared to an initial group of 25 other European Small Cap (<€1

Billion) listed companies active in Life Sciences over the preceding 36 months. The reference group consists of the following companies:

COUNTRY	NUMBER	COMPANY
Belgium	1	Galapagos
Denmark	4	Bavarian Nordic, Neurosearch, Veloxis Pharmaceuticals, Genmab
France	5	Cellectis, Eurobio Scientific, Hybrigenics, Innate Pharma, Transgene
Germany	4	Evotec, Medigene, Morphosys, Heidelberg Pharma
Italy	1	Newron Pharmaceuticals
Norway	1	Photocure
Sweden	1	Medivir
Switzerland	4	Addex Therapeutics, Basilea Pharmaceutica, Kuros Biosciences, Santhera Pharmaceuticals
United Kingdom	5	Allergy Therapeutics, GW Pharmaceuticals, ImmuPharma, Oxford Biomedica, Premier Veterinary Group
TOTAL excluding Pharming Group	26	

The thresholds and payout percentages are given by the following table:

ACHIEVEMENT LEVEL	% OF GRANT ATTAINED
5% of the index:	100%
5-10% of the index:	80% of maximum
10-20% of the index:	60% of maximum
20-30% of the index:	50% of maximum
30-50% of the index:	20% of maximum
Lowe than 50% index:	0%

# LTIP 2016 EXPIRED WITH A 80% PAY-OUT

At 1 January 2019, after three years of the three-year period of the 2016 LTIP, the Pharming share price increased from €0.282, the closing price at 31 December 2015, to €0.757, the closing price at 31 December 2018. With this result, compared to the reference group, Pharming reached a rank of 2 out of 27 (including Pharming), which translates into a score more than 90% but less than 95% from the top of the reference group. As a result, 80% of the maximum allocated shares have vested and were issued to the LTIP participants.

The allocations under the 2017 and 2018 LTIP still have one and two years respectively to run. The minimum share prices (hurdles) for the 2017 and 2018 allocations to qualify for (part-)vesting, subject to meeting the relative performance criteria as outlined above, are: (1)  $\in 0.217$ , being the closing price at 31 December 2016 for the LTIP 2017 and  $(2) \in 1.13$ , being the closing price at 31 December 2017 for the LTIP 2018.

# CORPORATE SOCIAL RESPONSIBILITY

# LTIP 2019

For 2019, the Board of Supervisory Directors, following the recommendation of the Remuneration Committee, has determined that the number of shares (calculated at the closing price of 31 December 2018 of  $\in$ 0.757) shall be equal to 30% of each of the Board of Management's 2019 base salaries.

# This results in the following allocations:

- Board of Management: Mr. Sijmen de Vries 201,050 shares, Mr. Bruno Giannetti 131,331 shares, Mr. Robin Wright 125,476 shares.
- Senior managers and key staff: For a selected group of senior managers and key staff, 2,000,000 shares are available. A maximum number of 35,000 shares per senior manager or key staff member can be allocated.
- The Annual General Meeting of 18 June 2014 approved the reinstallation of LTIP participation for members of the Board of Supervisory Directors. At the Annual General Meeting of 2019, the following allocations of LTIP shares will be proposed:
- Board of Supervisory Directors: Chairman 50,000 shares, Vice-Chairman and/or Board Committee Chairs 40,000 shares, other members 35,000 shares.

In the event of a change of control of the Company, becoming unconditional, all outstanding but unallocated LTIP share allocations will vest automatically and unconditionally. In case of an event resulting in a change of control or in case of the announcement of a proposed formal public offer for the shares in the Company, the Board of Supervisory Directors can decide to settle the allocated shares for the Board of Management and for the Board of Supervisory Directors in cash. The Notes to the Financial Statements contain further details with regard to the remuneration of the Board of Supervisory Directors and the Board of Management, as well as the Company's remuneration policy and pension schemes.

# Main Responsibilities:

# **PATIENT SAFETY**

Our highest priority is patient safety. By consistently reviewing and improving our processes we work to improve the quality of our product and the treatment our patients receive further. Our product and all our planned pharmaceutical products are produced and sold to the highest of regulatory standards to ensure safety and quality. In addition, our in-house Quality Assurance (QA) department conducts internal and external audits of manufacturing facilities, testing laboratories, suppliers of materials and service providers on a regular basis. These procedures have been implemented to monitor, control and improve the quality of our products continuously.

# **FAMILY VALUES**

We see our employees as the key drivers of success, and we actively encourage employee development and growth. In 2018 our headcount grew by 22%. We expanded our office in the USA, added new Dutch facilities and expanded our production capabilities. This growth has given us the opportunity to re-examine our processes and workflows, to take time to group together motivated and highly-intelligent people that adhere to our family values: Patient safety, ethical behaviour and honest, transparent communication. We have focused on learning and defining new roles, recognising and solving gaps or reorganising departments to tackle the issues that our growth presents.

## SUSTAINABLE CORPORATE CULTURE

Pharming aims to be an attractive employer and offers a safe and healthy, inclusive and engaging working environment focused on maintaining our values in everything that we do. We endeavour to carry out all business in a highly ethical, fair and honest manner. We stimulate and support our employees to actively pursue personal development goals and endeavour to offer opportunities for internal professional growth and promotions wherever and whenever possible. Our organisational structure allows for open communication. Our employees are encouraged to share their ideas and improvements with the Company's management. Our corporate culture programme is working on improving our interdepartmental communications and enabling us to align an international work force.

# PROVIDING SUSTAINABLE RETURN ON INVESTMENT

Economic sustainability is one of our top priorities after safety of our animals, people and patients. In order to provide a sustainable return on investment for our shareholders, we aim to innovate, become more efficient and increase value in every department. Our policy is to provide all stakeholders with timely, equal and simultaneous information regarding matters that may have an influence on our share price. One way that we are working towards this is by holding many non-deal road-shows, also across the Netherlands, including live group meetings and webinars in which we meet with our (retail) investors to provide clear explanations of our published information and to ensure their questions are answered.

> "Innovating for the future. Transforming the future for our patients"

# Ethical conduct

Pharming endeavours to carry out its business ethically and honestly, simultaneously considering the interests of all those who may be affected by its activities in any way. To achieve success, the members of the Board of Supervisory Directors, Board of Management and employees must comply with a number of behavioural standards, which have been stated in a set of general principles referred to as the Code of Conduct. Our current Code of Conduct has been in place across our business since 2013. It ensures our people across the world understand what is expected of them when acting in or on behalf of the Company. The Code of Conduct is available on the Company's website.

We take this ethical approach to all parts of the business. Everything from our primary research to our commercial activity in all markets is conducted from these good principles of fairness and honesty. For example, we distributed thousands of vials of RUCUNEST® in 2018 free to patients unable to pay for the drug, or who could not get adequate insurance, or who could not get insurance cover quickly enough and needed a supply of drug before their insurance was confirmed. This was increased slightly by patients who had been let down by their previous drug company or prophylaxis drug supplier during shortages of competitor products at the start of the year. These free vial supplies would have been worth approximately €28 million at full US prices.

'Safety First' is one of the highest priorities within our business strategy'

# Whistleblowers' procedure

Pharming's whistleblowers' policy can be found on the Company's website. This policy describes the internal reporting and investigation procedures for suspected irregularities pertaining to the general, operational and/ or financial activities in the Company. The whistleblowers' procedure applies to all Pharming entities in all countries. Pharming will not discharge, demote, suspend, threaten or harass any employee or consultant in the process of any lawful actions by the employee or consultant regarding good faith reporting of complaints or issues nor as a result of their participation in any related investigation.

# Health and safety

'Safety First' is our highest priority within our business strategy. We are therefore extremely proud that the accident frequency rate within our Company continued at zero accidents and zero near-miss events in 2018. This is the result of strong enforcement of existing safety standards and procedures, improved implementation of accident investigation recommendations and good practice management. Safety is continuously monitored in everything we do. For that reason, we pay great attention to education and information on all aspects of safety.

# Animal Care Code of Conduct and welfare policy

Pharming's transgenic platform technology involves animals who only comply when treated extremely well, and therefore animal safety and welfare is of paramount importance. Pharming produces products in specific non-invasive animal systems, such as in the milk of transgenic mammals. Pharming's current specific human protein products are purified from this milk, which has so far provided products suitable and safe for human use but without causing any distress of any kind to the animals. Pharming has a strict Animal Care Code of Conduct in place, which enforces the strict regulatory control of all transgenic materials and animals with special regard to the environment and particularly the continuous wellbeing of our animals.

Our Animal Care Code of Conduct emphasises the importance of carrying out our activities with transgenic animals in a consistent and safe manner, and in conformity with the laws and regulations in force in the countries of operation.

Special attention is given to the strict separation of transgenic and non-transgenic materials and animals. In addition, the Company follows strict procedures to prevent the prohibited release of transgenic animals, their semen or any other reproductive transgenic material into nature. Pharming is largely dependent on its transgenic animals and values animal health and welfare very highly. The Company has an animal welfare policy, which ensures that Pharming

will not develop products with adverse effects on animal health and welfare in either use or production. Accordingly, Pharming carefully and continuously monitors the health and welfare of its animals.

# "We endeavour to carry out all business in a highly ethical, fair and honest matter."

# Environment and traceability of supply chain

As a biotechnology company that manufactures and develops biopharmaceuticals, Pharming complies with the applicable environmental rules and regulations. The entire supply chain, from animal feed and animal waste products and from milk to the finished pharmaceutical product, is covered by our highly-detailed and fully cGMP-compliant (industry standard) quality systems which are constantly observed and tested.

Suppliers and contractors are audited on a regular basis. All elements of our operations are inspected by various specialised governmental agencies on a regular basis. In accordance with the international biopharmaceutical regulations, the entire supply chain is fully traceable. Our staff are highly trained and regularly requalified for compliance with the total quality system in our entire supply chain.

# Human capital

Pharming places confidence in its employees as the most essential resource as well as vital stakeholders in our business. We continue to succeed only through the outstanding skill and commitment of our people. We are dedicated to attracting, developing and retaining the most talented employees within our field. Our human resource policies aim to engage employees with the necessary expertise, skill and knowledge, and also to cultivate a corporate culture of inclusion and diversity. We have already built a team of diverse international people and we see it as a priority to focus on the proper development of our Pharming family.

As our numbers grow, 22% in 2018 after 48.5% in 2017, we have invested in developing employee engagement. By reviewing our internal processes and assessing possible gaps, we are learning and defining new roles, innovating for the future of our company. Through open and transparent communication from the Board of Management and Executive Committee to the wider employee base, we have capitalised on our internal knowledge and experience to engage our global workforce by encouraging initiative, responsibility and communication. Our employees are unified under our corporate values of honesty, ethical behaviour and patient safety.

*"Family values:* Patient safety, ethical behaviour and honest transparent communication"

# Organisational Development

2018 allowed Pharming the chance to extend the scope of our capabilities. Our international team comprises offices in France, the UK, the US and Germany, with multiple production facilities and our headquarters in the Netherlands. Our company now incorporates the full business cycle from conceptual research through manufacturing of products to the marketed product, and we continue to grow. Throughout 2018, we have placed a greater emphasis on quality, efficiency and consistency in our organisation. We have created more structural efficiency and streamlined processes. We have added new facilities and subsidiaries for production and for specific research projects. As our organisation continues to grow, we will extend our new processes to improve performance further and to ensure high quality internal and external communication. Maintaining our high technical and ethical standard in international management, ensuring effective processes and active leadership, sometimes over long-distance, while simultaneously ensuring absolute compliance with rules and regulations in the various jurisdictions in Pharming activities, is the key driver in our organisation's development and will remain so in the future.

# Diversity and inclusion

Diversity and inclusion are essential to our company culture. A workforce diverse in, among other things, age, race, gender, nationality, sexual orientation, physical ability, thinking style and background enriches our work environments and helps to ensure our long term success. With operations and stakeholders all over the world, we see cultural diversity as a strength. We strive to ensure there are equal opportunities for all. In 2018, we had 20 different nationalities amongst our employees. Also, the number of women in senior management positions is increasing.. This remains a point for attention. However, as a small and highly specialised organisation, Pharming is committed to recruiting and promoting employees on the basis of talent and ability, without negative or positive bias and irrespective of gender, nationality or age in the organisation. No reports of gender discrimination have ever been made.

#### **INTERNATIONAL COMPANY**

# **20 NATIONALITIES**



There are currently 20 nationalities working for Pharming

# 62% WOMEN - 38% MEN



There are currently 114 women and 69 men working for Pharming

# Employee statistics

At 31 December 2018, 183 people were employed (2017: 150). During 2018, the Company hired 44 new employees (2017: 66) and 11 employees left the Company (2017: 11). At the reporting date, we had grown further, to 194 employees.

The Company's business involves specific high-technology processes and requires the employment of highly skilled and motivated personnel. Therefore, it is important for Pharming to create an attractive work environment that retains and motivates a diverse range of personnel and at- tracts talent in a competitive and global marketplace. The turnover rate is relatively low (7.1%), and has no significant effect on the continuity of our business.

HEADCOUNT AT 31 DECEMBER
The Netherlands
France
Germany
United Kingdom
United States
TOTAL

HEADCOUNT AT 31 DECEMBER
General & Administration
Operations (Manufacturing)
Research & Development
Marketing & Sales
TOTAL

"As our staff numbers grow, 22% in 2018; we have invested in fostering employee engagement and alignment."

2018	2017
112	92
12	10
3	3
1	1
55	44

183

2018	2017	2016
52	24	13
42	61	40
37	29	34
52	36	14
183	150	101

150

# **INFORMATION FOR SHAREHOLDERS AND INVESTORS**

# GENERAL

Pharming's policy is to provide all shareholders and other parties with timely, equal and simultaneous information about matters that may influence the share price. In addition, we aim to explain our strategy, business developments and financial results.

We communicate with our shareholders and investors through the publication of the annual report, meetings of shareholders, press releases, online webinars and our website. Pharming organises analysts and press meetings and/or conference calls or webinars, when presenting half year and annual financial results or other significant news. These meetings and/or conference calls are announced in advance by means of press releases and on pharming's website. Audio and/or web casts of these conference calls and corporate presentations are made available on the website after the meetings.

In addition to the scheduled half-yearly and yearly result presentations, we maintain regular contact with financial analysts and institutional investors through meetings and road shows. The company is regularly present at conferences and corporate and scientific presentations are made available at the company's website.

Activities for shareholders and investors included:

- A full presentation of our annual results to financial journalists and analysts, including audio commentary, Q&A sessions and posting on our website;
- Various additional webinars and conference calls with analysts, investors and providers of finance;
- Regular road show meetings with potential and existing shareholders and sell side analysts;
- Regional meetings with groups of existing shareholders in the Netherlands to explain public announcements or results; and
- Timely updates in the investor relations section of our website.

# SHARE INFORMATION

Pharming Group N.V.'s shares have been listed on Euronext Amsterdam (symbol: PHARM) since 1999.

The shares (ISIN Code: NL0010391025) are only traded through the book-entry facilities of Euroclear Nederland. The address of Euroclear Nederland is: Herengracht 459-469, 1017 BS Amsterdam, the Netherlands.

ABN AMRO Bank N.V. is the paying agent with respect to the shares. The address of the paying agent is: ABN AMRO Bank N.V., Gustav Mahlerlaan 10, 1082 PP Amsterdam, the Netherlands

FINANCIAL CALENDAR 2019				
16 May	Publication of financial results for the first three months of 2019 at 07:00 CET			
22 May	Annual General Meeting of shareholders			
25 July	Publication of financial results for the first six months of 2019 at 07:00 CET			
24 October	Publication of financial results for the first nine months of 2019 at 07:00 CET			

# ANNUAL REPORT | FINANCIAL STATEMENTS 2018

# **CONSOLIDATED STATEMENT OF INCOME**

For the year ended 31 December

# REVENUES COSTS OF SALES **GROSS PROFIT OTHER INCOME** Research and development General and administrative Marketing and sales COSTS **OPERATING RESULT**

Fair value gain (loss) on revaluation derivatives \*

Other financial income

Other financial expenses \*

FINANCIAL INCOME AND EXPENSES

# **RESULT BEFORE INCOME TAX**

Income tax credit (expense)

NET RESULT FOR THE YEAR

ATTRIBUTABLE TO:

Owners of the parent

#### **TOTAL NET RESULT**

Basic earnings per share (€)

Fully-diluted earnings per share (€)

\* Prior year's financial statements have been restated, as disclosed in note 4

NOTES	2018	<b>2017</b> restated*
6	135,130	89,620
8	(22,180)	(12,445)
	112,950	77,175
7	684	790
	(28,882)	(18,657)
	(12,221)	(5,974)
	(34,539)	(31,422)
8	(75,642)	(56,053)
	37,992	21,912
9	(495)	(42,063)
10	18	5,228
10	(36,658)	(70,766)
	(37,135)	(107,601)
	857	(85,689)
11	24,136	9,442
	24,993	(76,247)
	24,993	(76,247)
	24,993	(76,247)
33	0.041	(0.152)
33	0.038	n/a

# **CONSOLIDATED STATEMENT OF COMPREHENSIVE INCOME**

For the year ended 31 December

amounts in € 'ooo	NOTES	2018	<b>2017</b> restated*
NET RESULT FOR THE YEAR		24,993	(76,247)
Currency translation differences	18	348	(998)
ITEMS THAT MAY BE SUBSEQUENTLY RECLASSIFIED TO PROFIT OR LOSS		348	(998)
OTHER COMPREHENSIVE INCOME (LOSS), NET OF TAX		348	(998)
TOTAL COMPREHENSIVE INCOME (LOSS) FOR THE YEAR		25,341	(77,245)
ATTRIBUTABLE TO:			
Owners of the parent		25,341	(77,245)

\* Prior year's financial statements have been restated, as disclosed in note 4

# **CONSOLIDATED BALANCE SHEET**

As at 31 December

#### **NON-CURRENT ASSETS**

Intangible assets

Property, plant and equipment

Long-term prepayments

Deferred tax assets

Restricted cash

**TOTAL NON-CURRENT ASSETS** 

#### CURRENT ASSETS

Inventories

Trade and other receivables

Cash and cash equivalents

**TOTAL CURRENT ASSETS** 

#### TOTAL ASSETS

### EQUITY

Share capital

Share premium \*

Legal reserves

Accumulated deficit \*

SHAREHOLDERS' EQUITY

#### **NON-CURRENT LIABILITIES**

Loans and borrowings \*

Deferred tax liabilities

Contract liabilities

Finance lease liabilities

Other financial liabilities

## **TOTAL NON-CURRENT LIABILITIES**

#### **CURRENT LIABILITIES**

Loans and borrowings \*

Contract liabilities

Derivative financial liabilities \*

Trade and other payables

Finance lease liabilities

Other financial liabilities

**TOTAL CURRENT LIABILITIES** 

TOTAL EQUITY AND LIABILITIES

\* Prior year's financial statements have been restated, as disclosed in note 4

NOTES	2018	<b>2017</b> restated*
12	52,435	56,631
13	8,402	8,234
14	2,006	2,296
29	35,082	9,442
15	1,204	1,336
	99,129	77,939
16	17,315	18,334
17	17,814	11,260
15	80,311	58,657
	115,440	88,251
	214,569	166,190
	6,215	5,790
	387,525	363,818
	1,647	(938)
	(333,636)	(352,560)
18	61,751	16,110
19	37,267	59,161
29	87	-
20	667	1,467
21	164	390
30	32,034	28,319
	70,219	89,337
19	35,235	22,398
20	800	804
22	228	10,080
23	28,589	27,198
21	263	263
30	17,484	-
	82,599	60,743
	214,569	166,190

The notes are an integral part of these financial statements

# CONSOLIDATED STATEMENT OF CHANGES IN EQUITY

For the year ended 31 December
--------------------------------

Attributable to owners of the parent

amounts in € 'ooo	NOTES	NUMBER OF SHARES (IN '000)	SHARE CAPITAL	SHARE PREMIUM
BALANCE AT 1 JANUARY 2017		455,587	4,556	301,876
Result for the year			-	-
Other comprehensive income (loss) for the year			-	-
TOTAL COMPREHENSIVE INCOME (LOSS) FOR THE YEAR			-	-
Share-based compensation	18,24	-	-	-
Bonuses settled in shares	18	909	9	246
Shares issued for cash/ conversion of bonds	18	63,477	635	50,274
Warrants exercised/ issued	18,27	58,123	581	17,657
Options exercised	18	919	9	167
TOTAL TRANSACTIONS WITH OWNERS, RECOGNISED DIRECTLY IN EQUITY		123,428	1,234	68,344
BALANCE AT 31 DECEMBER 2017		579,015	5,790	370,220
Restatement		-	-	(6,402)
BALANCE AT 31 DECEMBER 2017 AFTER RESTATEMENT		579,015	5,790	363,818
Result for the year			-	-
Other comprehensive income (loss) for the year			-	-
TOTAL COMPREHENSIVE INCOME (LOSS) FOR THE YEAR			-	-
Legal reserves development expenses	18		-	-
Share-based compensation	18,24	-	-	-
Bonuses settled in shares	18	1,625	16	1,284
Shares issued for cash/ conversion of bonds	18	2,746	28	3,117
Warrants exercised/issued	18,27	11,122	111	6,031
Options exercised	18	26,993	270	13,275
TOTAL TRANSACTIONS WITH OWNERS, RECOGNISED DIRECTLY IN EQUITY		42,486	425	23,707
BALANCE AT 31 DECEMBER 2018		621,501	6,215	387,525

BALANCE AT 1 JANUARY 2017
Result for the year
Other comprehensive income (loss) for the year
TOTAL COMPREHENSIVE INCOME (LOSS) FOR T
Share-based compensation
Bonuses settled in shares
Shares issued for cash/ conversion of bonds
Warrants exercised/ issued
Options exercised
TOTAL TRANSACTIONS WITH OWNERS, RECOGI
BALANCE AT 31 DECEMBER 2017
Restatement
BALANCE AT 31 DECEMBER 2017 AFTER RESTAT
BALANCE AT 31 DECEMBER 2017 AFTER RESTAT
Result for the year
Result for the year Other comprehensive income (loss) for the year
Result for the year Other comprehensive income (loss) for the year <b>TOTAL COMPREHENSIVE INCOME (LOSS) FOR T</b>
Result for the year Other comprehensive income (loss) for the year <b>TOTAL COMPREHENSIVE INCOME (LOSS) FOR T</b> Legal reserves development expenses
Result for the year Other comprehensive income (loss) for the year <b>TOTAL COMPREHENSIVE INCOME (LOSS) FOR T</b> Legal reserves development expenses Share-based compensation
Result for the year Other comprehensive income (loss) for the year <b>TOTAL COMPREHENSIVE INCOME (LOSS) FOR T</b> Legal reserves development expenses Share-based compensation Bonuses settled in shares
Result for the year Other comprehensive income (loss) for the year <b>TOTAL COMPREHENSIVE INCOME (LOSS) FOR T</b> Legal reserves development expenses Share-based compensation Bonuses settled in shares Shares issued for cash/ conversion of bonds

BALANCE AT 31 DECEMBER 2018

	NOTES	LEGAL RESERVES	ACCUMULATED DEFICIT	TOTAL EQUITY
		60	(279,025)	27,467
		-	(79,957)	(79,957)
		(998)	-	(998)
E YEAR		(998)	(79,957)	(80,955)
	18,24	-	2,712	2,712
	18	-	-	255
	18	-	-	50,909
	18,27	-	-	18,238
	18	-	-	176
SED		-	2,712	72,290

# Attributable to owners of the parent

		(938)	(356,270)	18,802
			3,710	(2,692)
MENT		(938)	(352,560)	16,110
		-	24,993	24,993
		348	-	348
E YEAR	2	348	24,993	25,341
	18	2,237	(2,237)	-
	18,24	-	3,889	3,889
	18	-	(1,964)	(664)
	18	-	-	3,145
	18,27	-	-	6,142
	18	-	(5,757)	7,788
SED		2,237	(6,069)	20,300
		1,647	(333,636)	61,751

# CONSOLIDATED STATEMENT OF CASH FLOWS

For the year ended 31 December

amounts in € 'ooo	NOTES	2018	2017
OPERATING RESULT		37,992	21,912
NON-CASH ADJUSTMENTS:			
Depreciation, amortisation, impairment	8	6,559	3,415
Accrued employee benefits	24	3,270	2,712
Release contract liabilities	6,20	(804)	(943)
OPERATING CASH FLOWS BEFORE CHANGES IN WORKING CAPITAL		47,017	27,096
CHANGES IN WORKING CAPITAL:			
Inventories	16	1,019	(393)
Trade and other receivables	17	(6,554)	(3,345)
Payables and other current liabilities	23	1,391	14,837
TOTAL CHANGES IN WORKING CAPITAL		(4,144)	11,099
Changes in non-current assets, liabilities and equity		(1,098)	15
CASH GENERATED FROM (USED IN) OPERATIONS BEFORE INTEREST AND TAXES		41,775	38,210
Interest received	10	18	3
Income taxes paid	11	(1,417)	
NET CASH FLOWS GENERATED FROM (USED IN) OPERATING ACTIVITIES		40,376	38,213
Capital expenditure for property, plant and equipment	13	(2,496)	(3,248)
Investment intangible assets	12	(1,273)	(2,797)
NET CASH FLOWS USED IN INVESTING ACTIVITIES		(3,769)	(6,045)
Proceeds of loans and borrowings	19	-	91,333
Payments of transaction fees and expenses	19	-	(3,352)
Repayment on loans and borrowings	19	(15,137)	(86,258)
Redemption bonds	19	(2,257)	(3,934)
Interests on loans	19	(11,063)	(7,877)
Proceeds of equity and warrants	18	10,496	6,833
NET CASH FLOWS GENERATED FROM (USED IN) FINANCING ACTIVITIES		(17,961)	(3,255)
INCREASE (DECREASE) OF CASH	15	18,646	28,913
Exchange rate effects	15	2,876	(1,057)
Cash and cash equivalents at 1 January	15	59,993	32,137
TOTAL CASH AND CASH EQUIVALENTS AT 31 DECEMBER		81,515	59,993

The notes are an integral part of these financial statements

# NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

# **1. CORPORATE INFORMATION**

The consolidated financial statements of Pharming Group N.V., Leiden for the year ended 31 December 2018 were authorised for issue in accordance with a resolution of the Board of Supervisory Directors on 28 March 2019. The financial statements are subject to adoption by the Annual General Meeting of shareholders, which has been scheduled for 22 May 2019.

