#### REGISTRATION DOCUMENT

#### PHARMING GROUP N.V.

(a limited liability company incorporated under the laws of the Netherlands, with its corporate seat in Leiden)

This registration document (the **Registration Document**) is published in connection with an anticipated offering and/or admission to listing and trading of shares issued in the capital of Pharming Group N.V. (**Pharming** or the **Company**, which shall, where the context so requires, include one or more of its subsidiaries.

Any reference to **Shares** in this Registration Document comprises the ordinary shares in the capital of the Company, including any shares in the capital of the Company issued from time to time hereafter. The Shares are listed and traded on Euronext Amsterdam under the symbol **PHARM** and ISIN Code NL0000377018.

This Registration Document constitutes a registration document for the purpose of article 4 of EC Regulation 809/2004 and has been prepared pursuant to article 5:2 of the Financial Markets Supervision Act (*Wet op het financieel toezicht*) (the **AFS**) and the rules promulgated thereunder. This Registration Document has been approved by and filed with the Netherlands Authority for the Financial Markets (*Stichting Autoriteit Financiële Markten*) (the **AFM**).

This Registration Document may only be used in connection with the offering and/or listing and trading of Shares and constitutes a prospectus in accordance with Directive 2003/71/EC, as amended from time to time, if supplemented by a security note for the purpose of article 6 of EC Regulation 809/2004 as amended from time to time and a summary, each of which is approved by the AFM (the **Prospectus**).

16 October 2012

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#### 1. RISK FACTORS RELATING TO PHARMING

Pharming is subject to many risks and uncertainties that may affect its financial performance. If any of the events or developments described below occurs, Pharming's business, financial condition or results of operations could be negatively affected. In that case, the trading price of the Shares could decline, and investors could lose all or part of their investment in the Shares.

The risks listed below do not necessarily comprise all risks faced by the Company, but take into account those which are known to the Company and which the Company considers material. Additional risks and uncertainties not presently known to Pharming or that the Company currently deems immaterial may also have a material adverse effect on its business, results of operations or financial condition and could negatively affect the price of the Shares.

#### **Risk Factors**

## Clinical & Regulatory Risks

# Pharming may not obtain all regulatory approvals for its products

The process of undertaking and completing pre-clinical studies and clinical trials, and obtaining regulatory approvals, may take several years and requires the expenditure of substantial cash resources. 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 could severely harm its 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 pre-clinical or clinical) could result in Pharming stopping the development of a product or technology or requiring additional clinical trials or other testing and could have significant detrimental consequences for Pharming's business, financial position, results of operations, prospects and market price of the Shares.

Once a product receives regulatory approval, such approval can nonetheless be subject to limitations with regard to the indications for which it may be marketed. The approval may also be given subject to conditions, such as additional proof 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, this can result *inter alia* in restrictions on use and withdrawal of the product from the market and may adversely affect Pharming's business, financial position, results of operations, prospects and market price of the Shares.

# Pharming relies on third parties to conduct pre-clinical and clinical trials

Pharming does not have the ability to independently conduct pre-clinical and clinical trials for product candidates. Pharming must rely on third parties, such as contract research organisations, medical institutions, clinical investigators and contract laboratories to conduct the pre-clinical and clinical trials. Pharming has entered into agreements with third parties to conduct these trials for and on behalf of Pharming. The Company remains responsible that each of the pre-clinical and clinical trials is 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 the Company to comply with regulations and standards, commonly referred to as good clinical practices, for conducting, recording and reporting the results of pre-clinical and clinical trials to ensure that data and reported results are credible and accurate and that trial participants are adequately protected. The reliance on third parties does not relieve Pharming of these responsibilities and requirements. If these third parties do not successfully carry out their contractual duties or regulatory obligations or meet expected deadlines, or the third parties need to

be replaced or if the quality or accuracy of the date they obtain is compromised due to the failure to adhere to Pharming's pre-clinical and clinical protocols or regulatory requirements or for other reasons, the pre-clinical or clinical trials may be extended, delayed, suspended or terminated and Pharming may not be able to obtain regulatory approval for, or successfully commercialise, product candidates.

# Regulatory standards are constantly developing and the failure to comply with applicable regulatory requirements would have serious consequences for the Company

The industry in which Pharming operates is highly regulated and the applicable regulatory requirements vary considerably in the different geographic markets in which Pharming operates. These regulations are subject to change and development and future regulatory standards relating to, *inter alia*, biotechnology-derived products, may be imposed that are distinct from those currently employed. The Company cannot guarantee that it will be able to meet such standards as they evolve and are implemented.

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

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

The development of a therapeutic drug up to marketing approval by the competent authority is a lengthy process. During this time a research project must proceed through pre-clinical and several clinical stages of development, as well as the regulatory approval process. The consequence of this lengthy process and the uncertainties in connection with the research and development of pharmaceuticals is that only a small fraction of initial product candidates ultimately receive regulatory approval. In addition to its lead product Rhucin and its other products in development, Pharming seeks to discover products in a number of long-term research projects for which clinical trials have not been initiated yet. A failure to develop additional products successfully and within a reasonable time frame could have significant detrimental consequences for Pharming's business, financial position, and results of operations, prospects and market price of the Shares.

## **Commercial Risks**

# Pharming faces and expects to remain confronted with intense competition in the various markets for its products

Several other companies develop products for the treatment of Hereditary Angioedema or **HAE** attacks. Although Pharming is the sole provider of a recombinant therapy (either on the market or in development), the Company will face competition from these and existing products used to treat HAE attacks. In Europe, three other non-recombinant C1 inhibitor products and one product using another mechanism of action have been approved in the EU, each for the treatment of acute HAE attacks. In the USA one non-recombinant C1 inhibitor product and two products with alternative mechanisms of action have been approved for certain types of acute HAE attacks as well as one non-recombinant C1 inhibitor product for preventive treatment of HAE attacks. As a consequence, Pharming may not obtain a sufficient market penetration with Rhucin to allow it to become profitable. For its other 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.

Even if the Company successfully introduces Rhucin or another of its future products, new technologies from competitors can make Rhucin 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, amongst others, obtaining regulatory approvals. The above events may have a material adverse effect on Pharming's business, financial position, and results of operations, prospects and market price of the Shares.

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

Pharming's strategy for the commercialisation of some of its products, in particular those for larger indications, is to partner or out-license such products to third parties. If Pharming is not able to locate, and enter into favourable agreements with suitable third parties, it may have difficulties commercialising the relevant products. The process of establishing partnerships is difficult, time-consuming and involves significant uncertainty. Pharming's ability to predict the success of any partnership it may enter into is limited due to (amongst others) the complexity and uncertainty of these arrangements.

# Pharming's products may not gain market acceptance

Sales of medical products depend on physicians' willingness to prescribe the treatment, which is likely to be based on a determination by these physicians that the products are safe and efficacious from a therapeutic and cost perspective relative to competing treatments. Pharming cannot predict whether physicians will make this determination in respect of its products. Even if Pharming's products achieve market acceptance, the market may prove not to be large enough to allow Pharming to generate sufficient revenues.

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

For some of the essential materials incorporated into product candidates, Pharming relies on a single supplier. Any disruption in the supply of these materials could adversely affect its ability to successfully complete the clinical trials and other studies of its product candidates, delay submissions of the regulatory applications or adversely affect its ability to commercialise its product candidates in a timely and/or commercially manner, or at all.

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

Development methods and technologies which Pharming uses include, among others, nuclear transfer technology and genetic modification. These and other activities have been, and may in the future be, the subject of debate and negative publicity. In the past, organisations and individuals have tried to stop genetic modification through different ways of putting pressure on companies relating to these activities, including by use of media campaigns. These actions may have a material adverse effect on Pharming's business, financial position, operational performance, prospects and market price of the Shares.

Furthermore, the Company needs the market to accept its products in order to be able to commercialise them. Market acceptance is dependent on the opinions of the medical community, partners and competitors about numerous factors including the safety and efficacy of the relevant products. Any failure to obtaining market acceptance may also have a material adverse effect on Pharming's business, financial position, results of operations, prospects and market price of the Shares.

# Disappointing reimbursements paid by third parties and disappointing cost-effectiveness of Pharming's products once approved for marketing may have a material adverse effect on Pharming's financial results

Pharming's success is dependent on the reimbursement of the Company's products by third parties like the government health administration authorities, private health insurers and other organisations for the development of the products and/or technology. There is an increasing tendency of health insurers to reduce healthcare cost by limiting both coverage and the level of reimbursement for new therapeutic products and by refusing, in some cases, to provide coverage altogether. Not obtaining, or obtaining insufficient reimbursement from these parties may have an adverse effect on Pharming's business, financial position, results of operations, prospects and market price of the Shares.

In addition to reimbursements from third parties, the Company, if it succeeds in bringing a product to the market, also faces uncertainties about the cost-effectiveness of the product. The prices for the product that health care insurers and/or consumers are willing to pay may be lower than the production costs which may make the product uncompetitive and thereby adversely affect Pharming's business, financial position, results of operations, prospects and market price of the Shares.

# Pharming is highly dependent on its ability to obtain and hold rights to proprietary technology and to develop its technology and products without infringing the proprietary rights of third parties and to protect its proprietary technology

Patents, trade secrets and other proprietary rights are critical to Pharming's business. The Company has to protect its products and technology through patenting and licensing and at the same time develop its products without infringing the proprietary rights of third parties. The patent positions of pharmaceutical companies are highly uncertain and involve complex legal and factual questions, and the breadth of claims that will be allowed by patent authorities cannot be predicted with certainty. Pharming has several patent applications pending in the USA, Europe, Japan and in other countries. It is not certain that these pending patent applications will result in patent issues, that these patents will afford adequate protection or that the existing patents will not be challenged. 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 by Pharming to develop and commercialise its products.