Pharming Group N.V. is a limited liability public company, which is listed on Euronext Amsterdam ("PHARM"), with its headquarters and registered office located at:

# Darwinweg 24 2333 CR Leiden The Netherlands

Pharming Group N.V. is registered at the Chamber of Commerce in the Netherlands under number 28048592.

Pharming Group N.V. is the ultimate parent company of Pharming Group. A list of subsidiaries is provided in note 2.2.

Pharming is a specialty pharmaceutical company developing innovative products for the safe, effective treatment of rare diseases and unmet medical needs. Pharming's lead product, RUCONEST® (conestat alfa) is a recombinant human C1 esterase inhibitor approved for the treatment of acute Hereditary Angioedema ("HAE") attacks in patients in Europe, the US, Israel and South Korea. The product is available on a named-patient basis in other territories where it has not yet obtained marketing authorisation.

# 2. ACCOUNTING PRINCIPLES AND POLICIES

# 2.1 Basis of preparation

The consolidated financial statements of the Company have been prepared in accordance with International Financial Reporting Standards (IFRS) and IFRS interpretations committee (IFRS IC) interpretations applicable to companies reporting under IFRS as endorsed by the European Union and valid as of the balance sheet date. The consolidated financial statements have been prepared under the historical cost convention, unless otherwise stated. The preparation of financial statements in conformity with IFRS and book 2 title 9 of the Dutch Civil Code requires the use of certain critical accounting estimates. It also requires management to exercise its judgement in the process of applying the Company's accounting policies. The areas involving a higher degree of judgement or complexity, or areas where assumptions and estimates are significant to the consolidated financial statements are disclosed in note 2.4.

Two new standards and amendments have been applied for the first time for the reporting period starting at 1 January 2018: IFRS 9 Financial instruments and IFRS 15 Revenue from contracts with customers. The impact of adopting the new or amended IFRS standards are not material. Further information is presented in note 2.5.

These financial statements are presented in euros ( $\notin$ ) and rounded to the nearest thousand euro ( $\notin$ '000), unless otherwise stated.

# 2.2 Basis of consolidation

The consolidated financial statements include Pharming Group N.V. and its effectively controlled subsidiaries, after the elimination of all intercompany transactions and balances. Subsidiaries are consolidated from the date the acquirer obtains effective control until control ceases.

An entity is considered effectively controlled if the Company, directly or indirectly, has the power to govern the financial and operating policies of an entity so as to obtain benefits from its activities. Acquisitions of subsidiaries are accounted for using the acquisition method of accounting. The financial statements of the subsidiaries are prepared for the same reporting year as Pharming Group N.V., using the same accounting policies. Intercompany transactions, balances and unrealised gains and losses on transactions between group companies are eliminated.

Profit or loss and each component of other comprehensive income are attributed to the owners of the parent and to the non-controlling interests.

Total comprehensive income is attributed to the owners of the parent and to the non-controlling interests even if this results in the non-controlling interests having a deficit balance.

The following table provides an overview of the investments at 31 December 2018:

ENTITY	REGISTERED OFFICE	INVESTMENT %
Pharming B.V.	The Netherlands	100.0
Pharming Americas B.V.	The Netherlands	100.0
Pharming Intellectual Property B.V.	The Netherlands	100.0
Pharming Technologies B.V.	The Netherlands	100.0
Pharming Research & Development B.V. *	The Netherlands	100.0
Broekman Instituut B.V.	The Netherlands	100.0
Pharming Healthcare, Inc.	The United States	100.0
ProBio, Inc.	The United States	100.0

\* Pharming Research & Development B.V. has been established in December 2018 as a 100% subsidiary of Pharming Technologies B.V. Activities with respect to research and development for new products and new diseases have been transferred to this new entity. As a consequence the transaction has resulted in the renewal of past losses for which a deferred tax asset of €11.8 million has been recognised (see note 29).

# 2.3 Accounting principles and policies

# **Business combinations**

Business combinations are accounted for using the acquisition accounting method. Identifiable assets, liabilities and contingent liabilities acquired are measured at fair value at acquisition date. The consideration transferred is measured at fair value and includes the fair value of any contingent consideration. Where the consideration transferred exceeds the fair value of the net assets, liabilities and contingent liabilities acquired, the excess is recorded as goodwill. The costs of acquisition are recognised as an expense.

## **Foreign currency translation**

Items included in the financial statements of each of the Group's entities are measured using the currency of the primary economic environment in which the entity operates ('the functional currency'). The consolidated financial statements are presented in euros, which is the Company's functional and presentation currency. Non-monetary items that are measured in terms of historical cost in a foreign

currency are translated using the exchange rates as at the dates of the initial transactions. Monetary assets and liabilities denominated in foreign currencies are translated to the functional currency (generally euros) using exchange rates prevailing at the date of the transaction. Transactions executed in foreign currencies are translated at the exchange rate at the date of transaction.

The resulting transaction gains or losses are recognised in the statement of income. Assets and liabilities of foreign entities are translated to euros using year-end spot foreign exchange rates. The statements of income of foreign entities are translated at weighted average exchange rates for the year. The effects of translating these operations are taken directly to other comprehensive income within equity. On disposal of a foreign entity, the accumulated exchange difference is recognised in the statement of income as a component of the gain or loss on disposal. Until 2017 borrowings formed part of the net investment in Pharming Healthcare, Inc. From 2018 the Company has assessed that these borrowings form no longer part of the net investment as repayments are made. From 2018 the associated exchange rate differences are recognised through the statement of income.

The above-stated translation of foreign entities applies to the entity in the United States. The EUR/USD exchange rates applied at 31 December 2018 was 1.1439 (31 December 2017: 1.1977).

# Distinction between current and non-current

An asset is classified as current when it is expected to be realised (settled) within 12 months after the end of the reporting year. Liabilities are classified as current liabilities unless the Group has an unconditional right to defer settlement of the liability for at least 12 months after the end of the reporting year.

### Intangible assets

Intangible assets acquired separately are measured at historical cost. The cost of intangible assets acquired in a business combination is recognised and measured at fair value as at the date of acquisition. Following initial recognition, intangible assets are carried at cost less any accumulated amortisation and any accumulated impairment losses.

Intangible assets with finite lives are amortised over the useful life and assessed for impairment whenever there is an indication that the intangible assets may be impaired. Changes in the expected useful life, according the straightline method, or the expected pattern of consumption of future economic benefits embodied in the asset is accounted for by changing the amortisation period or method, as appropriate, and treated as changes in accounting estimates. The amortisation expense on intangible assets with finite lives is recognised in the statement of income in the relevant expense category consistent with the function of the intangible asset.

The remaining amortisation periods for intangible assets at 31 December 2018 are:

CATEGORY	DESCRIPTION	AMORTISATION PERIOD	
		TOTAL	REMAINING
Transgenic technology*	Patents and licenses	6 to 10 years	Not applicable
RUCONEST® for HAE (EU)	Development costs	10 years	2 years
ruconest® for HAE (US)	Re-acquired commercial rights	20 years	18 years
Development costs**	Development costs	Not yet in use	Not yet in use

\* Carrying value at 31 December 2018 of €nil

\*\* Regarding acquired assets for Pompe and Fabry's disease and internal generated assets for modifications of ruconest®

### Property, plant and equipment

Property, plant and equipment is stated at cost less accumulated depreciation charges and accumulated impairment charges. Generally, depreciation is calculated using a straight-line basis over the estimated useful life of the asset. The carrying values of property, plant and equipment are reviewed for impairment when events or changes in circumstances indicate that the carrying value may not be recoverable.

An item of property, plant and equipment is derecognised upon disposal or when no future economic benefits are expected from its use or disposal.

Any gain or loss arising on derecognizing of the asset (calculated as the difference between the net disposal proceeds and the carrying amount of the asset) is included in the statement of income in the year the asset is derecognised. Residual values, useful lives and depreciation methods are reviewed, and adjusted if appropriate, at each financial year-end.

All costs that are directly attributable to bringing an asset to the location and condition necessary for it to be capable of operating in the manner intended by management, will be capitalised. These costs include direct employee benefits, rent and testing costs. Capitalisation will be done until the asset is capable of operating in the manner intended by management.

# The depreciation periods for property, plant and equipment are:

CATEGORY	DEPRECIATION PERIOD
Land	Not depreciated
Land improvements	20 years
Operational facilities	10-20 years
Leasehold improvements	5-10 years
Manufacturing equipment*	5-10 years
Other property, plant & equipment	5-10 years

\* Depreciation charges for manufacturing equipment are based on actual use of the equipment involved, which is expected to take place in a period before technical expiration

# Impairment of assets

Assets that have an indefinite useful life and intangibles not vet available for use are not subject to amortisation and are tested annually for impairment. Assets that are subject to amortisation are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount may not be recoverable.

An impairment loss is recognised for the amount by which the asset's carrying amount exceeds its recoverable amount. The recoverable amount is the higher of an asset's fair value less costs to sell and value in use. For the purposes of assessing impairment, assets are grouped at the lowest levels for which there are separately identifiable cash flows. Non-financial assets that suffered impairment are reviewed for possible reversal of the impairment at each reporting date.

### Inventories

Inventories are stated at the lower of cost and net realisable value. The Company has three inventory categories:

- Finished goods: consists of batches of RUCONEST®. These batches comprise therapeutic product available for sales, clinical development and pre-clinical activities. Initial recognition is at cost, including raw materials used, external manufacturing and testing fees incurred to bring the product in a saleable or useable condition;
- Work in progress: semi-finished goods consisting of drug substance;
- Raw materials: consists of skimmed milk serving as a raw material for the batches of RUCONEST® and water for injection used in self-administration kits. Valuation per unit skimmed milk is based on the total costs of the rabbit facilities and the normal production levels.

Costs are determined using the first-in first-out (FIFO) method. Net realisable value is the estimated selling price in the ordinary course of business, less estimated costs of completion and the estimated costs necessary to make the sale, or, in case the products will be used for a clinical trial, the net realisable value is the reimbursement we expect to receive from partners in this trial. The costs of inventories are recognised as expense and included in costs of product sales if related to the sale of products. If related to the use in a clinical trial the expenses are included in the operating costs.

A provision is recognised for inventories if no future use or sale is expected before the expiration date or if product batches are expected not to be released due to quality issues.

### **Financial assets**

Financial assets are recognised when the Company becomes a party to the contractual provisions of a financial instrument. Financial assets are derecognised when the rights to receive cash flows from the financial assets expire, or if the Company transfers the financial asset to another party and does not retain control or substantially all risks and rewards of the asset. Purchases and sales of financial assets in the normal course of business are accounted for at settlement date (i.e., the date that the asset is delivered to or by the Company).

At initial recognition, the Company measures its financial assets at its fair value plus, in the case of a financial asset not at fair value through profit or loss, transaction costs that are directly attributable to the acquisition or issue of the financial asset.

After initial recognition, the Company classifies its financial assets as subsequently measured at either i) amortised cost, ii) fair value through other comprehensive income or iii) fair value through profit or loss on basis of both:

- The Company's business model for managing the financial assets:
- The contractual cash flow characteristics of the financial asset.

Subsequent to initial recognition, financial assets are measured as described below. At each balance sheet date, the Company assesses whether there is objective evidence that a financial asset or a group of financial assets is impaired and recognises a loss allowance for expected credit losses for financial assets measured at either amortised costs or at fair value through other comprehensive income. If, at the reporting date, the credit risk on financial instrument has not increased significantly since initial recognition, the Company measures the loss allowance for that financial instrument at an amount equal to 12 months of expected credit losses. If, at the reporting date, the credit risk on a financial instrument has increased significantly since initial recognition, the Company measures the loss allowance for the financial instrument at an amount equal to the lifetime expected credit losses.

## FINANCIAL ASSETS AT AMORTISED COST

Financial assets are measured at amortised cost if both i) the financial asset is held within a business model whose objective is to hold financial assets in order to collect contractual cash flows; and ii) the contractual terms of the financial asset give rise on specified dates to cash flows that are solely payments of principal and interest of on the principal amount outstanding.

A financial asset measured at amortised cost is initially recognised at fair value plus transaction cost directly attributable to the asset. After initial recognition, the carrying amount of the financial asset measured at amortised cost is determined using the effective interest method, less any impairment losses.

The Company's financial assets measured at amortised cost comprise trade and other receivables and cash and cash equivalents.

# FINANCIAL ASSETS AT FAIR VALUE THROUGH **OTHER COMPREHENSIVE INCOME**

A financial asset is measured at fair value through other comprehensive income if both i) the financial asset is held within a business model whose objective is achieved by collecting contractual cash flows and selling financial assets; and ii) the contractual terms of the financial asset give rise on specified dates to cash flows that are solely payments of principal and interest on the principal amount outstanding. The Company has no financial assets measured at fair value through other comprehensive income.

# FINANCIAL ASSETS AT FAIR VALUE THROUGH **PROFIT OR LOSS**

When any of the above-mentioned conditions for classification of financial assets are not met, a financial asset is classified as "at fair value through profit or loss" and measured at fair value with changes in fair value recognised in profit or loss.

A financial asset measured at fair value through profit or loss is recognised initially at fair value and its transaction cost is recognised in profit or loss when incurred. A gain or loss on a financial asset measured at fair value through profit or loss is recognised in the consolidated statement of income for the reporting period in which it arises.

The Company may, at initial recognition, irrevocably designate a financial asset as measured at fair value through profit or loss, if doing so eliminates or significantly reduces a measurement or recognition inconsistency that would otherwise arise from measuring assets or liabilities or recognising the gains and losses on them on different bases.

The Company's financial instruments measured at fair value through profit or loss comprise derivative financial liabilities.

# Trade and other receivables

Trade and other receivables are recognised initially at fair value. Subsequent measurement is at amortised cost using the effective interest method, less the expected credit loss. Trade receivables are amounts due from customers for goods sold in the ordinary course of business. They are generally due for settlement within 30 days and therefore are all classified as current. Due to the short-term nature of the current receivables, their carrying amount is considered to be the same as their fair value.

# **Cash and cash equivalents**

Cash and cash equivalents are defined as cash on hand, demand deposits and short-term, highly liquid investments (maturity less than 3 months) readily convertible to known amounts of cash and subject to insignificant risk of changes in value. Bank overdrafts are shown within borrowings in current liabilities on the statement of financial position. For the purpose of the statement of cash flow, cash and cash equivalents are net of outstanding bank overdrafts.

### Equity

The Company only has ordinary shares, and these are classified within equity upon issue. Shares transferred in relation to settlement of (convertible) debt and derivative financial liabilities are measured at fair value with fair value based on the closing price of the shares on the trading day prior to the settlement date. Equity is recognised upon the issue of fixed warrants with a fixed exercise price as well as upon the recognition of share-based payment expenses; shares issued upon exercise of such warrants or options are measured at their exercise price.

Transaction costs associated with an equity transaction are accounted for as a deduction from equity to the extent they are incremental costs directly attributable to the equity transaction that otherwise would have been avoided. Transaction costs related to the issue of a compound financial instrument are allocated to the liability and equity components of the instruments in proportion to the allocation of proceeds.

# **Financial liabilities and borrowings**

Financial liabilities are classified as either financial liabilities at fair value through profit or loss (derivative financial liabilities) or financial liabilities at amortised cost (borrowings and trade and other payables). All loans and borrowings are initially recognised at the fair value of the

consideration received less directly attributable transaction costs; transaction costs related to the issue of a compound financial instrument are allocated to the liability and equity components of the instruments in proportion to the allocation of proceeds. After initial recognition, interestbearing loans and borrowings are subsequently measured at amortised cost using the effective interest method.

Gains and losses are recognised in the statement of income when the liabilities are derecognised as well as through the amortisation process. Purchases and sales of financial liabilities are recognised using settlement date accounting.

A financial liability is derecognised when the obligation under the liability is discharged or cancelled or expired. Where an existing financial liability is replaced by another from the same lender on substantially different terms, or the terms of an existing liability are substantially modified, such an exchange or modification is treated as a derecognising of the original liability and the recognition of a new liability, and the difference in the respective carrying amounts is recognised in the statement of income.

# **Provisions**

Provisions are recognised when there is a present obligation (legal or constructive) as a result of a past event. It is probable that an outflow of resources embodying economic benefits will be required to settle the obligation and a reliable estimate of the obligation can be made. The expense relating to any provision is presented in the statement of income net of any reimbursement.

#### **Derivative financial liabilities**

Derivative financial liabilities are initially recognised at fair value and subsequently measured at fair value through profit or loss with changes in the fair value recognised in the statement of income as they arise.

# **Trade and other payables**

Trade and other payables are initially recognised at fair value. Subsequent measurement is at amortised cost using the effective interest method.

## **Revenue recognition**

The new standard IFRS 15 Revenues from contracts with customers is being adopted on the modified retrospective basis by the Company as at 1 January 2018. IFRS 15 did replace existing revenue recognition guidance in IFRS. It introduces a five-step model to determine when to recognise revenue and at what amount, based on transfer of control over goods or services to the customer:

- Identify the contract(s) with a customer; 1.
- 2. Identify the performance obligations in the contract; Performance obligations are promises in a contract to transfer to a customer goods or services that are distinct:
- 3. Determine the transaction price. The transaction price is the amount of consideration to which an entity expects to be entitled in exchange for transferring promised goods or services to a customer. If the consideration promised in a contract includes a variable amount, an entity must estimate the amount of consideration to which it expects to be entitled in exchange for transferring the promised goods or services to a customer;
- 4. Allocate the transaction price to each performance obligation on the basis of the relative stand-alone selling prices of each distinct good or service promised in the contract;
- 5. Recognise revenue when a performance obligation is satisfied by transferring a promised good or service to a customer (which is when the customer obtains control of that good or service). A performance obligation may be satisfied at a point in time (typically for promises to transfer goods to a customer) or over time (typically for promises to transfer services to a customer). For a performance obligation satisfied over time, an entity would select an appropriate measure of progress to determine how much revenue should be recognised as the performance obligation is satisfied.

All of the Group's revenue from contracts with customers is derived from delivery of goods, specifically vials of pharmaceutical products. The Group does not provide any services or equipment to its customers.

In accordance with IFRS 15, revenue will be recognised when the customer obtains control of the goods. For the Group's contracts the customer obtains control after shipment of the product, which arrives at the customer within a short time frame.

The vast majority of the Group's contracts for revenue with customers are subject to chargebacks, discounts and/ or rebates relating directly to customers or to ultimate reimbursement claims from government or insurance payers. These are accounted for on an estimated net basis, with any actual discounts and rebates used to refine the estimates in due course. These variable elements are deducted from revenue in the same period as the related sales are recorded. The Group received upfront payments for their European sales and distribution activities. These upfront payments

are considered as a single performance obligation together with the delivery of goods. They are initially recognised as a contract liability and released to the statement of income over time, in line with the terms of agreement with the distributor.

# **Costs of sales**

Costs of sales represent all production costs related to product sales, including production costs of the skimmed milk, external manufacturing costs and costs for product testing. The costs are measured at their actual costs based on FIFO and incurred to net realisable value if sales price is below actual costs.

# **Research and development costs**

Research expenditure is recognised as an expense in the period in which it is incurred. An intangible asset arising from development expenditure on an individual project is recognised only when the following criteria are met:

- The technical feasibility of completing the intangible asset so that it will be available for use or sale;
- Its intention to complete the asset, and to use or sell it;
- Its ability to use or sell the asset;
- The probability of future economic benefits;
- The availability of resources to complete the development;
- The ability to measure reliably the expenditure during the development.

Technical feasibility and ability to use or sell the asset are, in general, considered probable when the Company estimates that obtaining marketing approval is deemed likely.

Following the initial recognition of the development expenditure, the cost model is applied requiring the asset to be carried at cost less any accumulated amortisation and accumulated impairment losses.

Any expenditure capitalised is amortised over the period of expected useful life of the related patents. The carrying value of development costs is reviewed for impairment annually when the asset is not yet in use or more frequently when an indication of impairment arises during the reporting year.

# Other income

Pharming receives certain grants which support the Company's research efforts in defined research and development projects. These subsidies generally provide for reimbursement of approved costs incurred as defined in various grants. Subsidies are recognised if the Company can

demonstrate it has complied with all attached conditions and it is probable that the grant amount will be received.

The Company includes income from grant under other income in the statement of income in order to enable comparison of its statement of income with companies in the life sciences sector. Companies in this sector generally present governmental grants as income since these often are a significant source of income.

# Interest income

Interest income is recognised as interest accrues, using the effective interest method. For the purpose of the consolidated statement of cash flows, interest income derived from cash and cash equivalents have been presented as operating cash flows since the Company considers these interest items as the outcome of working capital management.

# **Operating costs**

Operating costs are expensed as incurred. Costs of research and development cover those activities that are carried out to gain new scientific or technical knowledge and understanding as well as the application of research findings or other knowledge to a plan or design for the production of new or substantially improved products. Costs of general and administrative nature apply to overhead expenses. Costs of marketing and sales relate to all expenses incurred to commercialise the product.

For the purpose of the consolidated statement of cash flows, interest income derived from cash and cash equivalents has been presented as operating cash flows since the Company considers this interest item as a result of working capital management.

## Short-term employee benefits

The Company does not provide any benefits based on financial measurement of the statement of income.

Liabilities for wages and salaries, including non-monetary benefits and accumulating sick leave that are expected to be settled wholly within 12 months after the end of the period in which the employees render the related service are recognised in respect of employees' services up to the end of the reporting period and are measured at the amounts expected to be paid when the liabilities are settled. The liabilities are presented as current employee benefit obligations in the balance sheet.

# Pension plan

For all Dutch employees, the Company participates in defined contribution pension plans with an independent insurance company. Defined contributions are expensed in the year in which the related employee services are rendered.

Employees in the United States are enabled to participate in a 401k plan, which also qualifies as a defined contribution plan. To become an eligible participant, an employee must complete 6 months of service and attain the age of 18 years. The employer matches 100% of the first 3% the employee contributes to their 401k plan and 50% of any amount over 3% up to 5%. Any employee contribution over 5% is not matched. Costs of the 401k plan are expensed in the year in which the related employee services are rendered.

# Share-based payment

The costs of option plans are measured by reference to the fair value of the options on the date on which the options are granted. The fair value is determined using the Black-Scholes model. The costs of these options are recognised in the income statement (share-based compensation) during the vesting period, together with a corresponding increase in equity (other reserves). Share-based payment charges do not affect liabilities or cash flows in the year of expense since all transactions are equity-settled.

Pharming's employee option plan states that an employee is entitled to exercise the vested options within five years after the date of the grant. The period in which the options become unconditional is defined as the vesting period.

## Long Term Incentive Plan

For a limited number of board members and officers, performance shares are granted free of charge. A maximum number of predetermined shares vest three years after the grant date, provided that the participant to the long-term incentive plan is still in service (continued employment condition), with actual shares to be transferred based on the relative achievement of Pharming's share price compared to a peer group. The maximum number of shares immediately vests upon a change of control.

The fair value is determined using Monte Carlo simulation. The costs of the LTIP are recognised in the income statement during the vesting period. The fair value at the grant date includes the market performance condition (relative total shareholder return performance) but excludes the three-year service condition.

# Leases

The determination of whether an arrangement is, or contains a lease is based on the substance of the arrangement and requires an assessment of whether the fulfilment of the arrangement is dependent on the use of a specific asset or assets and the arrangement conveys a right to use the asset.

Finance leases, which transfer to the Company substantially all the risks and benefits incidental to ownership of the leased item, are capitalised at the inception of the lease at the fair value of the leased property or, if lower, at the present value of the minimum lease payments. Lease payments are apportioned between the finance charges and reduction of the lease liability so as to achieve a constant rate of interest on the remaining balance of the liability. Finance charges are charged directly against the statement of income.

Lease agreements in which the lessor effectively retains substantially all the risks and benefits of ownership of the leased item, are classified as operating leases. Operating lease payments are recognised as an expense in the statement of income on a straight-line basis over the lease term.

#### Lease incentives

In certain lease agreements for property, plant and equipment, the lessor funds' assets in use and effectively controlled by the Company. Such constructions qualify as a 'lease incentive', in which case the Company fully capitalises the contribution of the lessor in property, plant and equipment with a corresponding increase in liabilities. The investment is depreciated in accordance with the accounting policies for property, plant and equipment, with the accrued lease incentive released to operational lease charges in the statement of income throughout the lease agreement period and on a straight-line basis.