The Company seeks protection of its other proprietary know-how through confidentiality and other agreements with employees and third parties. No assurance can be given that these agreements offer an adequate protection or that equivalent or superior know-how is not independently developed by competitors.

# Pharming operates in an industry sector that has a relative high risk of facing litigation

Pharming participates and will participate in an industry that has been subject to significant product liability, intellectual property claims and other litigation. Pharming cannot be certain that it was the first to invent the subject matter of its patent applications and patents, that it was the first to apply for such a patent, or that those technologies or products used by Pharming will not infringe third party intellectual property rights or that existing patents remain valid and enforceable. Pharming may face litigation or other legal proceedings concerning its intellectual property. These processes are time consuming and can be very costly. In the event of an unfavourable ruling in patent or intellectual property litigation Pharming could be subject to significant liabilities to third parties, be required to cease developing, manufacturing or selling the affected products or technology or be required to in-license the disputed rights from third parties and thereby adversely affect Pharming's business, financial position, results of operations, prospects and market price of the Shares. Although Pharming does not believe that there is any material litigation or other proceedings pending or threatened, it cannot be excluded that it will face such claims in the future or that such claims, although not considered material, will impose on Pharming considerable costs or will consume significant management resources. In addition it cannot be excluded that Pharming will be confronted with claims which are raised with the main aim of exploiting the nuisance value of publicly raised claims. In order to prevent 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.

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

Pharming has entered into (downstream) manufacturing and supply agreements for the production of rhC1INH, the drug substance of Ruconest/Rhucin, namely with Sanofi Chimie S.A. (Sanofi) and Merck Sharp & Dohme B.V. Pharming may have to develop and/or contract additional (upstream) manufacturing capabilities and may have to contract additional (downstream) manufacturing 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.

#### Personnel Risk

# Pharming is dependent on its ability to recruit and retain its management and key employees

Pharming depends to a large degree on the performance and expertise of its management 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 moreover on recruiting and retaining highly qualified employees in the future, especially in management and in the area of research and development. The loss of individual employees or failure to attract new highly qualified employees could have significant detrimental consequences for Pharming's business and financial position.

#### **Financial Risks**

## The Company is dependent on external funding in the near future

Pharming does not yet generate sufficient cash from product revenues to meet its current working capital requirements and is partially dependent on financing arrangements with third parties. The ability of Pharming to attract external funding is (*inter alia*) dependent on the external market conditions (equity and/or debt) and the Company's ability to generate cash inflows from development of sufficient revenues from sales in the European Union (EU) through its commercialisation partners, especially through its main EU partner Swedish Orphan Biovitrum International AB (SOBI) and the approval by the FDA of its lead product, the therapeutic protein recombinant human C1 inhibitor (Rhucin®/Ruconest®) and subsequent revenues generated from sales through its commercialisation partner Santarus, Inc. (Santarus) for the treatment of acute attacks of HAE for marketing in the United States of America (USA), Canada and Mexico and the ability to leverage its transgenic platform through commercialisation deals. In case no cash is received from capital market transactions and/or commercial agreements to be concluded after the date of this Registration Document, the available balance of cash at the date of this Registration Document is expected to deplete in November 2012.

Pharming has a history of operating losses and anticipates that it will continue to incur losses for the foreseeable future. Pharming has thus far incurred losses in each year since incorporation. These losses have arisen mainly from costs incurred in research and development of Pharming's products and general and administrative expenses.

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 pre-clinical and clinical trials and other research and development 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 achieve profitability 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 never achieve profitability. Even if Pharming achieves profitability in the future, Pharming may not be able to sustain profitability in subsequent periods.

Pharming expects to 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 its Shares and all or part of an investment in its Shares could be lost. In addition, to the extent Pharming raises capital by issuing additional Shares, shareholders' equity interests would 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 EU-territory which are paid in local currencies. Subject to commercialisation of Rhucin in the USA or in other countries outside the EU and the USA, Pharming will also receive payments in US dollar or possibly in other currencies. As a result, Pharming's business and share price will 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.

#### **Risk Management and Control Risk**

# Pharming's internal risk management and control system may under circumstances be inadequate

The board of managing directors of Pharming (the **Management Board**) is responsible for designing, implementing and operating the Company's internal risk management and control systems. The purpose of these systems is to manage in an effective and efficient manner the significant risks to which the Company is exposed and to provide a reasonable assurance that the financial reporting does not contain any errors of material importance. The Company's internal risk management and control systems are designed to provide reasonable assurance that strategic objectives can be met. The Company has developed an internal risk management and control system that is tailored to the risk factors that are relevant to the Company, allowing for its small size. However, such systems can never provide absolute assurance regarding achievement of Pharming's objectives, nor can they provide an absolute assurance that material errors, losses, fraud, and the violation of laws or regulations will not occur. In addition, the responsibilities of the former Chief Financial Officer have recently been assigned to the Chief Executive Officer of the Company, which implies that the Chief Executive Officer temporarily has a double function which may weaken the effectiveness of the internal control system.

#### 2. IMPORTANT INFORMATION

No person is or has been authorised to give any information or to make any representation with respect to Pharming, other than as contained in this Registration Document, and, if given or made, any other information or representation must not be relied upon as having been authorised by Pharming. The delivery of this Registration Document at any time after the date hereof will not, under any circumstances, create any implication that there has been no change in the Company's affairs since the date hereof or that the information set forth in this Registration Document is correct as of any time since its date.

Pharming Group N.V. accepts responsibility for the information contained in this Registration Document. Having taken all reasonable care to ensure that such is the case, Pharming Group N.V. further declares that the information contained in this Registration Document is, to the best of its knowledge, in accordance with the facts and contains no omission likely to affect its import.

#### **Notice to Investors**

The distribution of this Registration Document may be restricted by law in certain jurisdictions. Persons in possession of this Registration Document are required to inform themselves about and to observe any such restrictions.

#### Presentation of Financial and Other Information

Certain figures contained in this Registration Document have been subject to rounding adjustments. Accordingly, in certain instances the sum of the numbers in a column or a row in tables contained in this Registration Document may not conform exactly to the total figure given for that column or row.

All references in this Registration Document to "Euros" or "€" are to the currency introduced at the start of the third stage of the Economic and Monetary Union, pursuant to the Treaty establishing the European Economic Community, as amended by the Treaty on the EU. All references to "US dollars", "US\$" or "\$" are to the lawful currency of the USA.

Any financial information in this Registration Document that has not been extracted from Pharming's audited consolidated financial statements for the years ended 2010 and 2011 is unaudited.

#### **Exchange Rates**

Pharming publishes its consolidated financial statements in Euros. The exchange rates below are provided solely for information and convenience. No representation is made that the Euro could have been, converted into US\$ at these rates.

The table below shows the high, low, average and end of period exchange rates expressed in US dollars per €1.00 for the years given, using the noon buying rate in New York City for cable transfers in foreign currencies as certified for customs purposes by the Federal Reserve Bank of New York (the **Noon Buying Rate**) for the periods indicated.

Year ended 31 December	High	Low (US\$ per	Average Euro)	Period
2010	1.4536	1.1959	1.3261	1.3269
2011	1.4875	1.2926	1.3821	1.2973

On 30 September 2012, the Noon Buying Rate for the Euro was €1.00 = \$1.2856.

# **Enforceability of Judgments**

Pharming Group N.V. is a limited liability company incorporated under the laws of the Netherlands. All of the members of the Management Board and board of supervisory directors of Pharming (the **Supervisory Board**) are residents outside the USA, and a substantial portion of Pharming's assets and the assets of such persons are located outside the USA. As a result, it may not be possible for investors to effect service of process within the USA upon Pharming or such persons, or to enforce against them in the Netherlands or elsewhere judgments obtained in USA courts, including judgments predicated on the civil liability provisions of the securities laws of the USA or any state or territory within the USA.

#### Market Data and Other Information from Third Parties

Pharming believes that market information contained in this Registration Document provides fair and adequate estimates of the volume of the Company's markets and fairly reflects the Company's market position within these markets. However, the Company's management estimates have not been verified by an independent expert, and the Company cannot guarantee that a third party using different methods to assemble, analyse or compute market data would obtain or generate the same results. In addition, the Company's competitors may define their markets and their own relative positions in these markets differently than the Company does.

The Company has used data sources from third parties in relation to certain matters noted herein. Such publications generally state that their information is obtained from sources they believe reliable but that the accuracy and completeness of such information is not guaranteed and that the projections they contain are based on a number of assumptions. The information in this Registration Document that has been sourced from third parties has been accurately reproduced. The Company has not independently verified this data or determined the reasonableness of such assumptions. So far as the Company is aware and is able to ascertain from information sourced from third parties, no facts have been omitted which would render the reproduced information inaccurate or misleading.

Market data has been obtained from a variety of analyst reports from a wide variety of EU and US banks and brokerages including but not exclusively KBC, Kempen, Jefferies, ThinkEquity, UBS, Leerink and JMP. Other sources contributing to Pharming's understanding of the market data comes from published independent and peer reviewed scientific papers in the academic literature including but not exclusively new England Journal of Medicine, Immunological Reviews, and the journal, Angioedema. Pharming's commercial partners, SOBI and Santarus, also provided primary and secondary information on the market including a market research project and feedback from clinicians working in the field.

# **Documents Incorporated by Reference**

Certain parts of Pharming's audited annual reports for the years 2010 and 2011 and its unaudited report for the first half year ended 30 June 2012 with comparative figures for the first half year ended 30 June 2011, listed below, are incorporated by reference into this Registration Document. The information contained in these documents that is not incorporated, is either not relevant for investors or is covered elsewhere in this Registration Document. No other documents or information form part of, or are incorporated by reference into, this Registration Document. Copies of the documents incorporated by reference into this Registration Document may be obtained free of charge for the life of this Registration Document by sending a request in writing at: Darwinweg 24, 2333 CR Leiden, the Netherlands. All documents incorporated by reference into this Registration Document are also available via <a href="https://www.pharming.com">www.pharming.com</a>.