#### Income tax

The income tax expense or credit for the period is the tax payable on the current period's taxable income based on the applicable income tax rate for each jurisdiction adjusted by changes in deferred tax assets and liabilities attributable to temporary differences and to unused tax losses.

The current income tax charge is calculated on the basis of the tax laws enacted or substantively enacted at the end of the reporting period in the countries where the company and its subsidiaries operate and generate taxable income. Management periodically evaluates positions taken in tax returns with respect to situations in which applicable tax regulation is subject to interpretation. It establishes provisions where

appropriate based on amounts expected to be paid to the tax authorities.

Deferred income tax is provided in full, using the liability method on temporary differences arising between the tax bases of assets and liabilities and their carrying amounts in the consolidated financial statements. Deferred income tax is determined using tax rates that have been enacted or substantially enacted by the end of the reporting period and are expected to apply when the related deferred income tax asset is realised, or the deferred income tax liability is settled.

Deferred tax assets are recognised only if it is probable that future taxable amounts will be available to utilises those temporary differences and losses.

Current and deferred tax is recognised in profit or loss, except to the extent that it relates to items recognised in other comprehensive income or directly in equity.

# **Cash flow statement**

Operating cash flows in the statement of cash flows are reported using the indirect method. Under the indirect method the figure is produced by adjusting the profit and loss by removing the effects of non-cash items and changes in working capital. The Company has chosen the operating result as a starting point for the reconciliation as most of the other elements in the net result have a non-cash nature. Payments of the finance lease liabilities are included in the operating cash flows. They are part of the manufacturing costs, thus part of the working capital. This way the statement properly reflects the cash flows.

# Earnings per share

Basic earnings per share are calculated based on the weighted average number of ordinary shares outstanding during the period. Diluted earnings per share are computed based on the weighted average number of ordinary shares outstanding including the dilutive effect of shares to be issued in the future under certain arrangements such as option plans, warrants issued and convertible loan agreements.

# Segment reporting

Operating segments are reported in a manner consistent with the internal reporting of segmental information provided to the chief operating decision-maker function.

The Board of Management, which makes the Company's strategic decisions, has been identified as the chief operating

decision-maker responsible for allocating resources and assessing performance of the operating segments.

# **2.4** Significant accounting judgments and estimates

The preparation of financial statements requires judgments and estimates that affect the reported amounts of assets and liabilities, revenues and expenses, and related disclosure of contingent assets and liabilities at the date of the financial statements. The resulting accounting estimates will, by definition, seldom equal the related actual results. The estimates and assumptions that have a significant risk of causing a material adjustment to the carrying amounts of assets and liabilities within the next financial year are addressed below.

### Revenue

Revenue is recognised when control has been transferred to the customer. Gross turnover is reduced by chargebacks and rebates for government healthcare programs, discounts to specialty pharmacies and wholesalers, and product returns given or expected to be given, which vary by patient groups. Chargebacks and rebates for healthcare programs depend upon the submission of claims some time after the initial recognition of the sale. The liability for this variable consideration is made, at the time of sale, for the estimated chargebacks and rebates, based on available market information and historical experience. Because the amounts are estimated they may not fully reflect the final outcome, and the amounts are subject to change dependent upon, amongst other things, the types of patient groups. The level of these liabilities is being reviewed and adjusted regularly in the light of contractual and legal obligations, historical charges and trends, past experience and projected mixtures of patient groups. The Group acquires this information from both internal resources as external parties.

Future events could cause the assumptions on which the accruals are based to change, which could affect the future results of the Group.

# **Business combinations and contingent** consideration

In 2016 Pharming completed the acquisition of all North American commercialisation rights for its own product RUCONEST® from Valeant. The re-acquired rights are determined as an intangible asset, as part of a business combination. Pharming has paid an upfront amount of

US\$60 million and agreed to pay future amounts up to a further US\$65 million based on achievement of sales milestones. The future payments, based on achieving milestones, are considered to be contingent consideration. As the payments will be made in cash the contingent consideration is classified as a financial liability. It is recognised at its fair value at the acquisition-date, as part of the total consideration transferred, according IFRS 3 para 39. Fair value at acquisition-date was based on the probability of achieving the milestones. These fair values are based on risk-adjusted future cash flows discounted using appropriate discount rates. The fair values are reviewed on a regular basis, at least annually, and any changes are reflected in the income statement.

At 31 December 2018, the liability for contingent consideration amounted to €49.5 million (2017: €28.3 million). See note 30 Business combinations and contingent consideration. The amount originally arose on the acquisition of the commercialisation rights from Valeant Pharmaceuticals in 2016. This represents the present value of the estimated amount probably payable by Pharming in the event of achieving sales milestones and is calculated by applying the milestone criteria to probabilities of forecast future revenues and cash flows. Sensitivity analysis is given in note 32 *Financial risk management*. The assumptions relating to future revenues and discount rates are based on business forecasts and are therefore inherently judgemental. Future events could cause the assumptions used in these projections to change with a consequent adverse effect on the future results of the Company.

# **Development costs**

Expenditures for development can be recognised as an intangible asset when the following criteria are met:

- Technical feasibility of completing the asset so that it will be available for use of sale;
- Its intention to complete the asset and use or sell it;
- Its ability to use or sell it is clear;
- The probability of future economic benefits is good (is there a market for the product);
- The availability of resources to complete the development is not in question;
- The ability to measure reliably the expenditures on the project is not in question.

Development expenditures that meet these criteria are being capitalised. The Company has to make some judgements to determine if the above criteria will be met. For pharmaceutical products the capitalisation of development expenditures is usually restricted because the release of a new drug is strictly controlled by legislation and has to pass a number of (pre) clinical trials. The Company is working on modifications of its current product but since the active component in these modified products is exactly the same in formulation and mode of action as in the existing approved product ("RUCONEST®"), management strongly believes that final approval for these modifications will be obtained. For this reason, the costs related to these developments are being capitalised.

# Inventories

At year-end 2018, the Company has capitalised batches of RUCONEST® as well as skimmed milk with an aggregate carrying value of €17.3 million. These inventories are available for use in commercial, pre-clinical and clinical activities. Estimates have been made with respect to the ultimate use or sale of the product, taking into account current and expected sales as well as pre-clinical and clinical programmes for both HAE projects and other indications of the rhC1INH product. In doing so, best estimates have been made with respect to the timing of such events in view of both the existing and expected remaining shelf life of the product involved. The actual cash proceeds from these product sales are difficult to predict in terms of volumes, timing and reimbursement amounts.

Inventories are stated at the lower of cost and net realisable value. The estimation of the net realisable value is based on the allocation of inventories to the different markets with different prices, based on sales forecasts by management and commercial partners, and clinical programmes. Actual sales can differ from these forecasts.

# Derivative instruments presented as financial liabilities

Derivative instruments which are not equity instruments under IAS 32, IFRS 9 and IFRS 13 and other standards, such as warrants to acquire Pharming shares which have a cashless exercise option and the conversion option for repayment of the instalments into shares, are presented as financial liabilities.

All Pharming warrants are essentially the commitment to issue a fixed number of shares for a fixed amount of cash, but the possibility of cashless exercise (where a holder decides to accept fewer shares so as to avoid paying the relevant amount of cash, thus resulting in a number of shares to issued which can vary downward from the original number) requires that such warrants are treated as financial liabilities. As such, these derivative instruments are initially recognised at fair value and subsequently revalued at fair value through profit or loss with changes in the fair value recognised in the statement of income as they arise. Such revaluations do not represent the actual liability to issue shares, which is unchanged, but a notional market value of the instrument as if a new instrument with the same terms were issued on the measurement date. The revaluations are not cash movements or capable of being realised, and any accumulated revaluation total is returned to the profit & loss account (if a loss) or added to equity (if a gain) upon the extinction of the instrument through exercise or expiry, resulting in a net nil balance. These revaluations are presented as a separate line under financial income and expenses.

As at 31 December 2018, the Company has presented such derivative instruments as financial liabilities with a carrying value of €0.2 million. The revaluation shown in the profit & loss account represents the notional adjustment necessary to reflect the market values of similar warrant rights as if they were issued on the measurement date (31 December 2018) with the same terms and are based on models using assumptions with respect to, inter alia, the exercise of the warrants on or before maturity dates as well as (historical) volatility. Actual share price developments may trigger exercise of these warrants at a different time than assumed in the model, or result in their expiry unexercised, and may also result in the issue of shares to warrant holders at a time when the Pharming share price is higher or lower than anticipated at 31 December 2018. As a result, the difference between the open market value of shares transferred to warrant holders upon exercise and the carrying value at year-end 2018 as charged to the statement of income may be material but will be a non-cash movement to profit & loss or equity as described above. As the carrying value has significantly decreased as per 31 December 2018, the related risks have also been reduced significantly.

## **Property, plant and equipment**

At year-end 2018, Pharming has property, plant and equipment with a carrying value of &8.4 million. These assets are dedicated to the production of RUCONEST® inventories (&5.9 million) and, research and development activities, marketing and sales activities and corporate purposes (&2.5 million). It is assumed these asset groups will continue to be used in ongoing production, research and development or general and administrative activities over its anticipated lifetime. The carrying value of these assets may be impaired in the future in case of a decision to cancel and/or defer certain activities.

## **Deferred tax assets**

The Board of Management has considered the Company's history of losses, its current financial performance and expectations of future financial performance, and has concluded that it is probable that the benefits of the tax loss carry forward and the other deferred tax assets will be realised through future taxable profits. Accordingly, the Company has recorded deferred tax assets as set out in note 29.

# **2.5** Effect of new and forthcoming accounting standards

The IASB and IFRS IC have issued new standards, amendments to existing standards and interpretations, some of which are not yet effective or have not yet been endorsed by the European Union.

The adoption of these standards and interpretations did not have a material effect on the Company's financial performance or position.

# **EFFECT OF NEW ACCOUNTING STANDARDS**

# IFRS 15 Revenue from contracts with customers

The new standard IFRS 15 *Revenues from contracts with customers* is being adopted on the modified retrospective basis by the Company for 2018. Accordingly, it had no impact on the amounts reported in these consolidated financial statements. IFRS 15 replaces existing revenue recognition guidance in IFRS. It introduces a five-step model to determine when to recognise revenue and at what amount, based on transfer of control over goods or services to the customer.

### • Transition method

Pharming has adopted IFRS 15 as at January 1, 2018 and did not restate its 2017 comparative figures. The transition effect on equity as at January 1, 2018, is limited.

# Sale of goods

All of the Company's revenue from contracts with customers is derived from delivery of goods, specifically vials of pharmaceutical products. Until 2017, revenue has been recognised when the significant risks and rewards have been transferred to the customer, recovery of the consideration is probable, the associated costs and possible return of goods can be estimated reliably and there is no continuing management involvement with the goods. For revenue from sales of goods these conditions are almost always

met at the time the product is shipped and delivered to the customer, depending on the delivery conditions.

In accordance with IFRS 15, revenue should be recognised when the customer obtains control of the goods. The application of IFRS 15 did not result in any meaningful impact on our consolidated financial statements, as this is precisely how the contracts for revenue that we have at present are accounted for.

### Variable consideration

The vast majority of the Company's contracts for revenue with customers are subject to chargebacks for discounts and/or rebates relating to ultimate reimbursement claims from government or insurance payers. These are accounted for on an estimated net basis, with any actual discounts and rebates used to refine the estimates in due course. These variable elements are deducted in arriving at our net sales revenue figures, and so the treatment under IFRS did not change the calculation of these amounts. The Company therefore came to the same conclusion for the accounting treatment of variable consideration, including inter alia rebates, bonuses, discounts and payments to customers, that the impact on the financial statements relating to the new accounting standard is negligible.

• Equipment or services provided to customers Pharming does not provide any equipment or services to its customers. Under IFRS 15, the delivery of such items would qualify as a separate performance obligation.

## **IFRS 9 Financial instruments**

IFRS 9 Financial instruments replaces the provisions of IAS 39 that relate to the recognition, classification and measurement of financial assets and financial liabilities, derecognition of financial instruments, impairment of financial assets and hedge accounting. The new standard is based on the concept that financial assets should be classified and measured at fair value ("FV"), with changes in fair value recognised in profit and loss as they arise ("FVPL"), unless restrictive criteria are met for classifying and measuring the asset at either amortised cost or fair value through other comprehensive income ("FVOCI"). The Company has adopted this new standard for the reporting period starting 1 January 2018. The adoption did not result in material changes to the amounts recognised in the financial statements.

# EFFECT OF FORTHCOMING ACCOUNTING **STANDARDS**

A number of new standards and amendments to standards and interpretations are effective for annual periods beginning after 1 January 2019 and have not yet been applied in preparing these consolidated financial statements.

#### **IFRS 16 Leases**

IFRS 16 Leases is a new standard effective for annual period beginning after January 1, 2019 of which earlier application is permitted; however, the Group has not early adopted the new IFRS 16 in preparing these consolidated financial statements. The Group is required to adopt IFRS 16 Leases from January 1, 2019. The Group has assessed the estimated impact that initial application of IFRS 16 will have on its consolidated financial statements, as described below.

IFRS 16 introduces a single, on-balance sheet lease accounting model for lessees. A lessee recognises a right to-use asset representing its right to use the underlying asset and a lease liability representing its obligation to make lease payments. There are recognition exemptions for short-term leases and leases of low-value items. Lessor accounting remains similar to the current standard - i.e. lessors continue to classify leases as finance or operating leases.

IFRS 16 replaces existing leases guidance, including IAS 17, IFRIC 4 Determining whether an arrangement contains a lease, SIC-15 Operating leases-incentives and SIC-27 Evaluating the substance of transactions involving the legal form of a lease.

## i. Leases in which the Group is a lessee

The Group will recognise new assets and liabilities for its operating leases for the rent of office and laboratory facilities, as well as lease cars for employees (see note 31).

The nature of expenses related to those leases will now change because the Group will recognise a depreciation charge for right-to-use assets and interest expense on lease liabilities.

Previously, the Group recognised operating lease expense on straight-line basis over the term of the lease, and recognised assets and liabilities only to the extent that there was a timing difference between actual lease payments and the expense recognised.

No significant impact is expected for the Group's finance leases. Based on the information currently available, the Group estimates that it will recognise additional lease liabilities of € 6.2 million as of January 1, 2019. The Group does not expect the adoption of IFRS 16 to impact its ability to comply with the covenants of the loan described in note 19.

# ii. Transition

The Group plans to apply IFRS 16 initially on January 1, 2019, using the modified retrospective approach.

The Group plans to apply the practical expedient to grandfather the definition of a lease on transition. This means that it will apply IFRS 16 to all contracts entered into before January 1, 2019 and identified as leases in accordance with IAS 17 and IFRIC 4.

# 3. GOING CONCERN ASSESSMENT

In preparing and finalising the 2018 financial statements, the Board of Management of Pharming has assessed the Company's ability to fund its operations for a period of at least eighteen months after the date of signing these financial statements.

Based on the assessment on a going concern basis, the Company has concluded that funding of its operations for a period of 18 months after the signing date of these financial statements is realistic and achievable. In arriving at this conclusion, the following main items and assumptions have been considered:

- ◆ Cash and cash equivalents of €81.5 million as at 31 December 2018;
- ◆ Cash and cash equivalents of approximately €75 million (including restricted cash) as at the date of publication of these financial statements, which is sufficient to meet anticipated obligations;
- The receipts from commercial supply of product to our partners in Europe, the Middle East, Latin America, South Korea and Israel and proceeds from direct sales in the USA, Austria, France, Germany, Luxembourg, the Netherlands and the United Kingdom currently generate more cash than the Company requires for day to day expenses or to supply those sales, and thus the surplus cash generated will support our financial reserves further;
- Pharming has a previous history prior to 2017 of operating losses. The Board of Management, however,

anticipates that it will shortly reach the point where such quantities of RUCONEST® are being sold (directly or by our partners) that the proceeds to Pharming from such sales are more than sufficient to meet our operating costs, finance costs and all other cash requirements, including capital expenditure. This is expected to occur within 2019;

- The Company's anticipated operating cash outflows, and its planned and expected investments in (in) tangible assets for eighteen months from the date of this report. The cash outflow is expected to increase as a result of the increase in marketing and sales activities, production costs, development costs, and investment in assets will increase due to investments in production facilities, but these are expected to increase to a lesser extent than sales revenue increase, enabling sustained net cash generation;
- The Company's current finance structure, including both interest, repayment obligations and exit fee's, is included in the assessment of future obligations;
- The Company's obligation to pay certain sales milestones is included in the assessment of future obligations.

Overall, based on the outcome of this assessment, these financial statements have been prepared on a going concern basis. Notwithstanding their belief and confidence that Pharming will be able to continue as a going concern, the Board of Management emphasises that the actual cash flows may potentially ultimately (significantly) deviate up or down from our projections for various reasons. In the absence of an (improbable) absolute catastrophe such as banning of the product from sale in a major market, the Board of Management believe that the Company will have more than sufficient resources to meet all obligations as they fall due.

# **4. RESTATEMENT OF PRIOR YEAR**

The Company restated prior year's financial statements due to adjustment in the accounting of both the convertible bond as the \$100 million loan from Orbimed. The accounting for the conversion of the convertible bond appeared to be inappropriate and has been adjusted accordingly. The accounting for the effective interest on the loan has also been adjusted, in order to reflect the payable fees due to the quarterly repayments of this loan, in the effective interest reported in the financial income and expenses. For the full year 2017, the restated net loss becomes €76.2 million, an improvement of the net result of €3.7 million compared to the previously reported results.

The impact on the consolidated statement of income for the year 2017 and the consolidated balance sheet as at 31 December 2017, is as follows:

# CONSOLIDATED STATEMENT OF INCOME

For the year ended 31 December

amounts in € '000	<b>2017</b> as reported	RESTATEMENT	<b>2017</b> restated
OPERATING RESULT	21,912		21,912
Fair value gain (loss) on revaluation derivatives	(40,284)	(1,779)	(42,063)
Other financial income	5,228		5,228
Other financial and expenses	(76,255)	5,489	(70,766)
FINANCIAL INCOME AND EXPENSES	(111,311)	3,710	(107,601)
RESULT BEFORE INCOME TAX	(89,399)	3,710	(85,689)
Income tax credit (expense)	9,442		9,442
NET RESULT FOR THE YEAR	(79,957)	3,710	(76,247)
ATTRIBUTABLE TO:			
Owners of the parent	(79,957)	3,710	(76,247)
TOTAL NET RESULT	(79,957)	3,710	(76,247)
Basic earnings per share (€)	(0.160)	0.008	(0.152)

# CONSOLIDATED BALANCE SHEET

As at 31 December

AMOUNTS IN € 'OOO

Shareholders' equity

Total non-current liabilities

Total current liabilities

TOTAL EQUITY AND LIABILITIES

# **5. SEGMENT INFORMATION**

The Board of Management is the chief operating decisionmaker. The Board of Management considers the business from both a geographic and product perspective. From a product perspective, the Company's business is almost exclusively related to the recombinant human C1 esterase inhibitor business. From a geographic perspective, the Company is operating in the US, Europe and the Rest of the World. The Board of Management primarily measures revenues and gross profit to assess the performance of the geographic areas. Operating costs and assets are not allocated to the geographic areas.

Total external revenues and gross profit per geographic segment for the financial year 2018 and 2017 are:

amounts in € 'ooo	2018	2017
REVENUES:		
US	126,636	83,715
Europe	7,166	5,093
RoW	1,328	812
TOTAL REVENUES	135,130	89,620
GROSS PROFIT:		
US	111,581	75,451
Europe	290	1,067
RoW	1,079	657
TOTAL GROSS PROFIT	112,950	77,175

<b>2017</b> as reported	RESTATEMENT	<b>2017</b> restated
18,802	(2,692)	16,110
88,860	477	89,337
58,528	2,215	60,743
166,190		166,190

# 6. REVENUES

The revenue significantly increased due to higher sales in both the US market (€126.6 million in 2018 compared to €83.7 million in 2017) and Europe (€7.2 million in 2018 compared to €5.1 million in 2017). Revenue in Rest of the World in 2018 was €1.3 million compared to €0.8 million in 2017. The revenue fully relates to the transfer of goods and are recognised at a point in time.

In 2018, the Group released €0.8 million (2017: €0.9 million) from a contract liability to the revenue.

In 2018, two customers exceeded 10% of the Company's total revenue.

# 7. OTHER INCOME

Other income related to grants and amounted to €0.7 million in 2018 (€0.8 million in 2017). Grants reflect annual payroll-tax reimbursement granted by the Dutch and French government for research and development activities actually conducted by the Company.

# 8. EXPENSES BY NATURE

# **Costs of sales**

## Costs of sales are in 2018 and 2017:

amounts in € 'ooo	2018	2017
Cost of product sales	(20,576)	(12,535)
Inventory impairments	(1,604)	90
TOTAL	(22,180)	(12,445)

Cost of product sales in 2018 amounted to €20.6 million (2017: €12.5 million) and relates to actual product sales. Inventory impairments related to inventories designated for commercial activities amounted to an additional charge of €1.6 million in 2018 (2017: a reversal of €0.1 million). The impairment stems from the valuation of the inventories against lower net realisable value.

# **Costs of research and development**

Costs of research and development increased to €28.9 million in 2018 from €18.7 million in 2017. The increased costs are mainly related to improvements in production

capacity, the activities around new indications and formulations of ruconest® and for our follow up programs in Pompe disease and Fabry's disease.

# Costs of general and administrative

Cost of general and administrative increased to €12.2 million in 2018 from €6.0 million in 2017. The increased costs are mainly related to additional administration resources to support the growing commercial and operations activities in both US and EU.

# **Costs of marketing and sales**

Cost for marketing and sales increased in 2018 to €34.5 million from €31.4 million in 2017. The increased costs are almost entirely related to the further expansion of the sales organisation and infrastructure in the US.

# **Employee benefits**

amounts in € '000	2018	2017
Salaries	(22,887)	(18,837)
Social security costs	(2,251)	(1,651)
Pension costs	(1,034)	(642)
Share-based compensation	(3,889)	(2,712)
TOTAL	(30,061)	(23,842)

Salaries include holiday allowances and cash bonuses.

# The number of employees

weighted average full time equivalent	2018	2017
Research and development	96	77
General and administrative	21	21
Marketing and sales	39	29
TOTAL	156	127

The weighted average number of employees working outside the Netherlands was 63 (2017: 51).

Employee benefits are charged to research and development costs, or general and administrative costs, marketing and sales costs based on the nature of the services provided.

# **Depreciation and amortisation charges**

amounts in € 'ooo	NOTES	2018	2017
Property, plant and equipment	13	(1,090)	(569)
ntangible assets	12	(2,845)	(2,846)
TOTAL		(3,935)	(3,415)

The increase of depreciation charges of property, plant and equipment in 2018 as compared to 2017 stems from new investments. For property, plant and equipment, in 2018 an amount of €0.9 million was charged to research and development costs (2017: €0.5 million).

Т

Amortisation charges of intangible assets have been allocated to research and development costs and marketing and sales costs in the statement of income. In 2018 the amortisation charges were in line with prior year and mainly related to the amortisation of the re-acquired US commercialisation rights, which is applied over the economic useful life of 20 years.

# **Operating lease charges**

For the year 2018, the Company charged €1.9 million (2017: €1.6 million) to the statement of income with regard to lease commitments for office rent, equipment, facilities and lease cars.

These non-cancellable leases at 31 December 2018 have remaining terms of between one to eight years and generally include a clause to enable upward revision of the rental charge on an annual basis according to prevailing market conditions.

The expected operating lease charges after the end of the reporting year have been disclosed in note 31. Allocations of the operating lease charges to research and development costs or general and administrative expenses have been based on the nature of the asset in use.

# **Independent auditor's fees**

Fees of PricewaterhouseCoopers Accountants N.V. incurred in relation to 2018 and 2017 audit services were as follows:

amounts in € 'ooo	2018	2017
Audit of the financial statements	(526)	(264)
Audit related activities	-	-
Tax advisory	-	-
TOTAL	(526)	(264)

The increase of fees in 2018 compared to 2017 mainly relates to additional charges for prior year.

# 9. FAIR VALUE GAIN (LOSS) ON **REVALUATION DERIVATIVES**

amounts in € 'ooo	2018	<b>2017</b> restated *
Revaluation warrants	(302)	(14,349)
Revaluation conversion rights *	(193)	(27,714)
TOTAL	(495)	(42,063)

\* Prior year's financial statements have been restated, as disclosed under note 4

In 2018 and 2017, the Company incurred (non-cash) adjustment losses through revaluation and exercises of the derivative components of issued instruments (principally the ordinary convertible bonds and the warrants) against fair value, largely stemming from increases in the Company's share price. Refer to note 22 for more information on the derivative financial liabilities. The changes in value on the exercised conversion rights are related to the redemption by conversion of the bonds.

# **10. OTHER FINANCIAL INCOME AND EXPENSES**

AMOUNTS IN € '000	2018	<b>2017</b> restated*
Interest income	18	3
Foreign currency results	-	5,225
OTHER FINANCIAL INCOME	18	5,228
Interest expenses	(10)	(87)
Foreign currency results	(1,147)	-
Interest loans and borrowings *	(14,301)	(18,564)
Settlement fees and expenses	-	(28,470)
Contingent consideration	(21,200)	(23,645)
OTHER FINANCIAL EXPENSES	(36,658)	(70,766)
TOTAL OTHER FINANCIAL INCOME AND EXPENSES	(36,640)	(65,538)

\* Prior year's financial statements have been restated, as disclosed under note 4

# **Foreign currency results**

These results primarily follow from the revaluation of bank balances and loan denominated in foreign currencies, mainly US dollars, and the timing of foreign currency payments against the actual exchange rate as compared to the original exchange rate applied upon the charge of fees or expenses. The loss in 2018 is a result of revaluation of the loan in US Dollar, partly set off against the revaluation of the bank balances in US Dollar, both incorporated in our Dutch entities. The US dollar strengthened during 2018.

# Interest loans and borrowings

Interest on loans and borrowings relate to the amortised costs from loans and borrowings, principally the current term loan from Orbimed Advisors in 2018, and the previous loans from Kreos Capital and Silicon Valley Bank in 2017.

# **Settlement fees and expenses**

In 2018 no settlement fees and expenses occurred. Settlement fees and expenses in 2017 were related to the refinancing of the old loans and the amortising bonds by the loan from Orbimed and the adjustments of the amortised costs of the old instruments and the convertible bonds.

# **Contingent consideration**

The expense for the contingent consideration is related to the present value of the estimated likelihood of meeting all or some of the US\$65 million potential sales milestones which form part of the reacquisition transaction for North American commercial rights for RUCONEST®. See also note 30.

# **11. INCOME TAX**

# Income taxes on ordinary activities

The following table specifies the current and deferred tax components of income taxes in the income statement:

#### AMOUNTS IN € 'OOO

#### **INCOME TAX EXPENSE**

Current tax

Current tax on profit for the year

Adjustments for current tax of prior periods

**TOTAL CURRENT TAX EXPENSE** 

#### Deferred income tax

(Decrease) / increase in deferred tax assets

(Decrease) / increase in deferred tax liabilities

TOTAL DEFERRED TAX BENEFIT

INCOME TAX CREDIT (EXPENSE)

# **Effective income tax rate**

Pharming Group's effective rate in its consolidated income statement differed from the Netherlands' statutory tax rate of 25%. The following table reconciles the statutory income tax rate with the effective income tax rate in the consolidated income statement:

# AMOUNTS IN € 'OOO

Profit (loss) on ordinary activities before taxation

Profit (loss) on ordinary activities multiplied by sta in The Netherlands 25% (2017: 25%)

#### Effects of:

- Non taxable income (expense)

- Deferred tax income (expense) related to recogn

- Rate differential

- Other

# INCOME TAX CREDIT (EXPENSE) FOR THE

\* Prior year's financial statements have been restated, as disclosed in note 4

NOTES	2018	2017
	(1,332)	-
	-	-
	(1,332)	-
29	25,554	9,442
29	(86)	-
	25,468	9,442
	24,136	9,442

2018	<b>2017</b> restated*
857	(85,689)
(214)	21,422
(813)	(19,392)
30,833	8,609
(5,367)	(1,197)
(303)	-
24,136	9,442
	857 (214) (813) 30,833 (5,367) (303)

# Factors affecting current and future tax charges

The main difference between the theoretical tax and the effective tax for the year 2018 is primarily explained by the recognised deferred tax assets for which it is assessed that it is likely that these will be realised in the foreseeable future.

# 12. INTANGIBLE ASSETS

The 2018 rate differential indicates the effect of reduction in Dutch statutory rate as of 2020 as well as the effect of taxable income being generated and taxed in jurisdictions where tax rates differ from the statutory rate in The Netherlands.

The 2017 rate differential was the effect of the reduction of the US tax rate from 35% to 21%.

amounts in € 'ooo	TRANSGENIC TECHNOLOGY	RUCONEST® FOR HAE(EU)	DEVELOPMENT COSTS	RE-ACQUIRED RIGHTS	TOTAL
At cost	2,651	528	791	55,860	59,830
MCCUMULATED:					
Amortisation charges	(2,616)	(326)	-	(173)	(3,115)
Impairment charges	(35)	-	-	-	(35)
CARRYING VALUE AT 1 JANUARY 2017	-	202	791	55,687	56,680
Amortisation charges	-	(53)	-	(2,793)	(2,846)
Impairment charges	-	(55)	-	(2,, , , , , )	(2,010)
Capitalised development costs	-	-	2,797	-	2,797
Assets acquired	-	-	-	-	-
MOVEMENT 2017	-	(53)	2,797	(2,793)	(49)
At cost	2,651	528	3,588	55,860	62,627
ACCUMULATED:					
Amortisation charges	(2,616)	(379)	-	(2,966)	(5,961)
Impairment charges	(35)	-	-	-	(35)
CARRYING VALUE AT 31 DECEMBER 2017	-	149	3,588	52,894	56,631
Amortisation charges	-	(52)	-	(2,793)	(2,845)
Impairment charges	-	-	(2,624)	-	(2,624)
Capitalised development costs	-	-	1,273	-	1,273
Assets acquired	-	-	-	-	-
MOVEMENT 2018	-	(52)	(1,351)	(2,793)	(4,196)
At cost	2,651	528	4,861	55,860	63,900
ACCUMULATED:					
Amortisation charges	(2,616)	(431)	-	(5,759)	(8,806)
Impairment charges	(35)	-	(2,624)	-	(2,659)
CARRYING VALUE AT 31 DECEMBER 2018		97	2,237	50,101	52,435

In 2016, the Company has started to modify the current product RUCONEST® for more convenient forms of administration for use by the patient. This will result in variants of the existing product. One of these variants has been downprioritised, as a result of other opportunities with another version. As a result, the Company had to impair the capitalised costs related to the previous variant. This has led to an impairment charge of €2.6 million in 2018, reflected in the operating costs under research & development. A total amount of €1.8 million still has been capitalised and has been recognised as internally generated intangible assets as at 31 December 2018. Amortisation will start after completion which is expected between one and three years, depending on the different forms of administration for use.

In 2014, the Company acquired assets from Transgenic Rabbit Models SASU, for a total amount of €0.5 million, which has been recognised as intangible assets regarding development costs of two new product leads: alphaglucosidase for Pompe disease and alpha-galactosidase for Fabry's disease. The assets are recorded at historical costs, related to the development costs that Pharming avoids or saves by acquiring these assets. The development of these new product leads is expected not to be completed within 5 years.

The Company has capitalised development costs in the amount of €0.1 million in relation to RUCONEST® for HAE in the European Union. Following market launch of the product in 2010 the amortisation of the asset has started, and no more development costs have been capitalised ever since.

The re-acquired rights relate to the acquisition of all North American commercialisation rights from Valeant in 2016. We refer to note 30.

Intangible assets that are not yet in use are tested annually or more frequently if there are indications that a particular asset might be impaired. The fair value is determined using discounted cash flow projections based on financial plans approved by management. The considered period covers the period until expiration of the relevant patent. The weighted average cost of capital is based on Company standards for applicable markets and assets and is currently 13.9%.

# 13. PROPERTY, PLANT AND EQUIPMENT

amounts in € 'ooo	LAND AND LAND	OPERA- TIONAL FACILITIES	LEASEHOLD IMPROV- MENT	MANU- FACTURING EQUIPMENT	OTHER	ASSET UNDER CONSTRUC- TION	TOTAL
At cost	27	2,491	1,969	5,270	2,882	125	12,764
Accumulated depreciation	-	(1,798)	(1,968)	(1,388)	(1,567)	-	(6,721)
CARRYING VALUE AT 1 JANUARY 2017	27	693	1	3,882	1,315	125	6,043
Investments	-	83	11	-	730	2,423	3,247
Divestments	-	-	-	-	-	-	-
Depreciation charges	-	(177)	(1)	(487)	(391)	-	(1,056)
Depreciation of disinvestment	-	-	-	-	-	-	-
Currency translation	-	-	-	-	-	-	-
MOVEMENT 2017	-	(94)	10	(487)	339	2,423	2,191
At cost	27	2,575	1,980	5,270	3,612	2,548	16,012
Accumulated depreciation	-	(1,976)	(1,969)	(1,875)	(1,958)	-	(7,778)
CARRYING VALUE AT 31 DECEMBER 2017	27	599	11	3,395	1,654	2,548	8,234
Investments	-	3,151	-	-	1,774	(2,429)	2,496
Divestments	-	-	-	-	-	-	-
Depreciation charges	-	(466)	(2)	(1,251)	(622)	-	(2,341)
Depreciation of disinvestment	-	-	-	-	-	-	-
Currency translation	-	-	1	-	12	-	13
movement 2018	-	2,685	(1)	(1,251)	1,164	(2,429)	168
At cost	27	5,726	1,981	5,270	5,398	119	18,521
Accumulated depreciation	-	(2,442)	(1,971)	(3,126)	(2,580)	-	(10,119)
CARRYING VALUE AT 31 DECEMBER 2018	27	3,284	10	2,144	2,818	119	8,402

Depreciation charges on manufacturing equipment of €1.3 million in 2018 (2017: €0.5 million) have been charged to the value of inventories and an amount of €1.1 million of total 2018 depreciation charges has been charged to the statement of income (2017: €0.6 million).

In 2018 the Company invested €2.5 million, mainly in operational facilities, research and development facilities and laboratory equipment. In 2018 an additional milk production facility was put in use. The related assets were transferred from Assets under construction to Operational facilities..

At year-end 2018, the carrying value of assets hired under financial lease arrangements – and thus with a restricted title - was €0.8 million (31 December 2017: €1.1 million). This was related to manufacturing equipment.

# **14. LONG-TERM PREPAYMENT**

The Long-term prepayment (€2.0 million as at 31 December 2018) is related to the manufacturing agreement with BioConnection, a contract manufacturing organisation, and represents three instalments, of €0.5 million each, plus prepaid batches, made to secure and guarantee sufficient future production capacity. These instalments and prepayments represent prepaid production costs of drug product batches. The prepayment will be settled by BioConnection by deductions from the cost of future production of finished goods batches.

# 15. RESTRICTED CASH, CASH AND CASH EQUIVALENTS

amounts in € 'ooo	2018
Non-current restricted cash	1,204
Cash and cash equivalents	80,311
BALANCE AT 31 DECEMBER	81,515
Balance at 1 January	59,993
Exchange rate effects on cash	2,876
INCREASE (DECREASE) OF CASH	18,646

Restricted cash represents the value of banker's guarantees issued with respect to (potential) commitments towards third parties and a deposit issued in respect of lease cars of total US\$1.1 million.

# **16. INVENTORIES**

Inventories include batches RUCONEST®, work in progress and skimmed milk available for production of RUCONEST®.

amounts in € 'ooo	2018
Finished goods	15,949
Work in progress	661
Raw materials	705
BALANCE AT 31 DECEMBER	17,315

The inventory valuation at 31 December 2018 of €17.3 is stated net of a provision of €0.4 million (2017: €0.3 million) to write inventories down to their net realisable value, and net of a provision for obsolescence of €1.5 million (2017: €1.0 million).

Changes in the adjustment to net realisable value:

amounts in € 'ooo	2018	2017
BALANCE AT 1 JANUARY	(336)	(642)
Reversal of (addition to) impairment for the year	(1,604)	90
Related to costs of product sales	1,455	207
Related to operating costs	50	9
BALANCE AT 31 DECEMBER	(435)	(336)

In 2018, an addition to the impairment of €1.6 million was based on adjusted forecasts for sales (2017: reversal of €0.1 million). The changes related to the costs of product sales (€1.5 million in 2018) is the adjustment of sold vials which were valued at net realisable value. This amount increased compared to prior year as a result of increased sales levels. The changes related to the operating costs represent the costs of vials used for investigational medicinal product drugs for clinical studies.

Cost of inventories included in the cost of product sales in 2018 amounted €22.2 million (2017: €12.5 million). The vast majority of inventories at 31 December 2018 has expiration

dates starting beyond 2020 and is expected to be sold or used before expiration.

#### AMOUNTS IN € 'OOO 2018 2017 Trade receivables 15,335 8,895 Prepaid expenses 1,813 1,077 Value added tax 344 588 6,334 Other receivables 322 700 BALANCE AT 31 DECEMBER 17,814 11,260

# **17. TRADE AND OTHER RECEIVABLES**

2017 1.336 58,657 59,993 32,137 (1,057) 28,913

2017

8,271

3,729

18,334

Trade receivables are amounts due from customers for goods sold in the ordinary course of business. They are generally due for settlement within 30 days and therefore are all classified as current. The Company's outstanding trade receivables are mainly related to the sales in the US. The increase in trade receivables reflects the increase in sales.

The Company did not recognise any expected credit losses. Pharming has a limited number of customers with long term relationships, without a history of significant shortfalls.

The prepaid expenses increased in 2018 due to increased prepayments for future research and development activities and other fees.

Due to the short-term nature of the current receivables, their carrying amount is considered to be the same as their fair value.

# **18. SHAREHOLDERS' EQUITY**

The Company's authorised share capital amounts to €8.0 million and is divided into 800,000,000 ordinary shares with a nominal value of €0.01 each. All 621,501,238 shares outstanding at 31 December 2018 have been fully paid-up. Other reserves include those reserves related to currency translation, share-based compensation expenses and other equity-settled transactions. Please refer to the Consolidated statement of changes in equity and to note 33. This note further describes the background of the main equity movements in 2018 and 2017.

## Net result and accumulated deficit

Article 25.1 of the articles of association reads as follows: 'the management board shall annually determine, subject to the approval of the Board of Supervisory Directors, the amount of the distributable profit – the surplus on the profit and loss account - to be reserved.' The Board of Management has proposed to forward the net profit for the year 2018 to the accumulated deficit. Anticipating the adoption of the financial statements by the shareholders at the Annual General Meeting of shareholders, this proposal has already been reflected in the financial statements.

# Share-based compensation

Share-based compensation within equity includes those transactions with third parties, the Board of Management and employees in which payment is based in shares or options, based on current or future performance. For 2018 these transactions were valued at €3.9 million and for 2017 at €2.7 million (see note 24).

## **Bonuses settled in shares**

In 2018 the Company issued 1,624,879 shares with an aggregate value of €1.3 million to members of the Board of Management and various managers in lieu of bonuses. In 2017 a total of 908,437 shares were issued to pay off bonuses of €0.3 million.

## Warrants

In 2018 warrants, representing a total of 14,802,056 shares, were exercised in exchange for an actual total of 11,122,269 shares. In relation to the exercises, the Company received €0.3 million in cash and recovered 3,679,787 in total shares through the cashless exercise.

On 21 July 2017 the Company issued 9,174,372 warrants with an exercise period of 7 years and an exercise price of €0.455 to the new lender Orbimed Royalty Opportunities for the refinancing of the old loans and the amortising bonds. The warrants were initially recognised in equity for €2.5 million.

During 2017 the warrant holders were offered a cashless exercise mechanism in order to stimulate exercise of warrants and to minimise the issuance of shares to warrant holders and thus dilution to existing shareholders. This mechanism, together with the redemption of most of the ordinary convertible bonds due 2021 and the refinance, enabled the very large share overhang at the end of the previous year from warrants, convertible bonds and options to be minimised during the year. The remaining warrants have been reclassified to liabilities as at the date of the offer. From that date until their exercise date, the fair value changes have been reflected in the P&L, resulting in a loss of €8.3 million. Warrants, representing a total of 86,151,655 shares, were exercised in exchange for an actual total of 58,123,107 shares. In relation to the exercises, the Company received €6.7 million in cash and recovered 28,028,548 in total shares through the cashless exercise.

# **Options exercised**

In 2018, a total of 26,993,172 options were exercised in exchange for the same amount of shares. In 2017, a total of 1,091,651 options were exercised in exchange for 917,227 shares.

## **Conversions of bonds**

In 2018 a total of 2,746,476 shares were issued through conversions to redeem ordinary convertible bonds with a face value of €0.8 million. Derecognition prior to conversion of the fair values of the derivative financial liabilities recorded on issue resulted in adjustment in equity of €3.1 million.

In 2017, a total of 63,476,808 shares were issued through conversions to redeem amortising convertible bonds and ordinary convertible bonds with a face value of €18.1 million. Derecognition prior to conversion of the fair values of the derivative financial liabilities recorded on issue resulted in adjustment in equity of €32.8 million and a (non-cash) financial expense of 27.2 million.

# Adjustment to share capital

There were no adjustments to the authorised share capital in 2018 and 2017.

## Legal reserves

The legal reserves concern the currency translation differences of foreign investments and capitalised development expenses. Adjustments of the currency translation reserve reflect the effect of translating US operations denominated in US dollar since their functional currency is different from the reporting currency.

In 2018, an increase of €0.3 million (2017: a decrease of €1.0 million) took place due to the difference between the result of the foreign investments and the total exchange rate differences of the investment. We refer to note 2.3. The legal reserves as of 31 December 2018 include an amount of €2.2 million for capitalised development expenses.

# **19. LOANS AND BORROWINGS**

amounts in € 'ooo	2018
Loans	72,502
Convertible bonds	-
BALANCE AT 31 DECEMBER	72,502
- Current portion	35,235
- Current portion - Non-current portion	35,235 37,267

\* Prior year's financial statements have been restated, as disclosed in note 4

The remaining lifetime of the loans and borrowings is no longer than 3 years.

2017 restated\* 80,725 834 81,559 22.398 59,161

#### Loans

In 2017, the Company entered into a debt facility with Orbimed Royalty Opportunities II, LP to raise US\$100 million (€91.3 million at 2017 exchange rate).

Under the terms and conditions of this debt facility, the Lenders provided an amount of US\$100 million secured senior debt funding against 48 months promissory notes with interest of the sum of (i) the Applicable Margin of 11% plus (ii) the greater of (x) One-Month LIBOR and (y) 1.00%. Quarterly repayment of the loan has been started in September 2018. The Company has the option to prepay the loan before its maturity date. As further consideration for the facility, the Lenders received a 4% warrant coverage (9,174,372 warrants) with a strike price of €0.455 representing the closing price of Pharming shares immediately prior to the closing date, plus a 2.5% commitment fee of the principal sum and an assignment fee on the maturity date of US\$3.7 million. The warrants have been separated from the loan and recognised in equity. On repayment of the loan, the Company has to pay an exit fee of 5%.

The Company, and its subsidiaries, have pledged all receivables, movable assets and intellectual property rights as security to the lenders.

Recognition and movements of the Orbimed loan were as follows:

amounts in € 'ooo	2018	<b>2017</b> restated*
CARRYING VALUE INITIAL RECOGNITION		85,544
CARRYING VALUE AT 1 JANUARY	80,725	-
Amortised costs (financial income and expenses)	14,281	7,406
Interest paid (cash flow)	(11,063)	(5,726)
Repayment and exit fee	(15,137)	-
Revaluation loan	3,696	(7,412)
Restatement 2017 *		913
CARRYING VALUE AT 31 DECEMBER	72,502	80,725
- Current portion	35,235	21,886
- Non-current portion	37,267	58,839

\* Prior year's financial statements have been restated, as disclosed in note 4

The amortised costs (effective interest) and the interest paid in 2018, both increased compared to 2017 because they were effective for a full year (the loan started in July 2017). In the third quarter of 2018 the first quarterly instalment has been paid, including fees for repayment, followed by the second repayment in the fourth quarter.

# **Convertible bonds**

In 2016, the Company issued €12.5 million private ordinary convertible bonds ('Ordinary Bonds') carrying 8.5% annual interest. The Ordinary Bonds are redeemable at the Company's option at par after 3 years, if in a period of 30 consecutive trading days the volume weighted average price of the Shares is 30% above the conversion price, unless the holders elect to convert their Ordinary Bonds instead of being redeemed.

The holders may request redemption at par of any unredeemed or unconverted bonds on maturity. The investors received a total of 8,830,982 warrants in connection with this financing. The warrants have been separated from the bonds and recognised in equity.

The convertible bond portion was initially recognised at amortised cost. Payments of the bi-yearly interest took place in cash.

All the remaining bonds at year end 2017 were redeemed in accordance with their terms within January 2018. The remaining bonds in 2018 were partly converted into 2.7 million shares, and partly settled in cash. An amount of €0.4 million has been added to the share premium due the conversion into shares.

Movements of the convertible bonds were as follows:

amounts in € '000	2018	<b>2017</b> restated*
BALANCE AT 1 JANUARY	834	5,333
Amortised costs	19	1,251
Interest paid	-	(860)
Redemption*	(457)	-
Conversion into shares *	(396)	(4,890)
BALANCE AT 31 DECEMBER		834
- Current portion	-	511
- Non-current portion	-	323

\* Prior year's financial statements have been restated, as disclosed in note 4

# **20. CONTRACT LIABILITIES**

In 2010, the Company entered into a distribution agreement for the European market for RUCONEST® with SOBI, under which a €3.0 million upfront payment and a €5.0 million milestone payment were received in cash. The  $\notin$ 8.0 million is released to the statement of income, over time, in accordance with the remaining lifetime of the agreement following market approval for RUCONEST® in October 2010 and subsequent start of supplies. In both 2018 and 2017 €0.8 million was released from this agreement, and recognised as revenue.

In 2013, Pharming received an upfront payment of €1.1 million in cash from the China Shanghai Institute of Pharmaceutical Industry (CSIPI) with respect to a strategic collaboration in China for the development, manufacturing and commercialisation of new products at CSIPI, funded by CSIPI up to IND stage, based on the Pharming technology platform. In addition, Pharming has also granted CSIPI an exclusive license to commercialise RUCONEST® in China. In 2017 the last remaining €0.1 million was recognised as revenue from this agreement. In 2018 no release has taken place anymore.

AMOUNTS IN € 'OOO	2018	2017
BALANCE AT 1 JANUARY	2,271	3,214
Revenues from contract liabilities	(804)	(943)
BALANCE AT 31 DECEMBER	1,467	2,271
- Current portion	800	804
- Non-current portion	667	1,467

# **21. FINANCE LEASE LIABILITIES**

Certain assets of the Company are subject to finance leases. These leases mainly relate to manufacturing equipment.

amounts in € 'ooo	2018
BALANCE AT 1 JANUARY	653
Revaluation of finance lease liabilities	-
Interest expense accrued	55
Payments of finance lease liabilities	(281)
BALANCE AT 31 DECEMBER	427
- current portion	263
- non-current portion	164

Pharming has a finance lease arrangement related to an existing manufacturing agreement, in which a service provider invested into certain assets exclusively in use by the Company but operated by the service provider. The Company will reimburse the service provider an aggregate amount of €2.8 million over the lifetime of the agreement through payments of a variable service fee charge based on the actual production.

The amount of the net present value of the investment of €1.8 million has been presented as manufacturing equipment with a simultaneous increase of finance liabilities. An estimated 11.0% annual interest charge applies to this agreement. The service provider is and will remain to be the legal owner of the assets in use. The fair value of the finance lease obligations is approximately their carrying amount. No arrangements have been entered into for contingent rental payments.

Future minimum lease payments under finance leases as at 31 December 2018 and 2017 are as follows:

amounts in € '000	
Within one year	
After one year but not more than five years	
More than five years	

# BALANCE AT 31 DECEMBER

At year-end 2018, the carrying value of the assets involved as leased was €0.8 million (2017: €1.1 million) and related to manufacturing equipment.

2	017
	862
	-
	84
(2	293)
	653
	263
	390

2018		2017	
MINIMUM PAYMENTS	PRESENT VALUE OF PAYMENTS	MINIMUM Payments	PRESENT VALUE OF PAYMENTS
281	263	281	263
190	164	472	390
-	-	-	-
471	427	753	653

# 22. DERIVATIVE FINANCIAL LIABILITIES

Derivative financial liabilities include conversion options embedded in borrowings and warrants issued in relation to the issue of equity and the loans in 2013, 2015 and 2016.

In 2018, a total of 2,746,476 shares were issued to convert €0.5 million of the convertible bonds.

In 2018, in total 14,802,056 warrants were exercised compared to the exercise of in total 67,526,210 warrants in 2017.

In 2017, a total of 39,755,280 shares were issued to convert and redeem €11.3 million of the convertible bonds. For the instalments of the amortising bonds, a total of 23,721,528 shares were issued to convert and redeem the amortising bonds by €6.8 million.

The total number of conversion rights, related to the convertible and amortising bonds, decreased in 2017 from 199,864,272 to 2,746,476 conversion rights at December 31, 2017. During 2017, a total of 63,476,808 were converted into shares and 133,640,988 have been expired in 2017 due to redemptions and prepayments in cash.

Movement of derivative financial liabilities for 2018 and 2017 can be summarised as follows:

amounts in € 'ooo	NOTES	2018	<b>2017</b> restated*
BALANCE AT 1 JANUARY		10,080	9,982
Initial recognition upon issue		-	-
Reclassification from equity		-	19,552
Fair value losses (gains) derivative	s 9	495	42,063
Redemption cash settlement		(1,779)	-
Conversions into shares		(8,568)	(61,517)
BALANCE AT 31 DECEMBER		228	10,080

\* Prior year's financial statements have been restated, as disclosed in note 4

Fair value gains and losses on derivatives have been presented within financial income and expenses.