Reference to	Half year report 30 June 2012	Annual report 2011	Annual report 2010
Consolidated statement of financial position	6	47	45
Consolidated statement of income	7	48	46
Consolidated statement of comprehensive income	8	49	47
Consolidated statement of cash flows	9	50	48
Consolidated statement of changes in equity	10	51-52	49-50
Notes to the consolidated financial statements	11-19	53-92	51-90
Note on Equity	15	68-70	66-68
Note on Related party transactions	17-18	88	85
Note on Commitments and contingencies	18	88	86
Auditor's report	Not applicable	98	96

Including comparatives for the first half year ended 30 June 2011. The consolidated statement of financial position as per 30 June 2011 is not included as a comparative in the half year report 30 June 2012; this statement can be found on page 7 of the half year report 30 June 2011.

# **Forward-Looking Statements**

This Registration Document contains forward-looking statements, including statements about Pharming's beliefs and expectations. These statements are based on the Company's current plans, estimates and projections, as well as its expectations of external conditions and events. In particular the words "expect", "anticipate", "predict", "estimate", "project", "may", "could", "should", "would", "will", "intend", "believe" and similar expressions are intended to identify forward-looking statements. Forward-looking statements involve inherent risks and uncertainties and speak only as of the date they are made. Pharming undertakes no duty to and will not necessarily update any of them in light of new information or future events, except to the extent required by applicable law. Pharming cautions investors that a number of important factors could cause actual results or outcomes to differ materially from those expressed in any forward-looking statements. These factors include, but are not limited to those discussed in Chapter 1 "Risk Factors Relating to Pharming".

#### 3. SELECTED FINANCIAL INFORMATION

The summary consolidated financial information set forth below should be read in conjunction with the information in Chapter 4 "Operating and Financial Review" and Pharming's consolidated financial statements and the notes thereto that are incorporated by reference in this Registration Document. The year-end consolidated financial information 2010-2011 has been extracted from Pharming's audited year-end consolidated financial statements; the consolidated financial information for the half year 2011 and 2012 has been derived from Pharming's unaudited interim financial statements. The Company's independent auditors issued an unqualified audit opinion with respect to the 2010 and 2011 financial statements. The 2011 audit opinion issued on 2 April 2012 included an emphasis of matter stating that the Company does not expect to generate sufficient cash from commercial activities to meet its entire working capital requirements for one year after the date of these financial statements and therefore is partially dependent on financing arrangements with third parties to finance its ongoing operations. This condition, along with other matters as set forth in note 2 to the consolidated financial statements, indicates the existence of a material uncertainty which may cast significant doubt about the Company's ability to continue as a going concern. The 2010 opinion issued on 30 March 2011 included a similar emphasis of matter as the 2011 audit opinion.

Pharming's consolidated financial statements, from which the summary consolidated financial information set forth below has been derived, were prepared in accordance with IFRS as adopted in the EU. The summary consolidated financial information set forth below may not contain all of the information that is important to investors.

Due to the discontinuation of the DNage operations in the first quarter of 2011, the comparative financial data in the statement of income for 2010 has been restated in order to reflect the Company's results from continuing and discontinued operations for all periods presented.

## Consolidated Income Statement Information

	30 June		31 December	
	2012	2011	2011	2010 <sup>1</sup>
	(unaudited)		(audited)	
(in millions)	€	€	€	€
Continuing operations:				
Revenues and other income	1.9	1.4	3.2	1.1
Cost of revenues	(3.0)	(1.1)	(3.5)	(0.1)
Operational costs	(12.3)	(9.1)	(18.2)	(22.2)
Operating loss	(13.4)	(8.8)	(18.5)	(21.2)
Financial income and expenses (net)	(3.2)	0.2	0.7	(16.5)
Net loss from continuing operations	(16.6)	(8.6)	(17.8)	(37.7)
Discontinued operations	-	0.6	0.6	(18.7)
Net loss	(16.6)	(8.0)	(17.2)	(56.4)

Due to the discontinuation of the DNage operations in the first quarter of 2011, the comparative financial data for 2010 has been restated in order to reflect the Company's results from continuing

and discontinued operations for all periods presented. Reference is made to note 4 of Pharming's financial statements in the annual report 2011, which is incorporated by reference.

#### **Consolidated Balance Sheet Information**

	30 June		31 December	
	2012	2011	2011	2010
	(unaudited)		(audited)	
(in millions)	€	€	€	€
Restricted cash <sup>2</sup>	1.2	1.3	1.3	0.2
Cash and cash equivalents <sup>2</sup>	2.2	9.7	3.8	10.3
Total assets	17.8	29.8	24.7	37.3
Other current liabilities	9.4	6.7	8.1	9.7
Non-current liabilities	16.6	19.0	17.8	17.5
Equity	(8.2)	4.1	(1.2)	10.1

The cash position of Pharming is comprised of restricted cash plus cash and cash equivalents and amounted to €3.4 million on 30 June 2012, €5.1 million on 31 December 2011, €11.0 million on 30 June 2011 and €10.5 million on 31 December 2010.

#### Consolidated Cash Flow Statement Information

	30 June		31 December	
	2012	2011	2011	2010
	(unaudited)		(audited)	
(in millions)	€	€	€	€
Net cash flows used in operating activities Net cash flows used in	(8.2)	(8.9)	(16.9)	(3.2)
investment activities Net cash flows from	(0.6)	(0.6)	(1.1)	(0.9)
financing activities	7.1	10.2	12.7	12.9

Net cash flows used in operating activities included cash flows related to the discontinued operations from DNage of €2.9 million in 2010 and €nil in (the first half year of) 2011 and 2012. Net cash flows from/(used in) investment activities and financing activities did not include items related to the discontinued operations from DNage in any of the above-stated periods.

## Financial and Trading Update

There has been no significant change in the financial or trading position of Pharming since 30 June 2012, save for (i) the final repayment in July 2012 of the €8.4 million private convertible bonds issued in connection with an agreement by and between Pharming and various investors entered into in December 2011 (35,256,025 Shares with a fair value of €846.000), (ii) the closing of the €10.0 million equity working capital facility (**Working Capital Facility**) from which, under a first draw down in August 2012, €1.2 million was raised and, under a second draw down in September 2012, €1.1 million was raised, (iii) the announcement of a significant downsizing of the Netherlands based organisation which results in minimum annual cash savings of €1.4 million (employee benefits only) and with potential cash payments associated with the discontinuation of 23 labour agreements maximised at €0.8 million of which the main portion is to be paid in monthly instalments throughout 2013-2014 and is contingent upon the receipt of US\$10.0 million (as milestone payment relating to the Study C1 1310 (see below)) and concluding an

additional external financing agreement of at least €5.0 million, and (iv) net cash proceeds of US\$0.9 million associated with the sale of the US-based cattle platform research operations (land and buildings) as announced in July 2012, with total cash payments to 10 terminated US-based labour agreements in the third and fourth quarter of 2012 amounting to US\$0.2 million. Anticipated annual cash savings following closure of these facilities amount to US\$1.0 million in employee benefits and other operational payments. End of September 2012 the Company announced that the Study C1 1310 (**Study 1310**) was completed and that over the subsequent weeks, as usual in the conduct of clinical trials, the trial database would be finalised and locked; subsequently, the results are analysed and subsequently announced. Positive results of Study 1310 will trigger a US\$10.0 million milestone payment from Santarus.

#### 4. OPERATING AND FINANCIAL REVIEW

The following should be read in conjunction with Pharming's consolidated financial statements and notes thereto that are incorporated by reference in this Registration Document. The consolidated financial statements have been prepared in accordance with IFRS.

In addition to historical information, this Chapter 4 includes forward-looking information that involves risks, uncertainties and assumptions. Pharming's actual results and the timing of events could differ materially from those anticipated by these forward-looking statements as a result of many factors, including those discussed below and elsewhere in this Registration Document, particularly in Chapter 1 "Risk Factors Relating to Pharming".

#### Overview

Pharming was founded in 1988 and has its headquarters in Leiden, the Netherlands. Pharming became public in 1998 and is developing innovative products, focusing on the treatment of diseases with significant unmet medical needs. These products are developed utilising Pharming's proprietary transgenic production technology.

Pharming currently has a product portfolio which focuses on the development and commercialisation of Ruconest/Rhucin (recombinant human C1 inhibitor) for HAE, a genetic disorder and is evaluating Ruconest/Rhucin in other potential indications in the area of ischaemia reperfusion injury (e.g. Acute Myocardial Infarction (AMI)) to generate value both in the short-term and long-term. Furthermore, Pharming has other recombinant protein assets (e.g. rhFIB and hLF) but these will not be further developed without a strategic partner. In addition, Pharming seeks various partnerships to generate additional income through expanding the geographical reach of its Ruconest/Rhucin franchise and outlicensing of its transgenic platform.

In October 2010, Pharming received an MAA approval in the EU for its lead product Ruconest, a therapeutic protein for treatment of acute attacks of HAE. Following receipt of a 'refusal to file' letter from the FDA in February 2011 for the Biologics License Application (**BLA**) submitted in December 2010, the Company and its partner Santarus met with the FDA in March 2011 to discuss their 'refusal to file' letter and gain further clarification on the protocol for the ongoing study to support the BLA. Pharming announced that an amendment to the protocol was submitted in May 2011 for the Rhucin Phase III clinical study into which the first patient was enrolled in February 2011. In August 2011, Pharming and Santarus announced that they have reached agreement with the FDA under the Special Protocol Assessment (**SPA**) process, which implies that the FDA has confirmed that Pharming's proposed trial design, clinical endpoints and statistical analyses for its Phase III study (**Phase III study**) in order to obtain regulatory approval in the USA are acceptable to the FDA. In July 2012 the last patient was treated in the trial and the unblinded data is expected to be available by the end of the third quarter of 2012.