# 23. TRADE AND OTHER PAYABLES

AMOUNTS IN € 'OOO	2018	2017
Accounts payable	6,642	9,430
Taxes and social security	2,142	-
Deferred compensation due to related parties	718	751
Other payables and provisions	19,087	17,017
BALANCE AT 31 DECEMBER	28,589	27,198

The decrease in accounts payable mainly relates to adjusted payment terms for manufacturing expenses.

The increase in taxes and social security mainly relates to taxes to be paid in the US.

Other payables increased mainly as a result of charge backs and rebates to be paid in the US, over a major part of the year 2018.

The amount of deferred compensation due to related parties involves members of the Board of Management and Board of Supervisory Directors and includes bonuses, holiday allowances and holiday rights not yet delivered.

# 24. SHARE-BASED COMPENSATION

The Company has a long-term incentive plan and two option plans in place: one for the Board of Management and one for employees ('the option plans'). All these plans or arrangements are equity settled. The total expense recognised in 2018 for share-based payment plans amounts to €3.9 million (2017: €2.7 million).

## Models and assumptions

The costs of option plans are measured by reference to the fair value of the options at the grant date of the option.

IFRS 2 describes a hierarchy of permitted valuation methods for share-based payment transactions. If possible, an entity should use market prices at measurement date to determine the fair value of its equity instruments. If market prices are unavailable, as is the case with Pharming's option plans and long-term incentive plan, the entity shall estimate the fair value of the equity instruments granted. A valuation technique should be used to estimate the value or price of those equity instruments as it would have been at the

measurement date in an arm's length transaction between knowledgeable, willing parties.

The valuation technique shall be consistent with generally accepted valuation methodologies for pri financial instruments and shall incorporate all fac assumptions that knowledgeable market participa would consider in setting the price.

Whatever pricing model is selected, it should, as a minimum, take into account the following elements:

- The exercise price of the option;
- The expected time to maturity of the option;
- The current price of the underlying shares;
- The expected volatility of the share price;
- The dividends expected on the shares;
- The risk-free interest rate for the expected time to maturity of the option.

The six elements above are all incorporated in the Blac Scholes model used to determine the fair value of option The exercise price of the option and the share price are known at grant date. Volatility is based on the historica end-of-month closing share prices over a period prior the option grant date being equal to the expected option life, with a minimum of 3 years. It is assumed no divide payments are expected.

For the long-term incentive plan, the following eleme of Pharming and/or the peer group are included in or to determine the fair value of long term incentive pla share awards, using Monte Carlo simulation:

- Start and end date of performance period;
- The grant date;
- The share prices;
- Exchange rates;
- Expected volatilities;
- Expected correlations;
- Expected dividend yields;
- Risk free interest rates.

Volatilities are based on the historical end-of-month closing share prices over the 3 years.

Correlations are based on 3 years of historical correlations based on end-of-month closing quotes, taking into account exchange rates. Expected dividend yields for peers and riskfree interest rates (depending on the currency) are obtained from Bloomberg.

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# Long Term Incentive Plan

At the AGM of 16 April 2008, a long-term incentive plan was approved with an effective date of 1 January 2008. Under the LTIP, restricted shares are granted conditionally each year with shares vesting based on the market condition in which the total shareholder return performance of the Pharming share is compared to the total shareholder return of a peer group of other European biotech companies.

The reference group for the 2016-2018 programmes consists of the following 26 companies:

	MAIN LOCATION	NUMBER	COMPANY
	Belgium	1	Galapagos
	Denmark	4	Bavarian Nordic, Neurosearch, Veloxis Pharmaceuticals, Genmab
ck- ons. e	France	5	Cellectis, Eurobio Scientific, Hybrigenics, Innate Pharma, Transgene
al to	Germany	4	Evotec, Medigene, Morphosys, Heidelberg Pharma
on end	Italy	1	Newron Pharmaceuticals
, ind	Norway	1	Photocure
ents	Sweden	1	Medivir
der n	Switzerland	4	Addex Therapeutics, Basilea Pharmaceutica, Kuros Biosciences, Santhera Pharmaceuticals
	United Kingdom	5	Allergy Therapeutics, GW Pharmaceuticals, ImmuPharma, Oxford Biomedica, Premier Veterinary Group
losing	<b>TOTAL</b> Excluding Pharming Group	26	

# The vesting schedule is as follows. Ranking in the top:

ACHIEVEMENT LEVEL	% of grant attained
5% of the index:	100%
5-10% of the index:	80% of maximum
10-20% of the index:	60% of maximum
20-30% of the index:	50% of maximum
30-50% of the index:	20% of maximum
Lower than 50% index:	0%

Upon a change of control, all remaining LTIP shares will vest automatically.

An overview of the maximum number of LTIP shares granted in 2016-2018 and in total as well as the fair value per share award is as follows:

PARTICIPANT CATEGORY	2016	2017	2018	TOTAL
Board of Supervisory Directors	725,000	725,000	125,000	1,575,000
Board of Management	1,084,340	1,498,263	296,351	2,878,954
Senior managers	1,340,000	1,290,000	967,500	3,597,500
TOTAL	3,149,340	3,513,263	1,388,851	8,051,454
Fair value per share award (€)	0.079	0.407	0.671	

The following table provides an overview of LTIP shares granted, forfeited or issued in 2016-2018 as well as the number of LTIP shares reserved at 31 December 2018:

PARTICIPANT CATEGORY	GRANTED	FORFEITED N	IOT VESTED	RESERVED AT 31 DECEMBER 2018
Board of Supervisory Directors	1,575,000	-	(145,000)	1,430,000
Board of Management	2,878,954	-	(216,868)	2,662,086
Senior managers	3,597,500	(50,000)	(258,000)	3,289,500
TOTAL	8,051,454	(50,000)	(619,868)	7,381,586

The 2016 shares did vest at the end of the vesting period (31 December 2018) and a total of 80% of the granted LTIP shares will be issued. LTIP shares reserved at 31 December 2018 relate to the 2017 and 2018 shares available for participants still in service at the end of 2018. The Company expensed amounts of €0.9 million in 2018 compared to €0.8 million in 2017.

# Main characteristics of the option plans

The total number of shares with respect to which options may be granted pursuant to the option plans accumulated, shall be determined by Pharming, but shall not exceed 10% of all issued and outstanding shares of Pharming on a fully diluted basis. Shares transferred or to be transferred, upon exercise of options shall be applied to reduce the maximum number of shares reserved under the plans. Unexercised options can be re-used for granting of options under the option plans.

Pharming may grant options to a member of the Board of Management or an employee:

- At the time of a performance review;
- Only in relation to an individual: a date within the first month of his or her employment;
- In case of an extraordinary achievement;
- In case of a promotion to a new function within Pharming.

The option exercise price is the price of the Pharming shares on the stock exchange on the trading day prior to the date of grant or on the trading day prior to the meeting of the Board of Supervisory Directors during which it was resolved to grant options. Vested options can be exercised at any time within five years following the date of grant. Unexercised options shall be deemed lapsed and shall cease to exist automatically after five years. Exercise of options is subject to compliance with laws and regulations in the Netherlands. Exercise of options is including withholding taxes. Each option is equal to one share unless otherwise stated. Options are not applicable for early retirement.

# **Option plan Board of Management**

Article 2.1 of the option plan for the Board of Management states: 'the Board of Supervisory Directors may, at its sole discretion, (i) grant options to any member (ii) define the conditions attached to the options which need to be fulfilled before the options can be exercised (iii) determine the criteria for the granting of the options. The compensation committee of Pharming will propose (i) the criteria for the granting of options, (ii) whether the criteria for granting an

option have been met by a potential participant and (iii) the number of options to be granted.

The options will, at all times, be granted under the condition that the granting of such options will be approved by the general meeting of shareholders of Pharming.

Article 4.4 of the option plan for the Board of Management reads as follows: 'in case of the termination of the membership of a participant of the Board of Management, except for retirement and death, Pharming at its sole discretion is entitled to decide that the options of the participant shall lapse if the conditions set out in the option granting letter have not been fulfilled at the time of the termination of the membership of the Board of Management'. The Company in its sole discretion may decide to deviate from article 4.4.

At the AGM of 18 June 2014 two members of the Board of Management were granted a total of 19,200,000 options for the period 2014-2018 with annual vesting conditions for the period 2015-2019. The exercise price of the granted options for the first tranche of 2,400,000 options for Mr. S. de Vries and 1,440,000 options for Mr. B.M. Giannetti is €0.505. For the second tranche of 2,400,000 options for Mr. S. de Vries and 1,440,000 options for Mr. B.M. Giannetti is €0.341. For the third tranche of 2,400,000 options for Mr. S. de Vries and 1,440,000 options for Mr. B.M. Giannetti is €0.209. For the fourth tranche of 2,400,000 options for Mr. S. de Vries and 1,440,000 options for Mr. B.M. Giannetti is €0.335. The Fair values of the options vary between €0.177 and €0.366.

At the EGM of 28 October 2015, one member of the Board of Management was granted a total of 1,000,000 options upon appointment with a strike price of €0.335 based on the 20-day VWAP prior to the EGM, immediate vesting and a life of five years from that date. At the AGM of 25 May 2016 one member of the Board of Management was granted a total of 4,000,000 options for the period 2016-2020 with annual vesting conditions for the period 2017-2020. The exercise price of the granted options for the first tranche of 1,000,000 options for Mr. R. Wright is €0.209, and €0.335 for the second tranche. The fair values of the options vary between €0.045 and €0.114 per option.

Vesting of the next tranche of the granted options in 2014 and 2016 per individual member of the Board of Management was based on the requirement to be in service at 31 January 2018. For the options of S. de Vries (12,000,000 options valued at grant date for €3.5 million), B.M. Giannetti

(7,200,000 options valued at grant date for €2.1 million) and R. Wright (4,000,000 options valued at grant date for €0.3 million), Pharming expensed a total amount of €0.4 million in 2018 (2017: €0.8 million).

# **Option plan employees**

Article 2.1 of the option plan for employees' states: 'Pharming may grant options to any employee. The criteria for the granting of the options will be determined by the Board of Supervisory Directors of Pharming, at its sole discretion. The Board of Management will propose (i) whether the criteria for granting an option have been met by a potential participant and (ii) the number of options to be granted. Article 4.4 of the employee option plan deals with the vesting scheme of employee options and reads as follows: 'in case of the termination of the employment of a participant, except for retirement and death, Pharming at its sole discretion is entitled to decide that the options of the participant shall lapse.

The following schedule shall apply for the cancellation:

- In the event of termination of employment within one year as of a date of grant, all options shall lapse;
- In the event of termination of employment after the first year as of a date of grant, all options, less 1/4 of the number of options shall be lapsed. The number of options to be cancelled decreases for each month that the employment continued for more than one year as of that date of grant by 1/48 of the number of options granted of that date of grant.

In 2018, the Company granted 6,320,000 options to employees with a weighted average exercise price of €0.770; fair values for options granted in 2018 were in the range of €0.274 - €0.418.

In 2017, the Company granted 7,715,000 options to employees with a weighted average exercise price of €0.335; fair values for options granted in 2017 were in the range of €0.228 - €0.272.

(please also refer to note 33 in respect of movements since the reporting date):

(i 55 i					
	20	2018		017	
	NUMBER	WEIGHTED AVERAGE EXERCISE PRICE (€)	NUMBER	WEIGHTED AVERAGE EXERCISE PRICE (€)	
BALANCE AT 1 JANUARY	54,901,629	0.408	49,323,785	0.296	
Expired	(76,702)	0.071	(660,194)	0.575	
Granted pre 2018	525,453	0.335			
Exercised	(26,993,174)	0.291	(1,091,651)	0.216	
GRANTED UNDER PLAN FOR:					
Board of Management	-		-		
Employees	6,320,000	0.770	7,715,000	0.335	
FORFEITED UNDER PLAN FOR:					
Board of Management	-		-		
Employees	(356,250)	0.320	(385,311)	0.388	
BALANCE AT 31 DECEMBER	34,320,956	0.532	54,901,629	0.408	
-Vested	16,614,702	0.302			
-Unvested	17,706,254	0.757			

In 2018 a total of 26,993,172 options have been exercised with For the employees, the vesting period and conditions are similar, except the annually vesting date, starting an average exercise price of €0.291. at 1 September 2015 with the first of four tranches. For employees' subsequent sale of the shares is subject to the The weighted average share price at the date of exercise was vesting conditions of the option. The weighted average €1.282 in 2018. remaining contractual life in years of the outstanding options In 2017 a total of 1,091,651 options have been exercised with at 31 December 2018 is 3.2 years (2017: 3.1 years).

an average exercise price of €0.216.

All options outstanding at 31 December 2018 are exercisable with the exception of the unvested options granted to the Board of Management and employees still in service.

The 2014, 2015 and 2016 share options for the Board of Management vest annually. Four of five tranches of the 2014 grant and three of four tranches of the 2015 and two tranches of the 2016 grant are vested as at year-end, under the condition the board members are still in service at vesting date.

Exercise prices of options outstanding at 31 December 2018 and the exercise values are in the following ranges:

	20	018		2017
EXERCISE PRICES IN €	NUMBER	EXERCISE VALUE IN €'000	NUMBER	EXERCISE VALUE IN €'000
0.063 - 0.25	6,578,837	1,374,867	16,647,463	2,825,465
0.25 - 0.50	14,757,996	4,994,403	20,700,280	7,070,067
0.50 - 0.75	824,121	416,181	11,713,886	5,915,506
0.75 – 2.50	12,160,002	11,465,600	5,840,000	6,599,200
BALANCE AT 31 DECEMBER	34,320,956	18,251,051	54,901,629	22,410,238

The following assumptions were used in the Black-Scholes model to determine the fair value of options at grant date:

	2018	2017
Expected time to maturity (employees)	3.2 years	3.1 years
Expected time to maturity (Board of Management)	1.3 years	1.6 years
Volatility (employees)	53-58%	66-74%
Volatility (Board of Management)	-	75-84%
Risk-free interest rate (employees)	-0.25 - 0.20%	-0.24-0.07%
Risk-free interest rate (Board of Management)	-	-0.09 - 0.15%

The range of assumptions used in the Monte Carlo simulation to determine the fair value of long term incentive plan share awards at grant date were:

Volatilities	
Risk-free interest rates	
Dividend yields	
SHARE-BASED COMPENSATION	
Board of Management options	
Employee options	
Long term incentive plan	

BALANCE AT 31 DECEMBER

The decrease of Board of Management options expense in 2018 compared to 2017 results mainly from the decrease of the expense from the options granted in 2014 and 2015 compared to the expense in 2017. The employee options expense increased and reflects the increased fair value of the options granted in 2018.

Long-term incentive plan expenses increased due to the effects of a higher fair value of shares granted compared to 2017.

In 2018 bonus shares were granted to employees for a total amount of €0.7 million.

2018	2017
56%	68%
-0.41%	-0.15%
0.00%	0.00%

2018	2017
395	786
1,285	1,166
1,501	760
708	-
3,889	2,712

# 25. BOARD OF MANAGEMENT

Mr. S. de Vries (Chief Executive Officer), Mr. B.M. Giannetti (Chief Operations Officer) and Mr. R. Wright (Chief Financial Officer) have been members of the Board of Management for the entire year 2018.

The members of the Board of Management are statutory directors.

# Remuneration

Compensation of the members of the Board of Management for 2018 and 2017 was as follows:

amounts in € 'ooo	YEAR	BASE Salary	bonus (i)	SHARE-BASED PAYMENT (II)	POST-EMPLOYMENT BENEFITS (III)	other (iv)	TOTAL
S. de Vries	2018	490	428	325	81	32	1,356
S. de vries	2017	475	330	536	79	32	1,452
B.M. Giannetti	2018	320	233	201	77	8	839
B.W. Glaimetti	2017	309	186	328	78	15	916
D Wright	2018	306	148	167	34	-	655
R. Wright	2017	296	135	203	34	-	668
TOTAL	2018	1,116	809	693	192	40	2,850
TOTAL	2017	1,080	651	1,067	191	47	3,036

(i) Bonuses are related to the achievement of the corporate and personal objectives. Refer to the report of the Remuneration Committee for the review of the performance and the extent the goals have been met.

(ii) Share-based payments are long term benefits and for 2018 relates to options of €0.4 million (2017: €0.8 million) and long-term incentive plan of €0.3 million (2017: €0.3 million).

(iii) Post-employment benefits were in line with previous year.

(iv) Includes lease car compensation and other related expenses.

# **SHARES**

At 31 December 2018, the members of the Board of Management held the following number of shares:

SHARES HELD	AS AT 31 DECEMBER 2018
B.M. Giannetti	1,731,611
S. de Vries	6,120,518
R. Wright	256,400
TOTAL	8,108,529

Since 31 December 2017, all members of the Board of Management have increased their holdings during a regulated open period. All shares held by members of the Board of Management are unrestricted.

# Options

The following table gives an overview of movement number of option holdings of the individual mem Board of Management in 2018 and 2017, the exercise p and expiration dates:

	1 JANUARY 2017	granted 2017-2018
B.M. GIANNE	TTI	
	243,750	-
	1,625,000	-
	7,200,000	-
TOTAL	9,068,750	-
S. DE VRIES		
	375,000	-
	2,500,000	-
	12,000,000	-
TOTAL	14,875,000	-
R. WRIGHT		
	1,000,000	-
	4,000,000	-
TOTAL	5,000,000	-

# IN SERVICE: **31 DECEMBER** 28,943,750 2018

# Loans or guarantees

During the year 2018, no loans or guarantees have been granted to members of the Board of Management. No loans or guarantees to members of the Board of Management were outstanding at 31 December 2018.

(12,100,000)	(375,000)	2,400,000		
-	-	1,000,000	0.355	28 Oct 2020
-	-	4,000,000	0.209 - 1.130	25 May 2021
-	-	5,000,000		
(18,045,000)	(618,750)	10,280,000		

(5,945,000)	(243,750)	2,880,000		
-	(375,000)	-	0.56	13May 2017
(2,500,000)	-	-	0.09	14 May 2018
(9,600,000)	-	2,400,000	1.130	17 June 2019

-	(243,750)	-	0.56	13 May 2017
(1,625,000)	-	-	0.09	14 May 2018
(4,320,000)	-	2,880,000	0.341 -1.130	17 June 2019

**31 DECEMBER** 

2018

EXERCISE

PRICE (€)

nts in
bers of the
ise prices

EXERCISED

2018

FORFEITED/

2017-2018

EXPIRED

EXPIRATION

DATE

# 26. BOARD OF SUPERVISORY DIRECTORS

# Remuneration

The remuneration is based on the position an individual has in the Board of Supervisory Directors (BOSD), the Audit Committee (AC) and the Remuneration Committee (RC). For both 2018 and 2017 the annual compensation is as follows:

BOSD:	chairman €50,000 and member €36,000;
Audit Committee:	chairman €9,000 and member €3,000; and
Remuneration committee	chairman €6,000 and member €3,000.

An additional compensation of €1,000 per day is paid in case of extraordinary activities.

Compensation of the members of the Board of Supervisory Directors for 2018 and 2017 was as follows:

amounts in € 'ooo	YEAR	BOSD	AC	RC	EXTRA-ORDINARY	SHARE-BASED Payment	TOTAL
P. Sekhri	2018	50	-	-	-	30	80
	2017	50	-	-	-	32	82
J. Blaak *	2018	18	-	2	-	18	38
	2017	36	-	3	-	31	70
J.H.L. Ernst	2018	36	3	3	-	26	68
	2017	36	3	3	-	31	73
J.B. Ward	2018	36	-	6	-	26	68
	2017	36	3	6	-	31	76
A. de Winter	2018	36	9	-	-	26	71
	2017	36	9	-	-	31	76
J. Egberts	2018	36	3	-	-	20	59
	2017	36	3	-	-	25	64
TOTAL	2018	212	15	11	-	146	384
	2017	230	18	12	-	181	441

\* Mr. J. Blaak retired from the BOSD at 23 May 2018

# Shares, options and warrants

Members of the Board of Supervisory Directors do not participate in an option plan. In 2018, a total of 125,000 LTIP shares were granted at the AGM, held on 23 May 2018.

The following table gives an overview of movements in number of LTIP shares of the individual members of the Board of Supervisory Directors:

amounts in € 'ooo	YEAR	GRANTED	SETTLED	FORFEITED	NOT VESTED	RESERVED AT 31 DECEMBER 2018
J.H.L. Ernst	2018	25,000	-	-	-	25,000
	2017	125,000	-	-	-	125,000
	2016	125,000	-	-	-	125,000
	2015	125,000	(75,000)	-	(50,000)	-
	2014	125,000	(25,000)	-	(100,000)	-
J.B. Ward	2018	25,000	-	-	-	25,000
	2017	125,000	-	-	-	125,000
	2016	125,000	-	-	-	125,000
	2015	125,000	(75,000)	-	(50,000)	-
	2014	125,000	(25,000)	-	(100,000)	-
A. de Winter	2018	25,000	-	-	-	25,000
	2017	125,000	-	-	-	125,000
	2016	125,000	-	-	-	125,000
	2015	125,000	(75,000)	-	(50,000)	-
	2014	125,000	(25,000)	-	(100,000)	-
P. Sekhri	2018	30,000	-	-	-	30,000
	2017	150,000	-	-	-	150,000
	2016	100,000	-	-	-	100,000
	2015	100,000	(60,000)	-	(40,000)	-
J. Egberts	2018	20,000	-	-	-	20,000
	2017	100,000	-	-	-	100,000
	2016	100,000	-	-	-	100,000
	2015	100,000	(60,000)	-	(40,000)	-
TOTAL	2018	125,000	-	-	-	125,000
	2017	625,000	-	-	-	625,000
	2016	575,000	-	-	-	575,000
	2015	575,000	(345,000)	-	(230,000)	-
	2014	375,000	(75,000)	-	(300,000)	-

## Shares

At 31 December 2018, the members of the Board of Supervisory Directors held the following numbers of shares:

SHARES HELD	AS AT 31 DECEMBER 2018
P. Sekhri	110,000
A. de Winter	50,000
J.B. Ward	150,000
J.H.L. Ernst	200,000
J. Egberts	490,000
TOTAL	1,000,000

All shares held by members of the Board of Supervisory Directors are unrestricted.

### Loans or guarantees

During the year 2018, the Company has not granted loans or guarantees to any member of the Board of Supervisory Directors. No loans or guarantees to members of the Board of Supervisory Directors were outstanding at 31 December 2018.

# 27. WARRANTS

An overview of activity in the number of warrants for the years 2018 and 2017 is as follows:

	20	018	2017		
	NUMBER	WEIGHTED AVERAGE EXERCISE PRICE (€)	NUMBER	WEIGHTED AVERAGE EXERCISE PRICE (€)	
BALANCE AT 1 JANUARY	15,251,000	0.373	92,228,283	0.281	
Issued	-	-	9,174,372	0.455	
Exercised	(14,802,056)	0.376	(86,151,655)	0.283	
Expired	-	-	-	-	
BALANCE AT 31 DECEMBER	448,944	0.284	15,251,000	0.373	

The weighted average of the remaining contractual life in years of the outstanding warrants at 31 December 2018 is 2.9 years.

In 2018 no warrants were issued

In 2017, the Company issued a total of 9,174,372 warrants with an exercise price of €0.455 in connection with the refinancing of the old loans and the amortising bonds. All of these warrants have been reclassified as derivative financial liabilities.

Overall, the number of outstanding warrants at 31 December 2018 consisted of:

WARRANT PRICES IN €	
0.135	
0.284	
0.455	
BALANCE AT 31 DECEMBER 2018	

In order to protect the warrant holders from the (potential) effects of dilution, both the number of warrants as well as their exercise prices can be adjusted in the event of issue of new shares or share rights (e.g. Warrants) for conditions more favourable than for existing warrant holders (e.g. Issue of new shares at a consideration below the existing exercise price); a number of transactions, such as the issue of options to members of the Board of Management and employees, are excluded from these adjustment clauses.

# 28. RELATED PARTY TRANSACTIONS

Related parties' disclosure relates entirely to key management compensation. Key management includes the members of the Board of Management and the Board of Supervisory Directors of Pharming.

## AMOUNTS IN € 'OOO

Salaries and other short-term employee benefits

Post-employment benefits

Share-based compensation

# TOTAL

All direct transactions with members of the Board of Management and Board of Supervisory Directors have been disclosed in notes 25 and 26 of these financial statements. At 31 December 2018, the Company had a payable balance of a total amount of €0.7 million (2017: €0.8 million) to members of the Board of Management and Board of Supervisory Directors.



2018	2017
2,203	2,038
193	191
839	1,248
3,235	3,477

# 29. DEFERRED TAX

The significant components and annual movements of deferred income tax assets as of December 31, 2018 and January 1, 2018 , are as follows:

amounts in € 'ooo	NOTES	2018	2017
Intangible fixed assets		11,822	-
Short term assets		907	-
Other financial assets	30	10,941	-
Accruals		786	-
Other		-	-
Tax losses		10,626	9,442
TOTAL DEFERRED TAX ASSETS		35,082	9,442

amounts in € '000	INTANGIBLE FIXED ASSETS	SHORT TERM ASSETS / LIABI- LITIES	OTHER FINANCIAL LIABILITIES	ACCRUALS	OTHER	TAX LOSSES	TOTAL
AT 1 JANUARY 2017	-	-	-	-	-	-	-
(Charged)/credited							
- to profit or loss	-	-	-	-	-	9,442	9,442
- to other comprehensive income	-	-	-	-	-	-	-
AT 31 DECEMBER 2017	-	-	-	-	-	9,442	9,442
(Charged)/credited							
- to profit or loss	11,822	907	10,941	746	-	1,138	25,554
- to other comprehensive income	-	-	-	40	-	46	86
AT 31 DECEMBER 2018	11,822	907	10,941	786		10,626	35,082

Based upon latest budget 2019 and forecasts of years thereafter it is considered more likely than not that there will be sufficient taxable profits in the future such as to realise the deferred tax assets, and therefore these assets have been recognised in these financial statements.

Deferred taxes relating to intangible fixed assets represent the tax effect on temporary difference between the tax base and the carrying amount of research and development intangibles, which were transferred within the Group. These deferred taxes will be realised through the amortisation of the intangible assets once in use within the fiscal unity.

Short term assets and liabilities represent deferred tax assets recognised for temporary differences between the carrying amount and tax bases of deferred license fees. These deferred taxes will be realised in the next three years.

Deferred taxes relating to other financial liabilities represent the tax effect on temporary difference between the tax base and the carrying amount of contingent liabilities (see note 30).

Accruals represent deferred tax assets recognised for temporary differences between the carrying amount and tax bases of accrued liabilities.

The unused tax losses were incurred by the Dutch fiscal unity.

The calculation of the deferred tax losses is as shown below:

#### AMOUNTS IN € 'OOO

#### **NET OPERATING LOSSES - NETHERLANDS**

Net Operating Losses at year-end

Portion selected for deferred tax asset

Tax rates used:

2018/2019:25%

2020:22,55%

2021 and later: 20,5%

TOTAL TAX EFFECT NETHERLANDS

## **NET OPERATING LOSSES - US**

Net Operating Losses at year-end (\$ 11,824)

Portion selected for deferred tax asset

Tax rate used:

2018 and later: 21%

TOTAL TAX EFFECT US

Tax effect Netherlands - losses deferred

Tax effect US - losses deferred

# TOTAL DEFERRED TAX ASSET

The losses carry forward expire in the period 2021 - 2025. The current part of the net deferred tax assets is €7.1 million.

2018	2017
47,727	104,159
47,727	28,598
2,443	7,140
4,428	-
3,755	-
10,626	7,140
-	9,873
-	9,873
-	2,302
	2,302
10,626	7,140
-	2,302
10,626	9,442

The component and annual movement of deferred income tax liabilities as of December 31, 2018 and January 1, 2018, are as follows:

amounts in € 'ooo	2018	2017
Other liabilities	(86)	-
TOTAL DEFERRED TAX LIABILITIES	(86)	-

amounts in € 'ooo	OTHER LIABILITIES	TOTAL
AT 1 JANUARY 2017		
(Charged)/credited		
- to profit or loss	-	-
- to other comprehensive income	-	-
AT 31 DECEMBER 2017	-	-
(Charged)/credited		
- to profit or loss	(86)	(86)
- to other comprehensive income	-	-
AT 31 DECEMBER 2018	(86)	(86)

# **30. BUSINESS COMBINATIONS AND** CONTINGENT CONSIDERATION

In 2018, the Company did not complete any new acquisition of business.

In 2016 Pharming completed the acquisition of all North American commercialisation rights for its own product RUCONEST® from Valeant. Pharming paid an upfront amount of US\$60 million, and committed future payments up to a further US\$65 million, based on achievement of certain sales milestones. After this acquisition, Pharming became responsible for selling RUCONEST® directly in the US.

The fair value of the contingent consideration, which is reflected in Other financial liabilities, is based on becoming due within two years. Accordingly, the Company has increased the fair value of the contingent consideration from €28.3 million at year-end 2017 to €49.5 million at year-end 2018, by taking a charge to the income statement of €21.2 million

(2017: €23.6 million). See also note 10. Over the course of 2018, as sales have continued to grow and to accelerate, the paying of the first milestone became due. The Board of Management also believes that it is probable that the other sales milestones will be achieved within the coming years. The increased fair value of the contingent consideration reflects the increased probability of achieving those milestones.

# **31. COMMITMENTS AND CONTINGENCIES**

The Company has lease agreements for the rent of offices, laboratory and production facilities, as well as lease cars for employees. The total commitments decreased to €8.5 million at year-end 2018, from €9.7 million in 2017. The decrease is due to decreasing remaining terms of existing agreements.

amounts in € 'ooo	2018
Within one year	1,967
After one year but not more than five years	5,019
More than five years	1,471
TOTAL	8,457

Operating lease charges of €1.9 million were taken to the profit and loss in 2018 (2017: €1.6 million).

# Material agreements

At the end of 2018 the Company had several agreements with third parties related to the manufacturing of RUCONEST®and development of new products. In these agreements certain minimum volumes are committed. Total potential liabilities under these agreements are approximately €43 million (2017: €66 million), of which €18 million relates to 2019 and €25 million for 2020-2021. All expenditures relate to the cost of goods.

2017	
1,828	
5,770	
2,103	
9,701	

# **32. FINANCIAL RISK MANAGEMENT**

## General

Pharming is exposed to several financial risks: market risks (being currency risk and interest rate risk), credit risks and liquidity risks. The Board of Management is responsible for the management of currency, interest, credit and liquidity risks and as such ultimately responsible for decisions taken in this field.

# **Capital risk management**

The Company manages its capital to ensure that it will be able to continue as a going concern. This includes a regular review of cash flow forecasts and, if deemed appropriate, subsequent raising of funds through execution of equity and/ or debt transactions. In doing so, the Board of Management's strategy is to achieve a capital structure which takes into account the best interests of all stakeholders. Pharming's capital structure includes cash and cash equivalents, debt and equity. Compared to last year there have been no significant changes in risk management policies.

# **Currency risk**

This is the risk that the fair value of future cash flows of a financial instrument will fluctuate because of changes in foreign exchange rates. Pharming's policy for the management of foreign currency risks is aimed at protecting the operating results and positions held in foreign currencies, in particular of the United States dollar (US dollar). Certain payments and sales of RUCONEST® in the US are being and will be received in US dollar. Repayments and interest payments of the loans are made in US dollar. Some direct payments of US activities are carried in US dollar through the Dutch entities. At 31 December 2018 the Group's cash and cash equivalents, including restricted cash, amounted to €81.5 million. This balance consists of cash assets denominated in € for a total amount of €8.9 million and cash assets in US dollar for a total amount of US\$83.0 million or €72.6 million (applying an exchange rate EUR/US\$ at 31 December 2018 of 1.1439). The US dollar cash balance will be used for the commercialisation activities of the US organisation and to cover the operating costs of the activities in the EU and RoW.

The carrying value of the loan at 31 December 2018 was US\$82.9 million or €72.5 million. Next to the loan the Group has a contingent consideration of US\$56.6 million (€49.5 million) as a liability on the balance sheet. The other assets and liabilities denominated in USD amounted in total respectively US\$17.9 million (€15.6 million) and US\$18.1 million (€15.8 million). We performed a sensitivity analysis

by applying an adjustment to the spot rate at year-end. As the balance of the loan, the cash and cash equivalents, the contingent consideration and other assets and liabilities, denominated in US dollar, at year-end is US\$ 56.5 million, a 10% strengthening or weakening of the euro versus US dollar has an impact of €4.9 million on the Group's gain (strengthening of the euro) or loss (weakening of the euro).

The fact that US sales is increasing, and the repayment of the loan, denominated in USD, has started, there is no natural hedge anymore between those amounts. The Company is making plans for the introduction of an integrated treasury policy involving non-speculative hedging instruments such as forward purchases and sales to enable this risk to be managed and contained.

# Interest rate risk

Interest rate risk is the risk that the fair value of future cash flows of a financial instrument will fluctuate because of changes in market interest rates. Pharming's interest rate risk policy is aimed at minimising the interest rate risks associated with the financing of the Company and thus at the same time optimising the net interest costs. This policy translates into a certain desired profile of fixed-interest and floating interest positions, including those generated by cash and cash equivalents and those paid on finance lease liabilities. The Company performed a sensitivity analysis in which the effect of a 1% interest increase, or 1% interest decrease on the carrying value of the financial instruments at year-end 2018 was measured. Pharming concluded that the total effect taking place on the carrying value of these items would be approximately €0.8 million. If interest rates begin to rise, then the Company plans to begin a policy of nonspeculative interest rate hedges using ordinary commercial instruments designed for that purpose.

### Credit risk

Credit risk is defined as the risk that one party to a financial instrument will cause a financial loss for the other party by failing to discharge obligations. Pharming manages credit risk exposure through the selection of financial institutions having a high credit rating, using credit rating reports issued by institutions such as standard & poor's and Moody's. The exposure to credit risk at 31 December 2018 is represented by the carrying amounts of cash and cash equivalents and trade and other receivables.

The carrying amounts of the cash and cash equivalents (including restricted cash) as at 31 December 2018 amounted to €81.5 million and was held through financial institutions with a BBB+ and an A rating from Standard & Poor's, A1-A3 ratings from Moody's and A+ ratings from Fitch.

Trade and other receivables at 31 December 2018 amounted to €17.8 million. As at the date of these financial statements, these amounts have largely been settled, including receipts in cash and receipt of goods and services in exchange of prepaid expense items. Based on the credit ratings of cash and cash equivalents (including restricted cash) as well as the position taken with respect to trade and other receivables, the Company considers that this risk is adequately managed.

### Liquidity risk

The liquidity risk refers to the risk that an entity will encounter difficulty in meeting obligations associated with financial liabilities. Pharming's objective is to maintain a minimum level and certain ratio of cash and cash equivalents (including short-term deposits). The strategy of the Company is to repay its obligations through generation of cash income from operating activities such as product sales and licensing agreements. In case such cash flows are insufficient, the Company relies on financing cash flows as provided through the issuance of shares or incurring financial liabilities. Note 3 of these financial statements more extensively describe the Company's going concern assessment.

The following table presents the financial liabilities at yearend 2018, showing the remaining undiscounted contractual amounts due including nominal interest. Liabilities denominated in foreign currency have been converted at the exchange rate at 31 December 2018. Other financial liabilities comprise the contingent consideration provision for the expected future milestones due to Valeant, as explained further in note 30.

amounts in €'000	2019	2020	2021	2022	2023	TOTAL	total 2018-2022
Trade and other payables	28,589	-	-	-	-	28,589	27,198
Derivative financial liabilities	228	-	-	-	-	228	8,301
Loans and borrowings	39,034	35,033	16,163	-	-	90,230	116,917
Other financial liabilities	17,484	17,484	21,855	-	-	56,823	54,271
Finance lease liabilities	263	180	-	-	-	443	773
TOTAL	85,598	52,697	38,018	-	-	176,313	197,170

# Fair value estimation

The Company uses the following hierarchy for determining the fair value of financial instruments measured at fair value:

- Level 1: Quoted prices (unadjusted) in active markets for identical assets or liabilities:
- Level 2: Inputs other than guoted prices included within level 1 that are observable for the asset or liability, either directly (that is, as prices) or indirectly (that is, derived from prices);
- Level 3: Inputs for the asset or liability that are not based on observable market data or which are based on the probability of future events occurring (that is, unobservable inputs).

The following table presents the liabilities that are measured at fair value at year-end 2018 and 2017:

# AMOUNTS IN € 'OOO

Derivative financial liabilities\*

Other financial liabilities\*\*

# BALANCE AT 31 DECEMBER

\* Prior year's financial statements have been restated, as disclosed in note 4

\*\* This amounts reflects the fair value of the contingent consideration

The derivative financial liabilities measured at fair through profit or loss include warrants not public and for which no other observable inputs are avail Accordingly, the fair value of the warrants has been determined through the Black-Scholes model, app following parameters per the end of:

20'	18	<b>20</b> ' resta	
LEVEL 3	TOTAL	LEVEL 3	TOTAL
228	228	10,081	10,081
49,518	49,518	28,319	28,319
49,746	49,746	38,400	38,400

ir value		2018	2017
cly traded ilable. en	Expected time to maturity of warrants in issue	2.9 years	3.4 years
plying the	Volatility	58%	81%
	Risk-free interest rate	-0.10%	-0.26 - 0.16%

As described in note 2.4 (Significant accounting judgments and *estimates*) the Company has performed a sensitivity analysis which demonstrates the potential possible effects in the event that derivative financial liabilities are settled for shares at a fair value price different from the exercise value.

The following table includes carrying values and the estimated fair values of financial instruments:

2018		2017 restated*		
CARRYING VALUE	FAIR VALUE	CARRYING VALUE	FAIR VALUE	
81,515	81,515	59,993	59,993	
17,814	17,814	11,260	11,260	
72,502	72,502	80,646	80,646	
427	427	653	653	
28,589	28,589	27,198	27,198	
228	228	10,081	10,081	
	CARRYING VALUE 81,515 17,814 72,502 427 28,589	CARRYING VALUE         FAIR VALUE           81,515         81,515           17,814         17,814           17,2502         72,502           427         427           28,589         28,589	CARRYING VALUE         FAIR VALUE         CARRYING VALUE           81,515         81,515         59,993           17,814         17,814         11,260           72,502         72,502         80,646           427         427         653           28,589         28,589         27,198	

\* Prior year's financial statements have been restated, as disclosed in note 4

The above fair values of financial instruments are based on internal calculations with the exception of the warrant and conversion option in the derivative financial liabilities as calculated by an independent valuator. Cash and cash equivalents, trade and other receivables as well as trade and other payables are stated at carrying amount, which approximates the fair value in view of the short maturity

of these instruments. The fair values of finance lease liabilities and loans and borrowings (both non-current and current portion) are based on arm's length transactions.

The net debt sets out an analysis for each of the period presented, showing the remaining undiscounted contractual amounts due including nominal interest:

amounts in € '000	2018	2017
Cash and cash equivalents	80,311	58,657
Loans and borrowings - repayable within one year	(39,034)	(25,381)
Loans and borrowings - repayable after one year	(51,196)	(81,753)
NET DEBT	(9,919)	(48,477)
Cash and cash equivalents	80,311	58,657
Gross debt - fixed interest rates	(90,230)	(105,410)
Gross debt - variable interest rates	-	(1,724)
NET DEBT	(9,919)	(48,477)

# **33. EARNINGS PER SHARE AND FULLY-DILUTED SHARES**

Basic earnings per share is calculated based on the weighted average number of ordinary shares outstanding during the year. Diluted earnings per share is computed based on the weighted average number of ordinary shares outstanding including the dilutive effect of shares to be issued in the future under certain arrangements such as option plans and warrants issued. For 2018 and 2017, the basic and fully diluted profit (loss) per share is:

	2018	<b>2017</b> restated*
Net profit, (loss) attributable to equity owners of the parent (in €'000)	24,993	(76,247)
Weighted average shares outstanding	606,618,117	500,412,774
Basic profit (loss) per share (in €)	0.041	(0.152)
Weighted average fully-diluted shares outstanding	653,527,702	n/a
Fully-diluted profit per share (in €)	0.038	n/a

\* Prior year's financial statements have been restated, as disclosed in note 4

# **Fully-diluted shares**

The composition of the number of shares and share rights outstanding as well as authorised share capital as per 31 December 2018 and the date of these financial statements is provided in the following table.

Movements between 31 December 2018 and 28 March 2019:

	31 DECEMBER 2018	SHARES ISSUED	SHARES RESERVED	28 ма <b>ксн 201</b> 9
Shares	621,501,238	733,107		622,234,345
Warrants	448,944	(180,000)		268,944
Options	34,320,956	(550,597)		33,770,359
Convertible bonds	-			-
LTIP	7,381,586			7,381,586
ISSUED	663,652,724	2,510	-	663,655,234
Available for issue	136,347,276	(2,510)		136,344,766
AUTHORISED SHARE CAPITAL	800,000,000	-	-	800,000,000

- In March 2019, Pharming paid the first milestone due to Bausch Health Companies Inc. (formerly Valeant Pharmaceuticals International, Inc.) of €17.5 million (US\$20 million). This payment became due when cumulative net sales in the USA reached a certain undisclosed threshold level. Up to a total of an additional €39.3 million (\$45 million) of milestones may be due in future years if cumulative net sales in any one year reaches additional specific undisclosed higher levels.
- Also in March 2019, the Company committed to make a small €4.1 million investment in its fill and finish partner BioConnection B.V. ("BioConnection") composed of €1.6 million of cash and €2.5 million of debt converted to equity. This investment also involves the acceptance by Pharming of a corporate guarantee of up to €3 million in favour of ABN AMRO in respect of BioConnection. The entire transaction is intended to support BioConnection in taking out up to €12.1 million of new facilities to enable it to expand capacity almost four fold, to benefit specifically Pharming as well as other clients. BioConnection is a profitable company.

# **COMPANY STATEMENT OF INCOME**

For the year ended 31 December

AMOUNTS IN € 'OOO

#### REVENUES

COSTS

#### **OPERATING RESULT**

Fair value gain (loss) on revaluation derivatives \*

Other financial income and expenses \*

# FINANCIAL INCOME AND EXPENSES

**RESULT BEFORE INCOME TAX** 

Income tax credit (expense)

NET RESULT FOR THE YEAR

Share in result of investments

# **TOTAL NET RESULT**

\* Prior year's financial statements have been restated, as disclosed in note 3

2017 restated *	2018	NOTES	
136	25,725		
(10,620)	(14,786)		
(10,484)	10,939	13	
(42,063)	(495)		
(40,704)	(18,950)		
(82,767)	(19,445)		
(93,251)	(8,506)		
7,139	27,070		
(86,112)	18,564		
9,865	18,327		
(76,247)	36,891		
		disclosed in note a	nd as d

The notes are an integral part of these financial statements

# **COMPANY BALANCE SHEET**

For the year ended 31 December

(after proposed appropriation of net profit)

amounts in € 'ooo	NOTES	2018	<b>2017</b> restated *
Intangible assets		469	469
Property, plant and equipment	4	675	689
Deferred tax asset	5	34,296	7,139
Financial assets	9	108,147	91,795
NON-CURRENT ASSETS		143,587	100,092
Trade and other receivables	6	288	894
Cash and cash equivalents	7	6,006	9,032
CURRENT ASSETS		6,294	9,926
TOTAL ASSETS		149,881	110,018
Share capital		6,215	5,790
Share premium *		387,525	363,818
Legal reserves		1,647	(938)
Accumulated deficit *		(321,738)	(352,560)
SHAREHOLDERS' EQUITY	8	73,649	16,110
Loans and borrowings *	10	37,267	59,161
NON-CURRENT LIABILITIES		37,267	59,161
Loans and borrowings *	10	35,235	22,398
Deferred tax liabilities	5	86	-
Derivative financial liabilities	11	228	10,080
Taxes payable		1,601	173
Trade and other payables	12	1,815	2,096
CURRENT LIABILITIES		38,965	34,747
TOTAL SHAREHOLDERS' EQUITY AND LIABI		149,881	110,018

\* Prior year's financial statements have been restated, as disclosed in note 3

# NOTES TO THE COMPANY FINANCIAL STATEMENTS

# **1.GENERAL**

Within Pharming, the entity Pharming Group N.V. acts as a holding company of the operating companies. Its activities are limited to the arrangement of financial transactions with third parties and to provide the operating companies with support in the field of legal, financial, human resources, public relations, IT and other services.

# 2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

The Company financial statements have been prepared in accordance with accounting principles generally accepted in the Netherlands. The accounting policies applied are the same as those used in the consolidated financial statements in accordance with the provisions of article 362-8 of book 2 of the Dutch Civil Code, except for investments in subsidiaries which are accounted for using the equity method.

Investments in subsidiaries are those investments with a positive equity value. In the event the equity value of a group company together with any long-term interests that, in substance, form part of our net investment in the group company, becomes negative, additional losses are provided for, and a liability is recognised, only to the extent that we have incurred legal or constructive obligations or made payments on behalf of the subsidiary.

# **3. RESTATEMENT OF PRIOR YEAR**

The Company restated prior year's financial statements. The backgrounds of this restatement have been provided in note 4 of the consolidated financial statements.

# Company statement of income

For the year ended 31 December

amounts in € 'ooo	<b>2017</b> AS REPORTED	RESTATEMENT	<b>2017</b> restated
OPERATING RESULT	(10,484)	-	(10,484)
Fair value gain (loss) on revaluation derivatives	(40,284)	(1,779)	(42,063)
Other financial income and expenses	(46,193)	5,489	(40,704)
FINANCIAL INCOME AND EXPENSES	(86,477)	3,710	(82,767)
RESULT BEFORE INCOME TAX	(96,961)	3,710	(93,251)
Income tax credit (expense)	7,139	-	7,139
NET RESULT FOR THE YEAR	(89,822)	3,710	(86,112)
Share in results of investments	9,865	-	9,865
TOTAL NET RESULT	(79,957)	3,710	(76,247)

# Company balance sheet

As at 31 December

amounts in € '000	2017 AS REPORTED	RESTATEMENT	<b>2017</b> restated
Shareholders' equity	18,802	(2,692)	16,110
Total non-current liabilities	58,684	477	59,161
Total current liabilities	32,532	2,215	34,747
TOTAL EQUITY AND LIABILITIES	110,018	-	110,018

# 4. PROPERTY, PLANT AND EQUIPMENT

Property, plant and equipment include leasehold improvements related to office investments in the Company's headquarters and other items such as office furniture and equipment as well s hardware and softw

amounts in € '000	LEASEHOLD IMPROVEMENTS	OPERATIONAL FACILITIES	OTHER	TOTAL
At cost	747	544	675	1,966
Accumulated depreciation	(746)	(118)	(444)	(1,308)
CARRYING VALUE AT 1 JANUARY 2017	1	426	231	658
Investments	-	82	131	213
Depreciation charges	-	(113)	(69)	(182)
MOVEMENT 2017	-	(31)	62	31
At cost	747	626	806	2,179
Accumulated depreciation	(746)	(231)	(513)	(1,490)
CARRYING VALUE AT 31 DECEMBER 2017	1	395	293	689
Investments	-	96	116	212
Depreciation charges	(1)	(127)	(98)	(226)
movement 2018	(1)	(31)	18	(14)
At cost	747	722	922	2,391
Accumulated depreciation	(747)	(358)	(611)	(1,716)
CARRYING VALUE AT 31 DECEMBER 2018		364	311	675

# 5. DEFERRED TAX

The significant components and annual movements of deferred income tax assets as of December 31, 2018 and January 1, 2018 , are as follows:

# DEFERRED TAX ASSETS

Intangible fixed assets

Short term assets / liabilities

Other financial liabilities

Accruals

Other

Tax losses

TOTAL DEFERRED TAX ASSETS

2018	2017
11,822	-
907	-
10,941	-
-	-
-	-
10,626	7,139
34,296	7,139

amounts in € 'ooo	INTANGIBLE FIXED ASSETS	SHORT TERM ASSETS / LIABILITIES	OTHER FINAN- CIAL LIABILI- TIES	ACCRUALS	OTHER	TAX LOSSES	TOTAL
AT 1 JANUARY 2017	-	-	-	-	-	-	-
(Charged)/credited							
- to profit or loss	-	-	-	-	-	7,139	7,139
- to other comprehensive income	-	-	-	-	-	-	-
AT 31 DECEMBER 2017	-	-	-	-	-	7,139	7,139
(Charged)/credited							
- to profit or loss	11,822	907	10,941	-	-	3,487	27,157
- to other comprehensive income	-	-	-		-		-
AT 31 DECEMBER 2018	11,822	907	10,941			10,626	34,296

For more information on deferred taxes see note 29 to the consolidated financial statements.

The component and annual movement of deferred income tax liabilities as of December 31, 2018 and January 1, 2018 , are as follows:

amounts in € '000	2018	2017
DEFERRED TAX LIABILITIES		
Other liabilities	(86)	-
TOTAL DEFERRED TAX LIABILITIES	(86)	-

amounts in € '000	OTHER LIABILITIES	TOTAL
AT 1 JANUARY 2017		
(Charged)/credited		
- to profit or loss	-	-
- to other comprehensive income	-	-
AT 31 DECEMBER 2017	-	-
(Charged)/credited		
- to profit or loss	(86)	(86)
- to other comprehensive income	-	-
AT 31 DECEMBER 2018	(86)	(86)

### 6. TRADE AND OTHER RECEIVABLES

amounts in € 'ooo	2018
Prepaid expenses	286
Value added tax	-
Other receivables	2
BALANCE AT 31 DECEMBER	288

Trade and other receivables at 31 December 2018 are substantially short-term in nature and have largely been settled as per the date of these financial statements.

### 7. CASH AND CASH EQUIVALENTS

amounts in € 'ooo	2018
Cash and cash equivalents	6,006

BALANCE AT 31 DECEMBER 6,006

The holding company Pharming Group N.V. has entered into a joint liability agreement with a bank and other group companies. Pursuant to this agreement, the entity at 31 December 2018 is jointly liable for commitments relating to bank guarantees from other group companies for an aggregate amount of €0.2 million with a maturity of more than one year after the end of the reporting year.

### 8. SHAREHOLDERS' EQUITY

The Company's authorised share capital amounts to €8.0 million and is divided into 800,000,000 ordinary shares with a nominal value of €0.01 each. All 621,501,238 shares outstanding at 31 December 2018 have been fully paid-up.