Until the date of this Registration Document Pharming was primarily funded through private and public equity and/or debt transactions. In 2010, Pharming received an aggregate cash amount of €19.7 million in upfront and milestone payments of new agreements with partners SOBI and Santarus. Both 2010 agreements related to the Rhucin product and, in addition to existing agreements with Eczacibaşi Ilaç Pazarlama AS (EIP), MegaPharm Ltd (MegaPharm), Transmedic Pte (Transmedic) and Hyupjin Corporation (Hyupjin), the Company and its partners have now covered the territories of the EU, Iceland, Norway, Switzerland. Israel, the USA, Mexico, Canada, Brunei, Indonesia, Malaysia, Philippines, Singapore, Thailand, the Republic of Korea and (through an additional 2011 agreement with SOBI) parts of the Balkans, North Africa and the Middle East. Under the agreement with Santarus, Pharming is entitled to receive further milestones of US\$35.0 million upon the fulfilment of certain clinical, regulatory and commercial milestones, with in addition the possibility to receive a total of US\$45.0 million in milestones based on certain aggregate sales levels. The commercialisation agreements require

Pharming's partners to buy finished products from Pharming for a transfer price that incorporates a (progressive) tiered royalty component based on annual net sales performance.

# Material Factors Affecting the Results of Operations and Financial Condition

Pharming believes that the factors described below have had and are expected to continue to have a material effect on its operational results and financial condition.

Pharming's revenue comprises mainly revenues from outlicensing (e.g upfront and development milestone payments) and proceeds from sales. Licensing revenues relate to income received from third parties for rights to products or technology developed by the Company and is recognised in the year to which the income relates. Proceeds from sales are currently limited to finished product of Ruconest shipped to SOBI.

During 2010, an upfront payment and milestone payments totalling €8.0 million following the MAA approval were received under the agreement with SOBI for the distribution of Ruconest and an upfront payment of US\$15.0 million was received from Santarus for the North American distribution rights in the USA, Canada and Mexico. The Company is receiving proceeds from net sales in the EU. The Company also intends to obtain revenues from payments under future partnerships in respect of its products, government grants, licensing and partnerships using its technology, interest income as well as other miscellaneous income.

To date, Pharming's primary sources of liquidity have been funds generated through equity and debt financing. In 2007, Pharming raised €70.0 million gross proceeds through the issuance of the 6.875% convertible public bonds due 31 October 2012 (the 2007 Bonds). This loan has been redeemed and converted in full. Between December 2010 and March 2011, Pharming received €16.1 million (gross), pursuant to an equity financing arrangement with Socius CG II, LTD. (Socius). In January 2010, the Company secured a private convertible debt financing of €7.5 million maturing at 31 December 2010 and carrying 9% nominal interest per year (the 2010 Bonds). In April 2009, Pharming entered into a €20.0 million standby equity agreement with Yorkville Advisors Global Master SPV Ltd (Yorkville) with a duration of three years (the SEDA). In 2009, Pharming issued 13,071,669 Shares under the SEDA and raised a total amount of €6.6 million in cash. In 2010 another 14,260,818 Shares were issued under the SEDA for an aggregate cash consideration of €2.25 million. In July 2011, Pharming raised €3.2 million (gross) through the issuance of Shares to several US-based specialist investors. In December 2011, the Company entered into an agreement with various investors under which €8.4 million private convertible bonds were issued (the 2012 Bonds), subject to an increase of authorised share capital anticipated to take place in 2012. The Company issued the 2012 Bonds with a nominal value of €8.4 million carrying 8.5 percent interest per annum and to be repaid in six equal monthly tranches of €1.4 million between February and July 2012. In August 2012, the Company put in place the Working Capital Facility with a group of USA institutional investors allowing the Company to draw down up to €10.0 million over a two year period. To date, Pharming issued 164,304,453 Shares under the Working Capital Facility and raised a total amount of €2.3 million in cash.

To date, the majority of Pharming's expenditures have been for research and development activities. The Company expects research and development expenses to have reached a plateau over the next few years as partners are contributing to the development costs of additional indications for Ruconest/Rhucin and as the initiation of new development projects will, until clinical development stage is reached have limited financial impact and cost-sharing partners will be sought. In addition, general and administrative expenses necessary to support these programs are expected to remain the same.

Research and development costs are expensed as incurred and include costs associated with collaborative agreements. These costs consist of direct and indirect costs related to specific projects as well as fees paid to other entities, which conduct certain research activities on behalf of the Company.

Reference is also made to Chapter 5 "Business – Business Plan" for a description of the key assumptions underlying the business plan of Pharming for the next two years.

# Results of Operations 2011, 2010 and half year ended 30 June 2012 and 30 June 2011

# Consolidated Income Statement Information

	30 June 2012 2011		31 December 2011 2010 <sup>1</sup>	
	(unaudited)		(audited)	
(in millions, except per share data)	€	€	€	€
Continuing operations:				
Revenues and other income	1.9	1.4	3.2	1.1
Cost of revenues	(3.0)	(1.1)	(3.5)	(0.1)
Research and development General and administrative Impairment charges	(9.2) (1.7) (1.2)	(7.1) (1.7) -	(13.9) (3.3)	(18.4) (3.2)
Share-based compensation Operational costs	(0.2) <b>(12.3)</b>	(0.3) <b>(9.1)</b>	(1.0) <b>(18.2)</b>	(0.6) <b>(22.2)</b>
Operating loss	(13.4)	(8.8)	(18.5)	(21.2)
Effective interest bonds Fair value result derivatives Settlement bonds	(2.3) 2.0 (2.6)	0.4	1.0	(3.6) (7.7)
Anti-dilution provisions Earn-out interest Interest income and expenses, net Other items, net Financial income and expenses (net)	(0.1) (0.2) (3.2)	(0.1) (0.1) (0.2)	(0.2) (0.1) <b>0.7</b>	(2.9) (0.8) (0.1) (1.4)
Net loss from continuing operations	(16.6)	(8.6)	(17.8)	(37.7)
Discontinued operations Net loss	(16.6)	0.6 <b>(8.0)</b>	0.6 <b>(17.2)</b>	(18.7) <b>(56.4)</b>
Attributable to: Equity owners of the parent Non-controlling interest	(16.6) -	(7.9) (0.1)	(17.1) (0.1)	(50.2) (6.2)
Net loss per share: Continuing operations Discontinued operations Total	(0.03)	(0.02) - (0.02)	(0.14) (0.05) (0.19)	(0.24) (0.04) (0.28)

Due to the discontinuation of the DNage operations in the first quarter of 2011, the comparative financial data for 2010 has been restated in order to reflect the Company's results from continuing

and discontinued operations for all periods presented. Reference is made to note 4 of Pharming's financial statements in the annual report 2011, which is incorporated by reference.

#### Revenues and other income

Pharming's revenue and other income are comprised of revenues (license fee income, product sales) with other income relating to grants.

In the year 2010 the Company recognised license fee income of €0.5 million following the periodic release of upfront and milestone payments received through new commercial partnerships with Santarus and SOBI and which were largely recognised as of the fourth quarter of 2010; these amounts are released to the statement of income over the lifetime of the agreements. The full year effect of this continuing release of amounts received resulted to €1.9 million of license fee revenues in 2011 with €1.0 million recognised in both the first half year of 2011 and 2012.

Product sales represent supplies and start in the fourth quarter of 2010 following market launch in the EU of Ruconest. The 2010 product sales income amounted to €0.1 million and €1.1 million in 2011, of which €0.3 million in the first half year of 2011; this increased to €0.8 million in the first half year of 2012.

Income from grants in 2010 amounted to  $\in$ 0.5 million and included a one-time grant of  $\in$ 0.3 million; income from grants subsequently decreased to  $\in$ 0.2 million in 2011, with such income in the first half year of 2011 and 2012 both amounting to  $\in$ 0.1 million.

#### Cost of Revenues

Costs of revenues are related to the cost of goods sold, (anticipated) transfer price adjustments and other impairment charges related to inventories designated for sale. The €3.5 million cost of revenues in 2011 included €1.7 million inventory impairments on inventories designated for commercial activities following production-related events beyond control of the Company; Pharming has taken actions to recover at least the value expensed. In addition, (first half year) 2011 costs of revenues included an amount of €0.8 expensed in anticipation of a revised reimbursement strategy of SOBI (as ultimately implement) and which would result in a supply price below the carrying value of the inventories. First half year 2012 cost of revenues amounted to €3.0 million of which €0.8 million relating to product sales and €2.2 million to inventory impairments following the unlikelihood that certain inventories will be sold prior to expiration.

#### **Operational Costs**

Costs of research and development are primarily related to basic research as well as pre-clinical and clinical activities, including employee benefits incurred in respect of Pharming employees involved in these activities. In particular external costs may vary significantly due to the timing and extent of research and development activities. Costs of research and development of €18.3 million in 2010 decreased by €4.5 million to €13.8 million in 2011, which stems from lower inventory impairment charges of €0.1 million (2010: €2.1 million), cost containment measures and timing of various activities. Research and development costs in the first half of 2012 increased to €9.3 million compared to €7.1 million in the comparative period of 2011; the increase primarily stems from clinical activities related to Study 1310 and a second quarter 2012 non-cash write off on inventories previously reserved for research and development activities (€0.6 million).

General and administrative expenses relate to all cash-related expenses not related to the Company's business processes and include both third party fees and expenses and employee benefits. These expenses remained fairly constant at €3.2 million in 2010 and €3.3 million in 2011. Costs for the first half of 2011 and 2012 remained constant at €1.7 million.

Impairment charges of €1.2 million in the first half year of 2012 stem from the second quarter 2012 decision to discontinue the USA cattle facilities with a corresponding write off to reflect the anticipated net proceeds of the assets in a sales transaction (US\$1.0 million).

Expenses for share-based compensation are non-cash and relate to the fair value expenses of option plans as well as the Long Term Incentive Plan. These expenses have increased from €0.6 million in 2010 to €1.0 million in 2011; the increase in 2011 largely reflects a higher number of options granted to the Management Board. First half year share-based compensation expense in 2011 of €0.3 million mainly relate to the granting of Management Board options in the second quarter of 2011; the number of options for the Management Board in 2012 as granted in the second quarter of 2012 slightly increased but this resulted in a lower expense compared to 2011 as a result of a significant decrease of the fair value per option.

#### Financial Income and Expenses

## Effective Interest Bonds, Fair Value Result of Derivatives and Settlement Bonds

The results related to effective interest on bonds, the fair value results of derivatives and bond settlements are all primarily related to the financial impact of various convertible bonds and/or warrants issued with most warrants being issued in connection with convertible bonds.

Upon issuance of the 2007 Bonds on 31 October 2007, a derivative portion of €21.7 million and transaction fees of €3.0 million were carved out of the gross proceeds to arrive at a net liability of €45.3 million. This initial liability increased in subsequent periods through charging an effective interest rate in order to, ultimately, fully equal the total amounts of semi-annual interest payments of 6.875% and the redemption payment over the five year maturity period. Total effective interest on the 2007 Bonds in 2010 amounted to €3.6 million with the 2007 Bonds fully repaid in October 2010, whereas the interest effect of the €7.5 million 2010 Bonds issued in January 2010 was limited to €1.5 million since all were converted in the second and third quarter of 2010. As a result of the full clearance of all bonds in the course of 2010, no further bond interest expenses were recorded as of 2011.

The terms and conditions of the 2007 Bonds were such that the conversion price was variable following the issuance; as per 30 April 2008 the conversion price was fixed at €2.64 (subject to adjustments in accordance with the terms as set out in the terms and conditions of the 2007 Bonds). In view of this conversion price reset mechanism, the ultimate number of Shares to be issued upon any conversion upon initial recognition was variable and accordingly the 2007 Bonds included a derivative portion which should be measured at its fair value with subsequent changes in fair value recognised in the income statement. The fair value of the derivative was €7.4 million at 31 December 2007 and €3.4 million at 30 April 2008; the €4.0 million difference was released to the statement of income of 2008. Additional fair value results of €0.9 million in the fourth quarter of 2008 and €0.2 million in the first quarter of 2009 followed from the settlement of 2007 Bonds as far as the portion was allocated to the derivative. No further effects on the statement of income were recognised for this item after the first quarter of 2009.

Under specific conditions, the conversion price of the 2010 Bonds and the exercise price of the warrants entitling the holders thereof to subscribe for 15 million Shares issued in connection therewith (the **2010 Warrants**) could be reduced below €0.50 while additional 2010 Warrants would be issued. The initial maximum conversion price of €0.50 decreased in various stages through an adjustment of the nominal value per Share from €0.50 to €0.04 as well as the subsequent issue of 100 million Shares at a gross price of €0.12 per Share. Due to these adjustment mechanisms in the original issue conditions, the final number of 2010 Warrants issued to the holders of 2010 Bonds ultimately increased to 58,780,445, whereas the maximum conversion price decreased to €0.12. The 2010 Warrants were exercised cashless, implying that a theoretical profit (based on a contractually agreed reference price) on a part of the 2010 Warrants exercised is forfeited in order to pay for Shares transferred to the exercising party without any consideration (in cash or other assets). In 2010, bondholders exercised 53,572,112 2010 Warrants of which 30,143,090 used as payment on the 23,429,022 Shares issued at an exercise price of

€0.12; a total of 5,208,333 of the 2010 Warrants were still outstanding at 30 June 2012. Due to the underlying mechanisms of the 2010 Warrants, they qualify as a derivative financial liability with changes in the fair value carried through the statement of income. The fair value of the conversion option and the 2010 Warrants have been determined through an independent external valuator both as per the issue date as well as per each subsequent reporting period with subsequent value changes resulting in a loss for the year 2010 of €7.7 million and a €0.4 million profit in the year 2011. In the first half of 2012 the effect was a €0.1 million profit compared to a profit in the first half year 2011 of €0.4 million.

In the third quarter of 2011 the Company issued 29,000,000 Shares and committed to issue warrants entitling the holders thereof to subscribe for 20,300,000 Shares (the **2011 Warrants**) with an exercise price of  $\in$ 0.11 subject to an increase of the authorised share capital to be approved by the shareholders (which was obtained in the first quarter of 2012). The contingent right as well as the adjustment mechanisms of the 2011 Warrants qualify as a financial derivative liability. The investors were also involved in the 2012 Bonds but prior to entering into that agreement in 2011 it was agreed that the exercise price of the 2011 Warrants would be decreased from  $\in$ 0.11 to  $\in$ 0.06. Upon entering into the agreement the fair value of the derivative amounted to  $\in$ 1.6 million, which value decreased to  $\in$ 1.0 million at 31 December 2011. Accordingly, the fair value decrease of  $\in$ 0.6 million was charged as a profit to the statement of income for 2011. The fair value of the 2011 Warrants further decreased to  $\in$ 0.1 million at 30 June 2012 and this implied a first half year 2012 profit of  $\in$ 0.9 million compared to no result in the comparative period of 2011.

Following an announcement in December 2011 the Company in February 2012 issued the 2012 Bonds carrying 8.5% annual interest. Along with the issue of the 2012 Bonds, the Company also issued warrants entitling the holders thereof to subscribe for 38,717,484 Shares (the **2012-I Warrants**). An advance payment of 20 million Shares valued at €1.5 million was made in 2011; the amount was charged to liabilities in the first quarter of 2012. In connection to the issue of the 2012 Bonds the Company also incurred transaction fees and expenses of €0.6 million in total (€0.5 million charged to the 2012 Bonds liability and €0.1 million charged to financial expenses in relation to the derivative financial liabilities). The fair value of the 2012-I Warrants and the conversion right for the holders of the 2012 Bonds upon issue date amounted to €1.2 million; this value decreased to €0.2 million at 30 June 2012 with the €1.0 million fair value movement recognised as a profit on the fair value of derivatives.

In February 2012 the Company received €8.0 million in cash in relation to the issue of the 2012 Bonds. Net of derivative financial liabilities of €1.2 million and transaction fees of expenses allocated to the 2012 Bonds (€0.5 million), the initial carrying value amounted to €6.3 million. Pharming had the option to pay the monthly installment plus interest either in cash or Shares; the Company elected to pay all installments in Shares and as a result of certain conditions in the agreements this has resulted in a transfer of Shares for a value higher than if such a repayment had taken place in cash. The total fair value of Shares issued up to 30 June 2012 exceeded the carrying value of installments by €2.0 million with an amount of €0.6 million additionally expensed for additional Shares expected to be issued after 30 June 2012 in view of certain settlement clauses (e.g. to compensate holders of 2012 Bonds for a decrease of the share price), so that a total amount of €2.6 million was charged to the statement of income as a loss.

#### **Anti-Dilution Provisions**

In the fourth quarter of 2009 the Company settled the 2007 Bonds with an aggregate nominal value of €24.9 million through payment of €3.7 million in cash and issuance of 29,382,000 Shares. In addition, these bondholders received anti-dilution protection for as long as at least €7.0 million of the 2007 Bonds were outstanding. This period ended after final repayment of the outstanding 2007 Bonds as per 31 October 2010. The Shares and Share rights issued in 2010 through various equity and debt transactions prior to 31 October 2010 triggered an aggregate issue of 14,147,789 Shares in relation to the anti-dilution protection offered with an aggregate fair value of €2.9 million.

#### **Earn-Out Interest**

Upon acquisition of DNage in 2006, the Company agreed to pay various earn-outs to former DNage shareholders. Two of them related to milestones of €5.0 million, each of which were subject to achievement of certain clinical development achievements. The Company charged interest to the discounted value of the earn-outs as per the 2006 acquisition date of DNage and each subsequent period, assuming a discount rate of 20%-23% and taking into account the assumed timing of each payment as well as its probability. Following an agreement with the former DNage shareholders in the third quarter of 2010 the earn-out liabilities were settled in exchange for an issuance of 5,000,000 Shares plus 49% of the shares in DNage.

# **Net Interest Income and Expenses**

Interest income and expensed are derived from finance lease liabilities (interest expenses only) and balances of cash and cash equivalents, bank overdrafts and marketable securities.

In 2011 the Company entered into various finance lease arrangements with respect to manufacturing and laboratory equipment. In addition, one other agreement in which a third party has invested in equipment for the ultimate benefit of Pharming, and for which Pharming reimburses that party through an increase of the compensation for other services, has been categorised as an embedded finance lease agreement. Overall, these transactions have resulted in finance lease interest expenses of  $\{0.1 \text{ million}\}$  in the first half year 2011,  $\{0.2 \text{ million}\}$  for the full year 2011 and  $\{0.1 \text{ million}\}$  for the first half year 2012.

Net interest expense in 2010 amounted to €0.1 million due to various bank overdraft balances throughout the year (but cleared before the end of 2010). No material interest items have been recognised in the first half of 2011 and 2012.

# **Discontinued Operations**

Amounts presented as result from discontinued operations relates to the termination of DNage activities in the first quarter of 2011; the statement of income for 2010 has been restated to improve the comparability of results. These results can be split into operating losses, impairment results and non-cash tax results.

The operating losses of DNage for 2010 were €2.3 million and primarily related to (pre)clinical activities. In the first half of 2011 the operating losses of DNage were €0.2 million since the activities were terminated following a 31 January 2011 decision by the DNage shareholders to liquidate the entity.

In 2010 the parent entity of DNage incurred €3.9 million impairment charges on the remaining DNage goodwill capitalised following its acquisition in 2006. This amount related to all remaining goodwill and was based on the assumption that no future income would be generated from the DNage operations.