2017	
285	
588	
21	
894	

2017 9,032

#### 9,032

Movements in shareholders' equity for 2018 and 2017 were as follows:

amounts in € 'ooo	2018	<b>2017</b> restated*
BALANCE AT 1 JANUARY	16,110	27,467
Net profit (loss) *	36,891	(76,247)
Foreign currency translation	348	(998)
TOTAL COMPREHENSIVE	37,239	(77,245)
Share-based compensation	3,889	2,712
Bonuses settled in shares	(664)	255
Shares issued for cash	-	-
Warrants issued and exercised	6,142	18,238
Conversion option exercised	3,145	44,507
Options exercised	7,788	176
TOTAL TRANSACTIONS WITH OWNERS	20,300	65,888
BALANCE AT 31 DECEMBER	73,649	16,110

\* Prior year's financial statements have been restated, as disclosed in note 3

For a detailed movement schedule of equity for the years 2018 and 2017, please refer to the consolidated statement of changes in equity.

The difference between parent company equity and equity as per the consolidated financial statements consists of the shareholder's deficit of €11.9 million of Pharming Healthcare, Inc.

The investment in Pharming Healthcare, Inc. is included in the consolidated financial statements at its negative equity value, €11.9 million, while in the parent company financial statements the investment in Pharming Healthcare, Inc. has been valued at nil.

The parent company is not liable nor has it issued guarantees for the debts of Pharming Healthcare, Inc.

The movement in the equity difference between consolidated and parent company financial statements was as follows:

amounts in € 'ooo	2018
Consolidated financial statements	61,751
Negative equity Pharming Healthcare, Inc.	11,898
PARENT COMPANY FINANCIAL STATEMENTS	73,649

The difference in net result between consolidated and parent company financial statements can be specified as follows:

amounts in € '000	2018
Consolidated financial statements	24,993
Negative equity Pharming Healthcare, Inc.	11,898
PARENT COMPANY FINANCIAL STATEMENTS	36,891

### 9. FINANCIAL ASSETS

Movement of the provision for investments for the years 2018 and 2017 was as follows:

amounts in € 'ooo	2018	2017
BALANCE AT 1 JANUARY	(196,682)	(208,730)
Share in results of investments	6,429	9,865
Revaluation investment Pharming Healthcare, Inc.	11,898	-
Exchange rate effects	348	2,183
Other	-	-
BALANCE AT 31 DECEMBER	(178,007)	(196,682)

At year-end 2018 and 2017, the provision for subsidiaries was off-set with the following receivable balances from Pharming Group N.V.:

amounts in € 'ooo	2018	2017
Provision for investments	(178,007)	(196,682)
Receivable	286,154	288,477
INVESTMENT	108,147	91,795
Of which classified as provision for investments	-	-
RECEIVABLE FROM GROUP COMPANIES	108,147	91,795

The investment in Pharming Healthcare, Inc. is valued at nil as the parent company is not liable nor has it issued guarantees for the debts of Pharming Healthcare, Inc. Pharming Healthcare, Inc. has per 31 December 2018 a shareholder's deficit of €11.9 million (2017: a deficit of € 16.0 million). Pharming Healthcare, Inc. realised a net profit of € 3.8 million in 2018.

### **10. LOANS AND BORROWINGS**

The backgrounds of the loans and borrowings have been provided in note 19 of the consolidated financial statements.

### **11. DERIVATIVE FINANCIAL LIABILITIES**

The backgrounds of the derivative financial liabilities have been provided in note 22 of the consolidated financial statements.

### **12. TRADE AND OTHER PAYABLES**

2018	2017
811	852
-	-
718	751
286	493
1,815	2,096
	811 - 718 286

The amount of deferred compensation due to related parties involves members of the Board of Management and includes bonuses, holiday allowances and holiday rights.

### **13. OPERATING RESULT**

Operating results in 2018 and 2017 include costs of sharebased compensation in the amount of respective €3.6 million and €2.7 million, as disclosed in note 24 of the consolidated financial statements. These charges include those related to members of the Board of Management and employees.

### **14. EMPLOYEE INFORMATION**

All employees of Pharming Group N.V. in both 2018 and 2017 were based in the Netherlands and France. The weighted average number of full-time equivalent employees in 2018 was 29 (2017: 23) and the number of employees at 31 December 2018 was 31 (31 December 2017: 27). The weighted average number of employees working outside the Netherlands was 11 (2017: 10).

### **15. RELATED PARTY TRANSACTIONS**

Related parties' disclosure relates entirely to the key management of Pharming, being represented by the members of the Board of Management and the Board of Supervisory Directors. All direct transactions with members of the Board of Management and Board of Supervisory Directors have been disclosed in notes 25 and 26 of the consolidated financial statements. At 31 December 2018, the Company owed a total amount of €0.7 million to members of the Board of Management with respect to their compensation (see note 12 of the Company financial statements).

### 16. COMMITMENTS AND CONTINGENCIES

The Company has lease agreements for the rent of office and laboratory facilities, as well as lease cars for employees. The total commitments as per 31 December 2018 decreased to €2.0 million (2017: €2.4 million) due to decreasing remaining terms of existing agreements.

amounts in € '000	2018	2017
Within one year	280	283
After one year but not more than five years	1,103	1,124
More than five years	636	943
TOTAL	2,019	2,350

Operating lease charges of €0.3 million were taken to the profit and loss in 2018 (2017: €0.3).

### **17. DISTRIBUTION OF PROFIT**

The Board of Management, with the approval of the Board of Supervisory Directors, proposes to forward the net profit for the year 2018 of €36.9 million to the accumulated deficit.

## INDEPENDENT AUDITOR'S REPORT

To: the general meeting and board of supervisory directors of Pharming Group N.V.

### **REPORT ON THE FINANCIAL STATEMENTS 2018**

#### **OUR OPINION**

#### In our opinion:

- Pharming Group N.V.'s consolidated financial statements give a true and fair view of the financial position of the Group as at 31 December 2018 and of its result and cash flows for the year then ended in accordance with International Financial Reporting Standards as adopted by the European Union (EU-IFRS) and with Part 9 of Book 2 of the Dutch Civil Code;
- Pharming Group N.V.'s company financial statements give a true and fair view of the financial position of the Company as at 31 December 2018 and of its result for the year then ended in accordance with Part 9 of Book 2 of the Dutch Civil Code.

### WHAT WE HAVE AUDITED

We have audited the accompanying financial statements 2018 of Pharming Group N.V., Leiden ('the Company'). The financial statements include the consolidated financial statements of Pharming Group N.V. together with its subsidiaries ('the Group') and the company financial statements.

### The consolidated financial statements comprise:

- the consolidated balance sheet as at 31 December 2018;
- the following statements for 2018: the consolidated statement of income and the consolidated statements of comprehensive income, changes in equity and cash flows; and
- the notes, comprising significant accounting policies and other explanatory information.

#### The company financial statements comprise:

- the company balance sheet as at 31 December 2018;
- the company statement of income for the year then ended:
- the notes, comprising the accounting policies applied and other explanatory information.

The financial reporting framework applied in the preparation of the financial statements is EU-IFRS and the relevant provisions of Part 9 of Book 2 of the Dutch Civil Code for the consolidated financial statements and Part 9 of Book 2 of the Dutch Civil Code for the company financial statements.

#### THE BASIS FOR OUR OPINION

We conducted our audit in accordance with Dutch law, including the Dutch Standards on Auditing. We have further described our responsibilities under those standards in the section 'Our responsibilities for the audit of the financial statements' of our report.

We believe that the audit evidence we have obtained is sufficient and appropriate to provide a basis for our opinion.

#### Independence

We are independent of Pharming Group N.V. in accordance with the European Regulation on specific requirements regarding statutory audit of public-interest entities, the 'Wet toezicht accountantsorganisaties' (Wta, Audit firms supervision act), the 'Verordening inzake de onafhankelijkheid van accountants bij assuranceopdrachten' (ViO - Code of Ethics for Professional Accountants, a regulation with respect to independence) and other relevant independence requirements in the Netherlands. Furthermore, we have complied with the 'Verordening gedrags- en beroepsregels accountants' (VGBA - Code of Ethics for Professional Accountants, a regulation with respect to rules of professional conduct).



#### **Overview and context**

Pharming Group N.V. is a specialty pharmaceutical company headquartered in the Netherlands, focused on the production and development of innovative products for the safe, effective treatment of rare diseases and unmet medical needs.

The Group is comprised of several components and therefore we considered our group audit scope and approach as set out in the section 'The scope of our group audit'. We paid specific attention to the areas of focus driven by the operations of the Group, as set out below.

As part of designing our audit, we determined materiality and assessed the risks of material misstatement in the financial statements. In particular, we considered where management made important judgements; for example, in respect of significant accounting estimates that involved making assumptions and considering future events that are inherently uncertain. In paragraph 2.4 of the financial statements the Company describes the areas of judgment in applying accounting policies and the key sources of estimation uncertainty. Given the significant estimation uncertainty and the related higher inherent risk of material misstatement related to the accuracy of the revenue recognition in the United States of America, valuation of the contingent consideration and valuation of deferred tax assets, we considered these to be key audit matters as set out in the key audit matter section of this report. Another area of focus, that was not considered as key audit matter was the prior period error as disclosed in note 4 to the consolidated financial statements. As in all of our audits, we addressed the risk of management override of internal controls, including evaluating whether there was evidence of bias by management that may represent a risk of material misstatement due to fraud.

We ensured that the audit team included the appropriate skills and competences which are needed for the audit of a pharmaceutical company. We therefore included experts and specialists in the areas of financial instruments, tax and share based payments in our team.



### The outline of our audit approach was as follows:

### Materiality

◆ Overall materiality: € 882,000

#### Audit scope

- The group audit team performed most of the audit work, since the accounting for the Group's activities takes place at the headquarters in Leiden, the Netherlands.
- Inventory counts at the external inventory locations in the United States and France were conducted by local auditors based on our instructions.
- Our audit scope covered all subsidiaries included in Pharming Group N.V.

#### **Key audit matters**

- Revenue recognition in the United States of America;
- Valuation of the contingent consideration;
- Valuation of deferred tax assets.



#### MATERIALITY

The scope of our audit is influenced by the application of materiality, which is further explained in the section 'Our responsibilities for the audit of the financial statements'.

Based on our professional judgement, we determined certain quantitative thresholds for materiality, including the overall materiality for the financial statements as a whole as set out in the table below. These, together with qualitative considerations, helped us to determine the nature, timing and extent of our audit procedures on the individual financial statement line items and disclosures and to evaluate the effect of identified misstatements, both individually and in aggregate, on the financial statements as a whole and on our opinion.

**Overall group materiality** 

€ 882,000 (2017: € 570,000).

### **Basis for determining materiality**

We used our professional judgement to determine overall materiality. As a basis for our judgement we used 4% of adjusted result before income tax.

#### Rationale for benchmark applied

We used adjusted result before income tax as the primary benchmark, a generally accepted auditing practice, based on our analysis of the common information needs of users of the financial statements. We have excluded the nonrecurring financial expense related to the increase in the fair value of the contingent consideration relating to the repurchase of the RUCONEST® in North America for an amount of €21,200,000. These expenses are non-recurring because they relate to milestones that are to be paid onetime-only, as described under note 30 of the consolidated financial statements. Since the Company has transformed itself from a research and development company, to a more sales oriented company in the past years, we believe that adjusted result before income tax is a relevant metric for the financial performance of the Company, for which we applied a percentage of 4%.

We also take misstatements and/or possible misstatements into account that, in our judgement, are material for qualitative reasons.

We agreed with the board of supervisory directors that we would report to them misstatements identified during our audit above € 44,100 (2017: € 28,500) as well as misstatements below that amount that, in our view, warranted reporting for qualitative reasons.

### THE SCOPE OF OUR GROUP AUDIT

Pharming Group N.V. is the parent company of a group of entities with a similar internal control environment and one management. Even though the Group has its own sales organization in the United States, accounting for the Group's activities takes place at the headquarters in Leiden, the Netherlands. Therefore, we were able to perform most of the audit work for the Group at that location. Our audit scope covered all subsidiaries of Pharming Group N.V. The financial information of this Group is included in the consolidated financial statements of Pharming Group N.V.

Inventory counts at the external inventory locations in the United States and France were conducted by local auditors based on instructions sent by us. These instructions included the scope and timing of the procedures to be performed. In addition we reviewed and discussed their results from the procedures performed.

By performing the procedures above, we believe we have been able to obtain sufficient and appropriate audit evidence on the Group's financial information, as a whole, to provide a basis for our opinion on the financial statements.

### **KEY AUDIT MATTERS**

Key audit matters are those matters that, in our professional judgement, were of most significance in the audit of the financial statements. We have communicated the key audit matters to the board of supervisory directors. The key audit matters are not a comprehensive reflection of all matters identified by our audit and that we discussed. In this section, we described the key audit matters and included a summary of the audit procedures we performed on those matters.

We addressed the key audit matters in the context of our audit of the financial statements as a whole, and in forming our opinion thereon. We do not provide separate opinions on these matters or on specific elements of the financial statements. Any comments or observations we made on the results of our procedures should be read in this context.

The key audit matters 'Revenue recognition in the United States of America', 'Valuation of the contingent consideration' and 'Valuation of deferred tax assets' are similar in nature to the key audit matters we reported in 2017. The key audit matter 'Classification, valuation and disclosure of derivative financial instruments' and 'Funding' have not been included as key audit matters in 2018.

In 2017 we included the Company's derivative financial instruments as key audit matter based on the finance transactions in that year. No similar transactions took place in 2018. As a result, this was no longer considered a key audit matter this year.

In relation to 'Funding', the improved performance of the Group in 2018 resulted in the Group's positive net result and positive operating cash flow. Due to these considerations combined with managements' positive future outlook, the Group's funding risk has decreased during the year and therefore is no longer considered a key audit matter.

### **KEY AUDIT MATTER**

#### **Revenue recognition in** the United States of America See note 2.4

The supply price of the product sold by Pharming in the United States of America is subject to different governmental rebate programs. As a result management is required to assess the different rebate programs when recognising revenue. Which rebate program is applicable on the sale, depends in which program the patient is enrolled. Management is dependent of information received from different parties in the supply chain to make this assessment. The rebates for the financial year 2018, to be paid to the insurance companies, will be finally settled after the reporting date. Therefore, the amount recognized is subject to management estimates.

Once the Company has gathered the information, management is required to make estimates in respect of the number of patients in the different rebate programs and the average unit rebate amount to account for the variable consideration of rebates and chargebacks which are deducted from the Company's sales. Management's estimate to determine that it is highly probable that the variable consideration will not be reversed, is based on historical, as well as actual year to date sales information

Revenue recognition is considered as a key audit matter as it involves significant management judgement to estimate the accrued rebates per program at year-end and also might determine whether the Company reaches any milestone within the contingent consideration, which is mentioned in the KAM "Valuation of contingent consideration".

### **OUR AUDIT WORK AND OBSERVATIONS**

Our procedures included obtaining an understanding of management's revenue recognition process. We tested a sample of transactions to verify whether the revenue was accounted for in accordance with the revenue accounting policy as disclosed in Note 2.3 and 2.4 of the financial statements. In addition, we assessed whether the disclosed revenue accounting policy was in accordance with relevant accounting standards.

We tested the completeness of the recorded sales volumes by reconciliation of the flow of goods to external delivery documents on a sample basis. In addition we attended physical inventory observations at both client and third party warehouse service providers. We tested revenue transactions on a sample basis in order to verify that revenue is recognized accurately and in the appropriate period based on the source documentation. We tested pricing conditions by reconciling prices with the underlying contracts and have verified existence and timing by reconciling the recognition date to shipping documents.

We updated our understanding of the estimation process made around rebates and chargebacks including the assumptions for number of patient per rebate program and average unit rebate amount used by management. We agreed the sales figures used in the calculation, to the figures audited by us. We have tested the mathematical accuracy of the calculation underlying the management estimate

We confirmed the patient data and average unit rebate amount for the government programs, which are the key inputs for management's calculation, with a third party service provider. Using the actual patient data available for the first three quarters, we recalculated the estimated sales for the government programs for the sales for the remainder of the year.

We verified that management applied the same proportion of total sales as in the first three quarters of the year to estimate the number of patients per program for the remainder of the year. We also verified management's reconciliation of the proportion of sales for 2018 to the historical data of 2017 based on actual invoices received for rebates and chargebacks related to 2017. As a result,

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we verified that management accrued for rebates and chargebacks based on the appropriate historical data.

Furthermore, we read the board minutes and the available written communication with the sales partners in order to identify information that could impact revenue recognition.

Based on the procedures performed, we consider managements' estimates to be reasonable and therefore revenue for the financial year to be appropriate.

### **KEY AUDIT MATTER**

## Valuation of the contingent consideration See note 2.4, note 10 and note 30

In 2016 the Company re-acquired all commercial rights to sell RUCONEST® in North America. The purchase agreement included potential future payments up to an additional US\$ 65 million, based on achievement of certain sales milestones. This led to an initial recognition of the intangible asset 'Re-acquired rights' of  $\in$  55.8 million and a contingent consideration of  $\in$  4.7 million recognised in the Other financial liabilities.

The contingent consideration recognised in 2017 was based on the estimated likelihood of meeting the sales milestones and amounted to  $\notin$  28.3 million.

Due to the significant increase in sales during 2018, the first milestone of revenues has been reached, which triggers payment of a milestone of US\$ 20 million. Based on the aforementioned and expectations regarding future sales, management determined that the likelihood of reaching additional milestones has increased significantly. Therefore management concluded the contingent consideration should be accounted for assuming the additional milestones will be met, resulting in a contingent consideration of € 49.5 million as of December 31, 2018. Given the significant management judgment in determining the likelihood of reaching certain milestones and the impact thereof on the valuation of the contingent consideration we considered this to be a key audit matter.

# OUR AUDIT WORK AND OBSERVATIONS

For the contingent consideration we evaluated and challenged management's sales forecast. We challenged the sales forecasts by comparing prior year's 2018 forecast with the Company's actual performance in 2018. We did not identify significant deviations between 2018 sales forecast and actuals for 2018.

In addition, the sales forecast 2019 was evaluated by agreeing the sales to the budget approved by management and by benchmarking management's sales forecast against external revenue expectations obtained from market research by financial analysts.

Furthermore, we checked the mathematical accuracy of management's calculation of the contingent consideration. We reconciled the milestones included in the calculation of the contingent consideration to the sales milestones included in the contract. In addition, we evaluated the adequacy of the related disclosures and found these to be appropriate.

The above procedures did not result in any material exceptions.

### **KEY AUDIT MATTER**

#### Valuation of deferred tax assets See notes 2.4, 11 and 29

The Company has incurred significant tax losses in previous years. In the years before 2017, management did not recognize a deferred tax asset as they considered it not to be probable that this asset would be realized within the applicable expiry periods for the compensation of these losses.

The Company has positive taxable results in 2018, and management expects to have considerable taxable profits in the near foreseeable future. Based on these conditions, management expects it to be probable that the Company will be able to recover all of the tax losses and deferred tax assets from temporary differences.

The recoverability of the deferred tax assets requires significant management judgement around the assumptions used to determine future taxable profits. We considered this to be a key audit matter because the assessment process is complex, involves significant management judgments and is based on key assumptions on expected future market size and economic conditions, revenue growth and margin developments.

# OUR AUDIT WORK AND OBSERVATIONS

We evaluated the reasonableness of management's future forecast, and challenged the underlying key assumptions such as expected revenues from product sales and expenses. Regarding revenue expectations, we challenged the estimates made by management by assessing whether the estimates and assumptions regarding sales forecast quantities and sales prices are in line with historical revenues to date and current contracts in place.

The forecast was also assessed by benchmarking management's forecast on revenue and profitability against external data obtained from market research by financial analysts. We determined that the assumptions used by management were in line with the expectations.

We challenged management on their adequacy of their sensitivity analysis. We determined that the calculation was most sensitive to assumptions for revenue growth. We recalculated the degree to which these assumptions would need to change before this would lead to alternative conclusions. We discussed the likelihood of such changes with management and agreed with their conclusion that alternative conclusions are unlikely.

We recalculated the accuracy of the deferred tax asset using the applicable tax rate(s) and considered the local expiry periods together with any applicable restrictions in recovery.

Additionally, we assessed the adequacy of the disclosures with respect to the deferred tax assets.

Based on the audit procedures performed, we found that the assumptions made by management were reasonable.

#### FINANCIAL STATEMENTS

### **REPORT ON THE OTHER INFORMATION INCLUDED IN THE ANNUAL REPORT**

In addition to the financial statements and our auditor's report thereon, the annual report contains other information that consists of:

- The directors' report as defined on page 5 of the annual report;
- the other information pursuant to Part 9 of Book 2 of the Dutch Civil Code:
- The other information included in the report of the board of supervisory directors, information for shareholders and investors, the glossary and appendix.

Based on the procedures performed as set out below, we conclude that the other information:

- is consistent with the financial statements and does not contain material misstatements;
- contains the information that is required by Part 9 of Book 2 of the Dutch Civil Code.

We have read the other information. Based on our knowledge and understanding obtained in our audit of the financial statements or otherwise, we have considered whether the other information contains material misstatements.

By performing our procedures, we comply with the requirements of Part 9 of Book 2 of the Dutch Civil Code and the Dutch Standard 720. The scope of such procedures was substantially less than the scope of those performed in our audit of the financial statements.

Management is responsible for the preparation of the other information, including the directors' report and the other information in accordance with Part 9 of Book 2 of the Dutch Civil Code.

### **REPORT ON OTHER LEGAL AND REGULATORY REQUIREMENTS**

#### Our appointment

We were appointed as auditors of Pharming Group N.V. on 4 March 2008 by the board of supervisory directors following the passing of a resolution by the shareholders at the annual meeting held on that date and the appointment has been renewed annually by shareholders representing a total period of uninterrupted engagement appointment of ten years.

#### No prohibited non-audit services

To the best of our knowledge and belief, we have not provided prohibited non-audit services as referred to in Article 5(1) of the European Regulation on specific requirements regarding statutory audit of public-interest entities.

#### Services rendered

We provided no other services, in addition to the audit, to the Company and its controlled entities, for the period to which our statutory audit relates.

### **RESPONSIBILITIES FOR THE FINANCIAL STATEMENTS AND THE** AUDIT

**Responsibilities of management and the** board of supervisory directors for the financial statements

Management is responsible for:

- the preparation and fair presentation of the financial statements in accordance with EU-IFRS and with Part 9 of Book 2 of the Dutch Civil Code; and for
- such internal control as management determines is necessary to enable the preparation of the financial statements that are free from material misstatement, whether due to fraud or error.

As part of the preparation of the financial statements, management is responsible for assessing the Company's ability to continue as a going concern. Based on the financial reporting frameworks mentioned, management should prepare the financial statements using the going-concern basis of accounting unless management either intends to liquidate the company or to cease operations, or has no realistic alternative but to do so. Management should disclose events and circumstances that may cast significant doubt on the Company's ability to continue as a going concern in the financial statements.

The board of supervisory directors is responsible for overseeing the Company's financial reporting process.

### **OUR RESPONSIBILITIES FOR THE AUDIT OF THE FINANCIAL STATEMENTS**

Our responsibility is to plan and perform an audit engagement in a manner that allows us to obtain sufficient and appropriate audit evidence to provide a basis for our opinion. Our audit opinion aims to provide reasonable assurance about whether the financial statements are free from material misstatement. Reasonable assurance is a high but not absolute level of assurance, which makes it possible that we may not detect all misstatements. Misstatements may arise due to fraud or error. They are considered to be material if, individually or in the aggregate, they could reasonably be expected to influence the economic decisions of users taken on the basis of the financial statements. Materiality affects the nature, timing and extent of our audit procedures and the evaluation of the effect of identified misstatements on our opinion.

A more detailed description of our responsibilities is set out in the appendix to our report.

Amsterdam, 28 March 2019 PricewaterhouseCoopers Accountants N.V. R.M.N. Admiraal RA

ON THE FINANCIAL STATEMENTS 2018 OF PHARMING GROUP N.V.

In addition to what is included in our auditor's report, we have further set out in this appendix our responsibilities for the audit of the financial statements and explained what an audit involves.

### THE AUDITOR'S RESPONSIBILITIES FOR THE AUDIT OF THE FINANCIAL **STATEMENTS**

We have exercised professional judgement and have maintained professional scepticism throughout the audit in accordance with Dutch Standards on Auditing, ethical requirements and independence requirements. Our objectives are to obtain reasonable assurance about whether the financial statements as a whole are free from material misstatement, whether due to fraud or error. Our audit consisted, among other things of the following:

- Identifying and assessing the risks of material misstatement of the financial statements, whether due to fraud or error, designing and performing audit procedures responsive to those risks, and obtaining audit evidence that is sufficient and appropriate to provide a basis for our opinion. The risk of not detecting a material misstatement resulting from fraud is higher than for one resulting from error, as fraud may involve collusion, forgery, intentional omissions, misrepresentations, or the intentional override of internal control.
- Obtaining an understanding of internal control relevant to the audit in order to design audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control.
- Evaluating the appropriateness of accounting policies used and the reasonableness of accounting estimates and related disclosures made by management.
- Concluding on the appropriateness of management's use of the going-concern basis of accounting, and based on the audit evidence obtained, concluding whether a material uncertainty exists related to events and/or conditions that may cast significant doubt on the Company's ability to continue as a going concern. If we conclude that a material uncertainty exists, we are required to draw attention in our auditor's report to the related disclosures in the financial statements or, if such disclosures are

inadequate, to modify our opinion. Our conclusions are based on the audit evidence obtained up to the date of our auditor's report and are made in the context of our opinion on the financial statements as a whole. However, future events or conditions may cause the company to cease to continue as a going concern.