DNage in 2010 incurred a one-time impairment charge of €16.8 million to write-off the carrying value of intangible assets identified upon acquisition of the entity by Pharming in 2006. The charge reflects the outcome of the decision by the DNage shareholders to liquidate the entity.

In 2010 a €4.3 million deferred tax liability linked to the carrying value of intangible assets was released to the statement of income following impairment of the assets involved. No income tax items in relation to DNage were incurred as of 2011.

#### **Liquidity and Capital Resources**

Pharming's primary sources of liquidity have been funds generated through equity and debt financing, in addition to income generated through licensing agreements, product sales and government grants.

In 2007, Pharming issued 2007 Bonds with a nominal value of €70.0 million, which excluding transaction fees and expenses resulted in a cash receipt of €67.0 million. The cash generated from the 2007 Bonds was sufficient to cover Pharming's operations into 2009 so that no equity or debt agreements were entered into in 2008.

Under the terms of the SEDA, Yorkville could invest a total of up to €30.0 million in a three year period until April 2012. Pharming had the right, but not the obligation, to call the funds in regular tranches, up to €0.4 million per tranche, by issuing Shares at a 5% discount to the market price and provided the market price of the Shares was at least 20% above the nominal value of the Shares. In 2009, Pharming issued 13,071,669 Shares under the SEDA (including 1.2 million Shares which were issued upon execution of the SEDA in April and of the amendment in October) and raised a total amount of €6.6 million in cash.

In January 2010, Pharming entered into subscription agreements with institutional investors through the issuance of the 2010 Bonds. The holders of the 2010 Bonds ultimately converted the entire €7.5 million nominal value plus accrued nominal interest of €0.1 million as per the conversion date for an aggregate number of 47,710,616 Shares with a total fair value of €10.9 million.

In the second quarter of 2010, the Company issued 100,000,000 Shares to institutional investors for an aggregate value of €12.0 million in cash; due to fees and expenses the net proceeds amount to €10.7 million.

In the third quarter of 2010 another 14,260,818 Shares were issued under the SEDA for an aggregate cash consideration of €2.25 million.

In December 2010 the Company entered into an agreement with Socius under which Pharming issued debts notes with a nominal value of €12.0 million carrying nominal interest of 10% per annum over a four year period. The issuance of these debt notes triggered 24,339,623 warrants granted to Socius with a two year exercise period and an exercise price of €0.212, on aggregate reflecting an exercise value of €5.2 million of which the nominal value per Share of €0.04 is due in cash upon exercise (€1.0 million) with the remaining €4.2 million paid through issuance of interest-free debt notes Socius to the Company. Socius also obtained the right to subscribe for Shares up to €16.1 million, which right they immediately exercised and therefore in 2010 received 75,849,057 Shares valued at €0.212 each. Payment of the Shares issued was settled in cash (€3.0 million for the nominal value of €0.04 per Share) and through issuance of debt notes by Socius to Pharming (€13.1 million) carrying 0.65% nominal interest per annum over a four year period. Socius transferred a net amount of €4.8 million in December 2010 with remaining €9.0 million received in January 2011 and another €1.0 million following exercise of the warrants in March 2011.

In July 2011 Pharming completed a private placement to new US-based specialist investors in which the Company issued 29,000,000 Shares at a cash consideration of €0.11 per Share or €3.2 million in aggregate. The investors also obtained the right to receive 20,300,000 Shares with an exercise price of €0.11, subject to shareholder approval of an increase of the authorised share capital no later than at the AGM in 2012. On 3 February 2012, the Company held an EGM in which the shareholders approved the increase of authorised share capital from 550 million to 805 million Shares. Also, following participation of the investors in the 2012 Bonds, the exercise price of the 2011 Warrants was adjusted to €0.06. The exercise price of the 2011 Warrants was reduced to €0.013878 following the issue of Shares under the Working Capital Facility. The 2011 Warrants expire on 15 July 2017.

In December 2011 the Company entered into an agreement with *inter alia* investors of the July 2011 issue under which the 2012 Bonds were issued subject to an increase of share capital anticipated to take place in 2012. The EGM approval on 3 February 2012 triggered the immediately release of €8.0 million in cash to Pharming, which amount was held in escrow by an independent law firm since 31 December 2011. The Company issued the 2012 Bonds with a nominal value of €8.4 million carrying 8.5 percent interest per annum and to be repaid in six equal monthly tranches of €1.4 million between February and July 2012. The investors had the right to convert outstanding 2012 Bonds at a fixed conversion price of €0.12; the Company had the option to repay in either cash or Shares. In addition, the investors received

the 2012-I Warrants with an exercise price of €0.12 per warrant. The exercise price of the 2012-I Warrants was reduced to €0.013878 following the issue of Shares under the Working Capital Facility. The 2012-I Warrants expire on 6 February 2017. As per the date of this Registration Document, Pharming has fully repaid the 2012 Bonds plus interest in Shares; the total number of Shares issued by Pharming was 230,181,995 with a total fair value of €11,427,000 (20,000,000 Shares in 2011 with a fair value of €1,503,000; 174,925,970 Shares in the first half year 2012 with a fair value of €9,078,000; 35,256,025 with a fair value of €846,000 as a final settlement payment in July 2012). Until the date of this Registration Document, a total of 12,958,258 of the 2012-I Warrants have been exercised in October 2012 for a cash consideration of €180,000.

In August 2012, Pharming entered into the Working Capital Facility of up to €10.0 million for a two year term with a number of US institutional investors. In the third quarter of 2012, until the date of this Registration Document, Pharming issued 164,304,453 Shares under the Working Capital Facility against receipt of €2.3 million in cash. The investors under the Working Capital Facility received warrants entitling them to subscribe for 27,505,500 Shares and are furthermore entitled to additional warrants representing a maximum of 38,494,500 Shares subject to further draw downs under the Working Capital Facility (the **2012-II Warrants**). The exercise price of the 2012-II Warrants is €0.0233 per warrant (subject to adjustment). Until the date of this Registration Document, a total of 7,632,369 of the 2012-II Warrants have been exercised in October 2012 for a cash consideration of €178,000.The 2012-II Warrants expire on 1 September 2017.

# **Cash Flows**

The Company's total liquidity position comprises cash and cash equivalents (including restricted cash).

Net cash and cash equivalents in 2010 increased from €2.3 million at 1 January 2010 to €10.5 million at 31 December 2010. The €8.2 million net increase results from net cash outflows from operating activities of €3.2 million, investment cash outflows of €0.9 million, net cash inflows from financing activities of €12.9 million and the €0.7 million loss effect on cash and cash equivalents held in foreign currencies. The limited net operating cash outflows of €3.2 million in 2010 stem from €20.4 million contributions received from licensing partners (of which €19.7 million upfront and milestone payments from new partnerships with Santarus and SOBI). Investment cash flows of €0.9 million in 2010 mainly reflect payments in relation to assets under construction in relation to the manufacturing agreement with Sanofi. Financing activities of €12.9 million consisted of the €7.5 million proceeds of the 2010 Bonds, €11.2 million net proceeds from the equity issue in the second quarter of the year, €4.8 million received in relation to the Socius agreement and €2.25 million raised under the SEDA; these receipts were offset with €11.7 million repayments (nominal interest plus final redemption) on 2007 Bonds and €1.1 million payments in relation to fees and expenses incurred with respect to 2009 and 2010 financing transactions.

Net cash and cash equivalents in the first half of 2011 increased by €0.5 million from €10.5 million at the beginning of 2011 to €11.0 million at 30 June 2011; for the full year 2011, net cash and cash equivalents decreased by €5.4 million to €5.1 million. Net cash outflows from operating activities for the full year 2011 amounted to €16.9 million, of which €8.9 million in the first half 2011. The full year 2011 net increase by €13.8 million of net operating cash outflows compared to 2010 (€3.2 million) largely reflects 2010 upfront and milestone payments from Santarus and SOBI of €19.7 million and 2010 net operating cash outflows of the discontinued DNage business of €2.9 million compared to €nil in 2011. Excluding these effects the net operating cash outflows for 2010 would have amounted to €20.0 million so that 2011 would have decreased by €3.1 million; this decrease is largely related to timing of payments. Investment cash outflows in 2011 were primarily related to investments in the downstream activities at Sanofi. Financing cash inflows of €12.7 million in 2011 primarily stem from €10.0 million received from Socius in the first half year of 2011 (€9.0 million following the fourth quarter 2010 transaction and €1.0 million in relation to the exercise of all 24,339,623 warrants held by Socius) and €3.2 million received in the second half of 2011 following a private placement; other financing cash flows in 2011 include a finance lease refund, finance lease payments as well as payment of transaction fees and expenses.

In the first half year of 2012 net cash and cash equivalents decreased by €1.7 million from €5.1 million to €3.4 million. The decrease reflects a net cash outflow from operating activities of €8.2 million, investment cash outflows of €0.6 million and net cash inflows from financing cash inflows in the amount of €7.1 million. Net cash outflows used in operating activities primarily reflect payments in relation to ongoing (pre)clinical activities and the Company's transgenic platform while investment cash outflows reflect payments in relation to items required in relation to the collaboration with Sanofi. Net cash inflows from financing activities include €8.0 million received through issue of the 2012 Bonds, transaction fees and expenses and finance lease payments.

# **Negative Equity**

In December 2011 the Company announced that it had entered negative equity. This negative equity position of  $\in$ 1.2 million at year end 2011 increased by  $\in$ 7.0 million to  $\in$ 8.2 million at 30 June 2012 and mainly reflects the  $\in$ 16.6 million net loss for the first half year 2012, net of  $\in$ 9.4 million posted for Shares issued as a repayment of convertible bonds ( $\in$ 9.1 million) and other payments in Shares ( $\in$ 0.3 million).

The negative equity position has in itself no immediate impact on the execution of Pharming's business plan, nor does it imply that the Company is legally required to issue new share capital. However, the Company is considering various options in order to reduce the negative equity and return to a positive equity position.

#### **Principal Investments**

In 2010, aggregate investments amounted to €2.1 million which almost exclusively relates to assets acquired in relation to the transfer of activities to Sanofi. At the end of 2010 these items were under construction with €0.9 million paid in 2010 and an amount of €1.2 million presented under current liabilities.

Investments in the year 2011 amounted to €3.7 million (first half year of 2011: €0.6 million), which largely reflects additional investments in the Sanofi facility. Also, the Company in the first half year of 2011 entered into a financial lease agreement under which it received €0.6 million as a refund for a portion of the 2010 payments.

Investments in the first half year of 2012 were limited to €0.1 million.

No material investments have taken place after the first half year of 2012 until the date of this Registration Document.

Save for regular investments in property, plant and equipment items, no significant investments are planned in the near future.

# **Contractual Obligations**

The Company has entered into non-cancellable operating lease commitments for rent of offices and laboratories as well as lease cars. Based on the current status of these contracts, anticipated payments under these commitments for the fourth quarter of 2012 are €0.2 million, €0.7 million for 2013, €1.5 million for 2014-2016 and nil beyond 2016.

As per the date of this Registration Document, the Company had entered into several agreements with third parties under which Pharming has to pay cash against delivery of goods or services or in case certain performance criteria have been met. In general, these primarily relate to the manufacturing of rhC1INH; only a minor part of these payments relate to milestone payments for research and development activities, including clinical trials. Total potential payments under these agreements are approximately €109.0 million, of which €2.7 million is expected to be paid in the fourth quarter of 2012, €5.8 million in 2013, €38.0 million for 2014-2016 and €62.5 million beyond 2016.

# **Off Balance Sheet Arrangements**

Pharming has no off balance sheet arrangements.

# **Dividend Policy**

Pharming has not paid dividends since its incorporation and currently intends to retain future earnings, if any, to finance the growth and development of its business. As a result, the Company does not anticipate paying any dividends for the foreseeable future.

Pharming's dividend policy will, however, be reviewed from time to time and payment of any future dividends will be effectively at the discretion of the Management Board, subject to approval of the Supervisory Board, after taking into account various factors including Pharming's business prospects, cash requirements, financial performance and the requirements of Dutch law. Under Dutch law, payment of dividends may be made only if the shareholders' equity exceeds the sum of the called up and paid-in share capital plus the reserves required to be maintained by law and by the articles of association.

#### 5. BUSINESS

#### Overview

Pharming is developing innovative products for the treatment of unmet medical needs. Ruconest (Rhucin in non-European territories) is a recombinant human C1 inhibitor approved for the treatment of angioedema attacks in patients with HAE in all 27 EU countries plus Norway, Iceland and Liechtenstein, and is distributed in the EU by SOBI. The rights to distribute Ruconest in the Balkan region, Middle East and North Africa are also held by SOBI.

Rhucin is partnered with Santarus Inc (NASDAQ: SNTS) in North America. Pharming is currently conducting a Phase III clinical trial to achieve registration in the US. The product is also under evaluation for indications in the areas of transplantation and ischaemia reperfusion injury.

The commercial attractiveness of the Company stems from its innovative platform for the production of protein therapeutics and its extensive technology and processes know-how for the purification and formulation of these products. Pharming has an agreement with Renova Life to assess the feasibility of developing recombinant human Factor VIII (rhFVIII) for the treatment of Haemophilia A patients, as a first step in broadening the range of proteins manufactured using the platform.

## **History**

Pharming was founded in 1988 as a spin-off from GenPharm International. In 1998 it became public through an initial public offering at EASDAQ, the Pan-European electronic trading platform for growth companies (which ceased to exist in 2003). In 1999 Pharming was listed on the Amsterdam Stock Exchange (now called Euronext Amsterdam by NYSE Euronext). In 2001 and 2002 the Company underwent a major financial and corporate restructuring reducing its workforce from 240 people to below 50 while focusing most of its resources on the development of Rhucin. In 2004 the Company strengthened its financial position through a private placement of Shares.

In late 2006 the Company acquired DNage, a small biotech company focusing on diseases associated with old age, to expand its technology platforms and to obtain access to potential future new product lines. As a result of a portfolio prioritisation, DNage subsequently was partially spun-off in the course of 2010 and upon failure to attract third party financing after the expiration of agreed bridge funding by Pharming, DNage was declared bankrupt in February 2011.

After having failed to obtain the MAA for rhC1INH in late 2007, the Company re-submitted a new dossier for market authorisation in Europe in September 2009 after obtaining the additional data as requested by the committee in 2007/2008. The MAA was granted in October 2010 and the product is now marketed under the trade name Ruconest®.

In the course of 2008 and 2009 the Company cancelled approximately €59.1 million of the €70.0 million outstanding 2007 Bonds by partial payment in cash and issuance of Shares to the bondholders. In 2009 and 2010, the Company issued Shares and the 2010 Bonds in private placements to strengthen its financial position. In the fourth quarter of 2010 the €10.9 million remaining outstanding Bonds 2007 was fully repaid in cash. The 2010 Bonds have been converted in Shares in the course of 2010.

In July 2010, Pharming announced it had entered into a settlement agreement as a result of which Pharming's maximum earn-out payments due to the former DNage shareholders of up to €10 million were settled through a payment of 5 million Shares and a 49% equity interest in DNage. It was also announced that the remaining 51% interest of the Company in DNage was expected to further decrease as and when DNage would secure new specialised investors willing to share the risks and rewards by purchasing newly issued equity in DNage. Pharming provided DNage with a limited bridge funding of €1.2 million.

In December 2010, the Company entered into an agreement with Socius under which Pharming issued Shares and warrants for a gross amount of €16.1 million. The warrants were exercised in March 2011. The total cash received by Pharming from Socius, net of fees, amounted to €14.8 million (€4.8 million in 2010 and €10.0 million in the first guarter of 2011).

In December 2010, Pharming also submitted the Rhucin® BLA to the FDA for the treatment of acute angioedema attacks in patients with HAE.

In January 2011, and following the settlement agreement of July 2010, Pharming and other DNage shareholders announced that they had discontinued the funding of DNage since DNage had not been able to secure new investors. DNage entered into voluntary liquidation and was declared bankrupt in February 2011.

In February 2011, the FDA requested that the Rhucin® BLA, which had been filed in December 2010 for the treatment of acute angioedema attacks in patients with HAE, include results from an additional ongoing Phase III study prior to reviewing the BLA. In August 2011, an SPA was agreed with the FDA on the requirements for a BLA file.

In July 2011, the Company completed a financing of  $\in$ 3.2 million adding new US-based specialist investors in exchange for the issue of Shares and 2011 Warrants. In December 2011, Pharming announced the issue of a  $\in$ 8.4 million loan by means of the 2012 Bonds to institutional investors, including the investors participating in the July 2011 financing. The 2012 Bonds were fully paid off in Shares with the final installment paid in July 2012.

The USA pivotal trial (Study 1310) completed recruitment in July 2012 but due to an internal oversight the unblinding of the top-line data was delayed by up to three months in order to complete the statistical package required by the FDA. As a consequence, Pharming's Chief Medical Officer R.R.D.I. (Rienk) Pijpstra shortly thereafter resigned from the Company. This delay highlighted a potential cash shortfall at the Company and Pharming announced that it had engaged Nomura Code alongside long term advisor, Roth Capital Partners, to assist in a review of strategic options which could include a merger, equity investment or sale.

In June 2012, Pharming decided to close its US-based cattle platform research operations which were comprised of farm based research facilities, land and staff involved in research and maintenance of the Company's transgenic cattle herd. The decision reflected the declining importance of transgenic cattle research, and legacy proteins such as fibrinogen, lactoferrin and collagen, to Pharming's future strategy and the increasing business development focus on current and new projects, such as C1 inhibitor and Factor VIII. Early July 2012, the sale of the associated assets was announced.

In August 2012, Pharming entered into the Working Capital Facility of up to €10.0 million for a two year term with a number of US institutional investors. The Company also announced a strategic restructuring plan of its Dutch operations. The plan included a request for collective redundancies, which was filed with the Netherlands Authority for Labour Relations and Unemployment Benefits (**UWV Werkbedrijf**) in accordance with the *Wet Melding Collectief Ontslag*. The process entails a formal procedure, required when there is a need for downsizing an organisation by 20 staff or more. In September 2012, Pharming's works council rendered a positive advice with respect to the restructuring and agreed to a social plan. Subsequently the Company has requested UWV Werkbedrijf to approve the discontinuation of 23 labour agreements. The approval is anticipated to be received in the course of the fourth quarter of 2012, after which the formal discontinuations will be effected in late 2012 and/or early 2013.

End of September 2012 the Company announced that the Study 1310 was completed and that over the subsequent weeks, as usual in the conduct of clinical trials, the trial database would be finalised and locked; subsequently, the results are analysed and subsequently announced.

# Strategy

The mission of Pharming is to develop innovative therapeutics for unmet medical needs and to provide solutions to the potential limitations of existing recombinant protein production methods. Pharming's technologies include novel platforms and know-how for the production of protein therapeutics, as well as technology and processes for the purification and formulation of these products. Pharming's commercial focus is primarily aimed at specialty pharmaceutical markets and is intended to cover the entire value chain through internal expertise and external collaborations.