• Evaluating the overall presentation, structure and content of the financial statements, including the disclosures, and evaluating whether the financial statements represent the underlying transactions and events in a manner that achieves fair presentation.

Considering our ultimate responsibility for the opinion on the consolidated financial statements, we are responsible for the direction, supervision and performance of the group audit. In this context, we have determined the nature and extent of the audit procedures for components of the Group to ensure that we performed enough work to be able to give an opinion on the financial statements as a whole. Determining factors are the geographic structure of the Group, the significance and/or risk profile of group entities or activities, the accounting processes and controls, and the industry in which the Group operates. On this basis, we selected group entities for which an audit or review of financial information or specific balances was considered necessary.

We communicate with the board of supervisory directors regarding, among other matters, the planned scope and timing of the audit and significant audit findings, including any significant deficiencies in internal control that we identify during our audit. In this respect, we also issue an additional report to the audit committee in accordance with Article 11 of the EU Regulation on specific requirements regarding statutory audit of public-interest entities. The information included in this additional report is consistent with our audit opinion in this auditor's report. We provide the board of supervisory directors with a statement that we have complied with relevant ethical requirements regarding independence, and to communicate with them all relationships and other matters that may reasonably be thought to bear on our independence, and where applicable, related safeguards.

From the matters communicated with the board of supervisory directors, we determine those matters that were of most significance in the audit of the financial statements of the current period and are therefore the key audit matters. We describe these matters in our auditor's report unless law or regulation precludes public disclosure about the matter or when, in extremely rare circumstances, not communicating the matter is in the public interest.

# **OTHER FINANCIAL INFORMATION**

For the year ended 31 December 2018

### 1. Appropriation of result

Article 25.1 of the articles of association reads as follows: 'the management board shall annually determine, subject to the approval of the Board of Supervisory Directors, the amount of the distributable profit – the surplus on the profit and loss account - to be reserved.'

Leiden, 28 March 2019 The Board of Management

Sijmen de Vries - Chairman of the Board of Management and Chief Executive Officer Bruno Giannetti - Chief Operations Officer Robin Wright - Chief Financial Officer

### **GLOSSARY**

#### AGM

Annual General Meeting of Shareholders.

#### AKI

Acute Kidney Injury, or CIN Contrast-Induced Nephropathy (a more dangerous version of AKI) is a form of damage which occurs in stress situations such as when a patient is injected with contrast medium (essentially a radio-visible dye or other liquid which is more easily seen) as part of a contrast-enhanced examination, for example a computerised tomography (CT) scan.

#### AMI

Acute Myocardial Infarction, commonly known as a heart attack, results from the interruption of blood supply to a part of the heart causing heart cells to die. Heart attacks are the leading cause of death for both men and women worldwide. AMR Antibody-mediated rejection occurs when a transplanted organ or tissue is perceived by the recipient as a foreign body, usually because of sub-optimal matching (histocompatibility). The immune system is activated and the perceived foreign body is attacked, which can lead to organ failure and immunological rejection of the organ.

#### BLA

In the US, pharmaceuticals are approved for marketing under the provisions of the Public Health Service (PHS) Act. The Act requires any firm which manufactures a pharmaceutical for sale in interstate commerce in the USA to hold a US license for the product. To permit such a firm to commercialise a new biological product in the US, the FDA needs to approve a Biologics License Application (BLA). A BLA is a submission that contains specific information on the manufacturing processes, chemistry, pharmacology, clinical pharmacology and the medical effects of the biologic product. If the information provided meets FDA requirements, the application is approved and a license is issued allowing the company to market the pharmaceutical. Biological products include inter alia monoclonal antibodies, growth factors, blood products, peptides and proteins intended for therapeutic use. The relevant FDA centre is the Center for Biologics Evaluation and Research (CBER).

#### BOM

The Board of Management of Pharming Group N.V.

#### C1INH

C1 esterase inhibitor or C1INH is a serine protease inhibitor

protein present in human blood serum. C1INH is involved in the regulation of the first protein (C1) in the complement system, which is part of the immune system. Insufficient C1 inhibitor action or availability leads to uncontrolled inflammation and HAE attacks.

#### CSIPI

or China State Institute of Pharmaceutical Industry, a Sinopharm company, is our collaborative partner in China.

#### СНМР

The Committee for Medicinal Products for Human Use (CHMP) plays a vital role in the marketing procedures for medicines in the European Union. Amongst other things, the CHMP is responsible for preparing the EMA's opinions on all questions concerning medicinal products for human use, in accordance with Regulation (EC) No 726/2004.

#### Clinical trial/studies

Clinical trials are tests on human individuals, ranging from healthy people to patients, to evaluate the safety and efficacy of new pharmaceutical products before they can be approved for general or specific use. Clinical trials typically range from Phase I (safety study in healthy volunteers) to Phase IV (mandatory post-approval studies of specific features) and even Phase V (non-essential post-approval study of specific effects).

#### СМО

A Contract Manufacturing Organisation (CMO) is an organisation that provides clients from the pharmaceutical industry with comprehensive services from late-stage drug development through manufacture.

#### DGF

A DGF or delayed graft function is a common complication affecting all solid organs in the post-transplant period. DGF results in significant morbidity and mortality from early graft dysfunction and from decreased long-term graft survival. The condition also prolongs hospitalisation and requires substitute therapies for these patients, such as dialysis or ventilation support. DGF remains a critical unmet medical need despite improvements in immunosuppression, organ preservation, and surgical technique. C1 inhibitor has been shown in numerous models of organ transplantation to improve early graft function. In the USA alone, over 25,000 solid organs were transplanted in 2005, including kidney, liver, lung and heart transplants.

#### EGM

Extraordinary General Meeting of Shareholders.

#### EMA

The European Medicines Agency (EMA) is the regulatory office for pharmaceuticals in the European Union and is responsible for approving new drugs prior to marketing of the product ensuring their safety and efficacy, and monitoring approved drugs after launch to ensure consistency of safety.

#### Fabry's

Fabry's disease (also known as Anderson-Fabry disease, angiokeratoma corporis diffusum, and alpha-galactosidase A deficiency) is a rare genetic lysosomal storage disease resulting from the deficient activity of a different enzyme, alpha-galactosidase A (aGalA), usually caused by an X-chromosome mutation of the GLA gene.

#### Factor VIII

is an essential blood-clotting protein, also known as antihaemophilic factor (AHF). In humans, factor VIII is encoded by the F8 gene. Defects in this gene result in haemophilia A, a recessive X-linked coagulation disorder.

#### FDA

The FDA or United States Food and Drug Administration is the regulatory office responsible for all drug approval in the United States.

#### GMP

GMP or Good Manufacturing Practice is a term that is recognised worldwide for the control and management of manufacturing and quality control testing of foods and pharmaceutical products.

#### HAE

HAE or Hereditary Angioedema is a human genetic disorder caused by insufficient activity of the C1 inhibitor protein, usually resulting from genetic deficiency in the patient. HAE patients suffer from recurrent unpredictable acute attacks of painful and in some cases fatal swelling of soft tissues (edema), including regions of the skin, abdomen and the mouth and throat. Attacks can last up to five days when untreated. In the Western world, approximately 1 in 30,000 individuals suffers from Hereditary Angioedema, having an average of seven to twelve acute attacks per year.

#### HAEA

The HAEA is the US Hereditary Angioedema Association, the patient's representative association for patients with HAE in the United States, providing resources including information and other support for HAE patients and their carers.

#### HAEI

The HAEI is the International Hereditary Angioedema Association, the patient's representative association for patients with HAE outside the United States, providing resources including information and other support for HAE patients and their carers.

#### **HEMOPHILIA**

A Haemophilia A is a hereditary disorder caused by defects in the Factor VIII gene. Lack of functional Factor VIII diminishes the body's clotting ability, which in turn can lead to damaging or fatal - bleeding episodes.

#### IFRS, IAS and IASB

International Financial Reporting Standards (IFRS) along with International Accounting Standards (IAS) are a set of international generally-accepted accounting standards issued by the International Accounting Standards Board (IASB).

#### IND

An IND (investigational new drug application) is the vehicle through which a sponsor advances to the next stage of drug development known as clinical trials (human trials).

#### IRI

Ischaemia Reperfusion Injury (IRI) is a complication arising from situations where a specific tissue in the body experiences lack of oxygen due to an interruption of the blood supply (ischaemia), which is then re-perfused (re-supplied) with blood, resulting in inflammation and tissue damage. This can occur in a transplanted organ, in the brain in case of stroke, and in the heart in case of myocardial infarction ('heart attack'). It can also occur in traumatic damage such as a wound or injury.

#### LTIP

Pharming's Long Term Incentive Plan.

#### MAA

A Marketing Authorisation Application is a request for market approval in any specific state or country, or generally across a coherent jurisdiction region such as the United States or the European Union.

## **GLOSSARY**

#### Orphan Drug

A drug being developed to treat a rare disease (defined as a disease affecting less than 200,000 individuals in the USA) can receive Orphan Drug designation from the FDA. This status is granted under the US Orphan Drug Act of 1983, which was established to encourage, support and protect the development of treatment for rare, but serious diseases. Orphan Drug status provides several advantages including market and/or data exclusivity for seven years, various financial incentives and a well-defined regulatory approval path. The EMA can grant a similar status to products being developed to treat rare diseases (affecting not more than five in ten thousand persons in Europe), namely Orphan Medicinal Product. This status is granted under the European Parliament and Council Regulation (EC) No 141/2000 of 16 December, 1999, on Orphan Medicinal Products, which introduces incentives for Orphan Medicinal Products research, development and marketing, in particular by granting exclusive marketing rights for a ten-year period.

#### POC

A Proof of Concept (POC)study is a study to verify that a hypothesis or theory is broadly correct and therefore has the potential of leading to an approved therapy.

#### Pompe

Pompe disease (also known as Acid Maltase Deficiency or Glycogen Storage Disease type II) is an inherited muscular myopathy disorder caused by the build-up of a complex sugar called glycogen in the body's cells. It affects around 1 in 40,000 people in general, varying within different ethnic groups. Pompe disease is a rare multisystem genetic disorder that is characterised by absence or deficiency of the lysosomal enzyme alpha-glucosidase (GAA).

#### Pre-eclampsia

is a life-threatening multisystem disorder in pregnancies leading to maternal and neonatal mortality and morbidity, usually first detected by hypertension and/or proteinuria, wherein the junction between the fetus and mother can become inflamed and where vascular leakage can occur.

#### Protein

Proteins are large organic molecules comprising at least carbon, hydrogen, oxygen and nitrogen, such as C1 esterase inhibitor, fibrinogen and collagen, and they form the basis to all living organisms. They are composed of one or more

chains of amino acids joined together by peptide bonds. The sequence of these amino acids as well as any surface sugar or acid groups attached to those amino acids is defined by genes, which sequences of the patient or animal's DNA in its chromosomes.

#### Recombinant

Recombinant refers to the combination of one form of genetic material (DNA) from one source with the DNA of a different biological source from a different species. Pharming, like all biotechnology firms, uses recombinant technology to produce versions of human proteins such as recombinant human C1 esterase inhibitor outside of human bodies.

#### rhC1INH

Recombinant human C1 esterase inhibitor or rhC1INH is the active component of RUCONEST®. Natural C1 esterase inhibitorgenerating DNA from a human source is used in Pharming's protein production technology to ensure expression of the C1 esterase inhibitor protein in the milk of the host. This product is very important for patients who are unable to make adequate C1 esterase inhibitor in their own bodies and thus suffer from HAE. It may also be very useful in certain other larger indications, such as pre-eclampsia, acute kidney injury or the prevention of complications that sometimes arise after organ transplantation.

#### rhFVIII

Recombinant human Factor VIII is a recombinant version of the natural human blood clotting factor and is in early-stage development for treatment of Haemophilia A.

#### **RUCONEST**®

RUCONEST® is the principal global registered trade mark for Pharming's first recombinant human C1 esterase inhibitor. Human C1 esterase inhibitor is a protein involved in the regulation of the first protein in the complement system (C1), which is part of the immune system.

#### SOBI

Swedish Orphan Biovitrum International AB.

#### Transgenic

An organism is called transgenic when its cells carry genetic material from another species in addition to its own genetic material. Pharming produces specific human products in the milk of transgenic rabbits and cows carrying a construct for the human recombinant gene responsible for expressing that product.

#### Valeant

Valeant Pharmaceuticals International Inc. now Bausch Health Companies Inc. was Pharming's former US distribution partner that took over distribution of RUCONEST® following its acquisition of Salix Pharmaceuticals Inc. in April 2015.

#### VWAP

Volume Weighted Average Price of shares.

#### 1(

### **APPENDIX**

### RUCONEST 2018 PUBLISHED MANUSCRIPTS

#### 1.

Baker JW, Bernstein JA, Harper JR, Relan A, Riedl MA. Efficacy of recombinant human C1 esterase inhibitor across anatomic locations in acute hereditary angioedema attacks. Allergy Asthma Proc. 2018;39(5):359-364.

#### 2.

Li HH, Riedl, MA, Bernstein, JA, Hardiman, Y, Harper J, Relan A. Abdominal presentation of acute attacks of hereditary angioedema and efficacy of recombinant C1 esterase inhibitor in symptom resolution. J Angioedema. 2018;1(3):1-8.

#### 3.

Riedl MA, Relan A, Harper JR, Cicardi M. C1 esterase inhibitor concentrates and attenuated androgens – Authors' reply. Lancet. 2018;391(10128):1356.

### RUCONEST 2018 PUBLISHED ABSTRACTS

1.

Anderson J, Haynes A, CaJacob T, Paige D. Efficacy of switching human plasma-derived C1 esterase inhibitor to recombinant human C1 esterase inhibitor as prophylaxis in a patient with type 1 hereditary angioedema. Allergy Asthma Proc. 2018;39(5):400.

#### 2.

Jones DH, Park N. Efficacy of recombinant human C1 esterase inhibitor as prophylaxis for hereditary angioedema attacks in a patient tolerant to other therapies. Allergy Asthma Proc. 2018;39(5):400.

#### 3.

Vegh AB, Park N, Cantwell T. Recombinant human C1esterase inhibitor for the prevention of acute hereditary angioedema attacks: a case report. Allergy Asthma Proc. 2018;39(5):400.

#### 4.

Vegh AB, Park N, Cantwell T. Recombinant human C1esterase inhibitor for the prevention of acute hereditary angioedema attacks: a case report. J Drug Assess. 2018;7(suppl 1):15.

#### )•

Hakl R, Valerieva A, Farkas H, Jesenak M, Hrubiskova K, Zanichelli A, Staevska, M, Bellizzi L Relan A, Cicardi M. Efficacy and Safety of Recombinant human C1 esterase inhibitor treatment for hereditary Angioedema attacks: Interim analysis of a European registry. Allergy. 2018;73(suppl 105):47.

#### 6.

Reshef A, Grivcheva-Panovska V, Kessel A, Kivity S, Klimaszewska-Rembiasz M, Moldovan D, Farkas H, Gutova V, Fritz S, Bellizzi L, Relan A, Giannetti B, Magerl M. Recombinant human C1 esterase inhibitor for the acute treatment of hereditary angioedema attacks in children. Allergy. 2018; 73(suppl 105):66.

#### 7.

Jones DH, Park N. Efficacy of recombinant human C1 esterase inhibitor as prophylaxis for hereditary angioedema attacks in a patient tolerant to other therapies. Allergy Asthma Proc. 2018;39(3):258.

#### 8.

Vegh AB, Park N, Cantwell T. Recombinant human C1 esterase inhibitor for the prevention of acute hereditary angioedema attacks: A case report. Allergy Asthma Proc. 2018;39(3):258.

#### 9.

Moldovan D, Bernstein JA, Hakl, R, Bellizzi L, Relan, A. Safety of recombinant human C1 esterase inhibitor for hereditary angioedema attacks in pregnant women. J Allergy Clin Immunol. 2018;141(suppl 2):AB53.

# RUCONEST 2018 PRESENTATIONS (ABSTRACTS NOT PUBLISHED)

#### 1.

Bernstein JA, Moldovan D, Hakl R, Bellizzi L, Relan A. Experience with recombinant human C1 esterase inhibitor for hereditary attacks during pregnancy. American College of Allergy, Asthma & Immunology (ACAAI), November 15-19, 2018, Seattle, WA.

#### 2.

Relan A, Reshef A, Grivcheva-Panovska V, Kessel A, Kivity S, Klimaszewska-Rembiasz M, Moldovan D, Farkas H, Gutova V, Fritz S, Bellizzi L, Giannetti B. Pharmacokinetics of recombinant human C1 esterase inhibitor for treatment of hereditary angioedema attacks in children. American College of Allergy, Asthma & Immunology (ACAAI), November 15-19, 2018, Seattle, WA.

#### 3.

Zanichelli A, Staevska M, Jesenak M, Hrubiskova K, Sobotkova M, Zachova R, Hakl R, Andrejevic S, Suiter T, Grivcheva-Panovska V, Karadza-Lapic L, Soteres D, Shapiro R, Rumbyrt J, Tachdjian R, Mehta V, Hsu F, Valerieva A. Recombinant C1 esterase inhibitor for shortterm prophylaxis in patients with hereditary angioedema. American College of Allergy, Asthma & Immunology (ACAAI), November 15-19, 2018, Seattle, WA.

#### 4.

Jones DH, Park N. Efficacy of recombinant human C1 esterase inhibitor as prophylaxis for hereditary angioedema attacks in a patient tolerant to other therapies. Aspen Allergy Conference (AAC), July 22-26, 2018, Aspen, CO.

#### 5.

Reshef A, Grivcheva-Panovska V, Kessel A, Kivity S, Klimaszewska-Rembiasz M, Moldovan D, Farkas H, Gutova V, Fritz S, Bellizzi L, Relan A, Giannetti B, Magerl M. Recombinant human C1 esterase inhibitor for the acute treatment of hereditary angioedema attacks in children. Aspen Allergy Conference (AAC), July 22-26, 2018, Aspen, CO.

#### 6.

Moldovan D, Bernstein JA, Hakl R, Bellizzi L, Relan A. Safety of recombinant human C1-esterase inhibitor for hereditary angioedema attacks in pregnant women. Intermountain West Allergy Association (IWAA), July 19-21, 2018, Park City, UT. 7.

Reshef A, Grivcheva-Panovska V, Kessel A, Kivity S, Klimaszewska-Rembiasz M, Moldovan D, Farkas H, Gutova V, Fritz S, Bellizzi L, Relan A, Giannetti B, Magerl M. Recombinant human C1 esterase inhibitor for the acute treatment of hereditary angioedema attacks in children. Intermountain West Allergy Association (IWAA), July 19-21, 2018, Park City, UT.

### 8.

Hakl R, Valerieva A, Farkas H, Jesenak M, Hrubiskova K, Zanichelli A, Staevska MT, Bellizzi L, Relan A, Cicardi M. Efficacy and Safety of Recombinant Human C1 Esterase Inhibitor Treatment for Hereditary Angioedema Attacks: Interim Analysis of a European Registry. 2018 Hereditary Angioedema (HAE) Global Conference, May 17-20, 2018, Vienna, Austria.

#### 9.

Reshef A, Grivcheva-Panovska V, Kessel A, Kivity S, Klimaszewska-Rembiasz M, Moldovan D, Farkas H, Gutova V, Fritz S, Bellizzi L, Relan A, Giannetti B, Magerl M. Treatment of Hereditary Angioedema Attacks in Children: A Phase 2 Trial of Recombinant Human C1 Esterase Inhibitor. 2018 Hereditary Angioedema (HAE) Global Conference, May 17-20, 2018, Vienna, Austria.

## **APPENDIX**

### Appendix: Main Financial Statements (unaudited) reported in US dollars

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

Exchange rate EUR/USD used:

-	Statement of income 2017:	1.1302
-	Statement of income 2018:	1.1811
-	Balance sheet 31 December 2017:	1.1977
_	Balance sheet 31 December 2018:	1.1439

- Statement of cash flows 2017: 1.1302
- Statement of cash flows 2018: 1.1811
- Cash balance as per 1 Janaury 2017: 1.0555

# CONSOLIDATED STATEMENT OF INCOME (IN US DOLLARS)

### For the year ended 31 December

For the year ended 31 December
amounts in \$ 'ooo
REVENUES
COSTS OF SALES
GROSS PROFIT
OTHER INCOME
Research and development
General and administrative
Marketing and sales
COSTS
OPERATING RESULT
Fair value gain (loss) on revaluation derivatives *
Other financial income
Other financial expenses *
FINANCIAL INCOME AND EXPENSES
RESULT BEFORE INCOME TAX
Income tax credit (expense)
NET RESULT FOR THE YEAR
ATTRIBUTABLE TO:
Owners of the parent
TOTAL NET RESULT
Basic earnings per share (\$)
Fully-diluted earnings per share (\$)
* Prior year's financial statements have been restat

<b>2017</b> restated*	2018	
101,289	159,602	
(14,065)	(26,197)	
87,223	133,405	
893	808	
(21,086)	(34,113)	
(6,752)	(14,434)	
(35,513)	(40,794)	
(63,351)	(89,341)	
24,765	44,872	
(47,540)	(585)	
5,909	21	
(79,980)	(43,297)	
(121,611)	(43,860)	
(96,846)	1,012	
10,671	28,507	
(86,174)	29,519	
(86,174)	29,519	
(86,174)	29,519	
(0.172)	0.048	
n/a	0.045	
		d

# CONSOLIDATED BALANCE SHEET (IN US DOLLARS)

#### As at 31 December

amounts in \$ '000	2018	<b>2017</b> restated*
NON-CURRENT ASSETS		
Intangible assets	59,980	67,827
Property, plant and equipment	9,611	9,862
Long-term prepayments	2,295	2,750
Deferred tax assets	40,130	11,309
Restricted cash	1,377	1,600
TOTAL NON-CURRENT ASSETS	113,394	93,348
CURRENT ASSETS		
Inventories	19,807	21,959
Trade and other receivables	20,377	13,486
Cash and cash equivalents	91,868	70,253
TOTAL CURRENT ASSETS	132,052	105,698
TOTAL ASSETS	245,445	199,046
EQUITY		
Share capital	7,109	6,935
Share premium *	443,290	435,745
Legal reserves	1,884	(1,123)
Accumulated deficit *	(381,646)	(422,261)
SHAREHOLDERS' EQUITY	70,637	19,295
NON-CURRENT LIABILITIES		
Loans and borrowings *	42,630	70,857
Deferred tax liabilities	100	-
Contract liabilities	763	1,757
Finance lease liabilities	188	467
Other financial liabilities	36,644	33,918
TOTAL NON-CURRENT LIABILITIES	80,324	106,999
CURRENT LIABILITIES		
Loans and borrowings *	40,305	26,826
Contract liabilities	915	963
Derivative financial liabilities *	261	12,073
Trade and other payables	32,703	32,575
Finance lease liabilities	301	315
Other financial liabilities	20,000	-
TOTAL CURRENT LIABILITIES	94,485	72,752
TOTAL EQUITY AND LIABILITIES	245,445	199,046

\* Prior year's financial statements have been restated.

For the year ended 31 December

#### **OPERATING RESULT**

#### NON-CASH ADJUSTMENTS:

Depreciation, amortisation, impairment

Accrued employee benefits

Release contract liabilities

#### **OPERATING CASH FLOWS BEFORE CHANGES**

#### CHANGES IN WORKING CAPITAL:

Inventories

Trade and other receivables

Payables and other current liabilities

#### TOTAL CHANGES IN WORKING CAPITAL

Changes in non-current assets, liabilities and equity

### CASH GENERATED FROM (USED IN) OPERA **BEFORE INTEREST AND TAXES**

Interest received

Income taxes paid

### NET CASH FLOWS GENERATED FROM (USE

Capital expenditure for property, plant and equipm

Investment intangible assets

### NET CASH FLOWS USED IN INVESTING ACT

Proceeds of loans and borrowings

Payments of transaction fees and expenses

Repayment on loans and borrowings

Redemption bonds

Interests on loans

Proceeds of equity and warrants

### NET CASH FLOWS GENERATED FROM (USE

#### INCREASE (DECREASE) OF CASH

Exchange rate effects

Cash and cash equivalents at 1 January

TOTAL CASH AND CASH EQUIVALENTS AT

	2018	2017
	44,872	24,765
	7,747	3,860
	3,862	3,065
	(950)	(1,066)
S IN WORKING CAPITAL	55,532	30,624
	1,204	(444)
	(7,741)	(3,781)
	1,643	16,769
	(4,894)	12,544
У	(1,297)	17
ATIONS	49,340	43,185
	21	3
	(1,674)	-
D IN) OPERATING ACTIVITIES	47,688	43,188
nent	(2,948)	(3,671)
	(1,504)	(3,161)
IVITIES	(4,452)	(6,832)
	-	103,225
	-	(3,788)
	(17,878)	(97,489)
	(2,666)	(4,446)
	(13,067)	(8,903)
	12,397	7,723
d in) financing activities	(21,214)	(3,679)
	22,023	32,677
	(631)	5,256
	71,854	33,921
31 DECEMBER	93,245	71,854