Pharming's strategy to become an international specialty pharmaceutical company is based on three pillars:

- Product development strategy: Pharming focuses on developing indications for which its platform can
  offer competitive advantage, most notably potential savings in manufacturing cost. For programs with
  a higher risk profile, or programs targeting larger indications, Pharming will pursue co-development
  partnerships.
- Commercialisation strategy: Pharming intends to form strategic partnerships to obtain access to other
  required competencies, such as marketing and sales. Pharming explores both partnering possibilities
  for commercialisation of its products and the option of setting-up its own commercialisation
  infrastructure in the future.
- 3. Financing strategy: Pharming focuses on the commercialisation of Rhucin/C1 inhibitor which in the near term provides royalties on sales and potential development milestones, both of which are sources of financing. The near term focus is on expanding geographical coverage of Rhucin/Ruconest and initiation of earlier stage risk sharing agreements on novel proteins. In order to facilitate such business development activities, Pharming continues to maintain international collaborations with leading academic and research institutional that will continue to position Pharming at the forefront of innovative science.

The development of C1 inhibitor for additional indications, followed by other selected products from its pipeline may be expected to generate value both in the short-term and long-term through agreements which include upfront cash milestones, development funding milestones and royalties on future commercial sales.

The key elements of Pharming's strategy to develop and commercialise selected therapeutic products to market include:

- strengthening of the financial position of the Company, for instance through (combinations of) licensing deals, loans and equity transactions;
- decreasing the operational cash burn of the Company through restructuring and ongoing cost containment;
- pursuing regulatory marketing approval from the FDA for Rhucin (rhC1INH) for acute attacks of HAE;
- developing rhC1INH for additional indications, including applications in the area of ischaemia reperfusion injury;
- entering into partnerships to commercialise its products, including Rhucin in all major regions, and thereby drive revenues through milestone and royalty payments;
- leveraging its proprietary transgenic technology to produce additional recombinant human protein therapeutics for development;

- entering into co-development partnerships to accelerate development of new indications and new product candidates; and
- pursuing and maintaining patent protection for its innovative technologies, products and processes, and pursuing Orphan Drug designation for its products where relevant.

#### **Business Plan**

Without prejudice to the risks described in Chapter 1 "Risk Factors Relating to Pharming", the key assumptions on which the business plan of Pharming for the next two years is based on the following:

- 1. The Company will be able to attract or generate sufficient cash to fund its activities.
- 2. Ruconest sales will continue to grow in Europe.
- 3. The FDA will ultimately approve Rhucin for HAE with up to US\$35.0 million in clinical, regulatory and commercial payments to be received from Santarus up to and including the FDA approval or first sales.
- 4. The ability to keep key employees or attract replacements if necessary.

The Company takes the following view of the risks associated with these assumptions and the sensitivity of these assumptions with respect to the business in the next two years.

The first assumption is a 'conditio sine qua non' and, by far, the most important assumption. The cash per 30 September 2012 amounted to €2.6 million of which €1.5 million was readily available and use of €1.1 million was restricted. Pharming's maximum projected operational, investment and finance lease payments for the 12 months after the date of this Registration Document are approximately €18.5 million. This maximum cash requirement will decrease significantly in case the Company achieves certain clinical and regulatory milestones as defined under the agreement with Santarus. Successful achievement of these milestones will trigger a maximum operational cash income of US\$15.0 million (applying the Noon Buying Rate at 30 September 2012 this would equal €11.7 million), which is expected to be received within 12 months after the date of this Registration Document.

A significant portion of the efforts of the Management Board is directed towards securing sufficient funds for the continued business of the Company. At the date of this Registration Document, Pharming expects to be able to secure these funds in a timely fashion. Pharming's view is based on the following:

- Firstly, the Company currently has the Working Capital Facility in place with a number of USA institutional investors which it can use, at its discretion, to issue Shares in return for cash until August 2014. Pharming can potentially issue Shares to these investors for a cash consideration of up to €10.0 million; as per the date of this Registration Document, an amount of €2.3 million has been drawn and thus an amount of €7.7 million remains available.
- Secondly, the Company has existing agreements in place with SOBI, Santarus, MegaPharm, EIP,
  Transmedic and Hyupjin which entitle Pharming to certain payments, related to the achievement of
  certain milestones, such as the achievement of certain clinical milestones under the Santarus
  agreement for North America, as well as proceeds from sales in the EU, Iceland, Norway and future
  proceeds from sales in Switzerland, Canada, Mexico, the USA, Turkey and Israel.
- Thirdly, Pharming is currently in discussions with several companies to establish additional agreements in major regions of the world.
- Fourthly, the Company may be able to issue new Shares either through private or public offerings.

After having secured EMA approval and after having agreed the parameters for the ongoing Phase III study with the FDA under the SPA rule, the Company expects that the results of Study 1310 will be known by the end of the third quarter of 2012, and that if successful, the BLA is filed in early 2013. Non-approval by the FDA would, however, cause a delay and may, ultimately, jeopardise the product development program as well as the commercialisation thereof in the USA and would adversely affect the Company's business, financial condition and prospects.

# Threats in respect of Commercialisation of Ruconest/Rhucin

The roll out of Ruconest® in Europe is progressing, although gaining market access across Europe has generally slower than Pharming initially expected, reflecting the process of obtaining national, regional and local listings and reimbursements (this is a challenge faced by the entire industry and is not unique to Pharming). Nonetheless, the Company anticipates that Ruconest will be available in all of the major European markets by the end of 2012.

Pharming's business model depends on commercial partners to market its product in the various territories. Pharming is also indirectly exposed to the risks of its chosen partners. The Company continues to believe that Rhucin is a valuable addition to the therapeutic options available to HAE patients and Pharming continues to support its commercialisation partners in their endeavours.

The ability to keep key employees or attract replacements if necessary is also important for the further growth of the Company. The business of Pharming is highly specialised and requires specific expertise from highly educated and trained professionals. Since there is severe competition on an international scale between companies in the relevant industry for talented and experienced individuals, there is a risk that one or more of these employees may leave causing delays in the execution of the business plan. Pharming tries to attract and retain talent by a combination of incentives including competitive compensation structures, participation in option and share plans and providing an attractive employment culture.

# **Operating Review**

This section provides an overview of the Company's main commercial agreements, the clinical development of Rhucin for HAE in the USA, the status of other proteins and, ultimately, the ongoing development of the transgenic platform.

#### **Commercial Agreements**

In 2004, the Company signed an agreement with Laboratorios del Dr. Esteve, S.A. (**Esteve**) in Spain for the exclusive development, marketing and sales of Rhucin in Spain, Portugal, Andorra and Greece.

In 2008, Pharming signed an exclusive licensing and distribution agreement with EIP, a leading Turkish pharmaceutical company for the marketing and sales of Rhucin in Turkey. The agreement with EIP lasts until five years after the official registration of Rhucin with the Turkish authorities; registration is anticipated beyond 2012. The commercial agreements with Esteve and EIP provide(d) for the payment to Pharming of certain (undisclosed) milestones depending on progress in registration and commercialisation as well as royalties on net sales and compensation for cost of goods.

In the second quarter of 2010, Pharming entered into an exclusive distribution partnership with Swedish-based SOBI for Iceland, Norway, Switzerland and all the territories of the EU except those then covered through the agreement with Esteve. SOBI is specialised in the marketing and selling of Orphan Drugs. This distribution partnership provided Pharming with a total of €8.0 million in upfront and milestone payments. In the third quarter of 2010, the Company entered into an exclusive distribution partnership with US-based Santarus for the North American territories (Canada, Mexico and the USA). This distribution partnership provided Pharming with an upfront payment of US\$15.0 million and entitles Pharming to further milestones of US\$35.0 million upon the fulfilment of certain clinical, regulatory and

commercial milestones, with in addition the possibility to receive a total of US\$45.0 million in milestones based on certain aggregate sales levels. Both SOBI and Santarus (will) buy finished product from Pharming for a transfer price that incorporates a (progressive) tiered royalty component based on annual net sales performance.

In the second quarter of 2011, Pharming entered into an agreement with MegaPharm, a privately owned Israeli pharmaceutical company, for the commercialisation of Ruconest in Israel for the treatment of acute angioedema attacks in patients with HAE. Under the agreement, MegaPharm will pay Pharming for completion of certain commercial, regulatory and clinical milestones. MegaPharm will purchase its commercial supply of Ruconest from Pharming at a supply price, based on a percentage of net sales of Ruconest.

In the third quarter of 2011, Pharming and SOBI agreed to extend the 2010 agreement with territories in the Balkans, North Africa, and the Middle East. Following an agreement with Esteve to return the rights to market Ruconest in Spain, Portugal, Andorra and Greece, the rights to commercialise Ruconest in these territories were subsequently granted to SOBI as well.

In the first quarter of 2012, Pharming entered into two commercial partnerships for the treatment of acute HAE attacks in patients. Transmedic, a privately owned Singapore pharmaceutical company, was granted the rights for the commercialisation of Ruconest in Brunei, Indonesia, Malaysia, Philippines, Singapore, and Thailand. Hyupjin, a Seoul based Korean specialty pharma company, obtained these rights in the Republic of Korea.

Pharming continues to discuss and negotiate with potential Rhucin licensing partners for all major territories outside those already covered through existing partnerships.

## Clinical Development for Rhucin in the USA

Pharming and its partner Santarus have reached agreement with the FDA about executing a Phase III study at the request of the FDA as preparation for filing for market authorisation of Rhucin in the USA.

On 28 February 2011, the Company and specialty biopharmaceutical company Santarus announced the receipt of a 'refusal to file' letter from the FDA for the Rhucin (recombinant human C1 inhibitor) BLA submitted by Pharming. In the letter the FDA indicated that the BLA was not sufficiently complete to enable a critical medical review.

In reaching its conclusion, the FDA indicated that the previously conducted studies evaluating Rhucin for the treatment of acute attacks of HAE did not provide data for a sufficient number of subjects to support the proposed dose of 50 U/kg and lacked prospective validation of the visual analog scale used in measuring the clinical effects of Rhucin. The FDA also provided other comments on the prior clinical studies and indicated that they will provide additional feedback on the design of the ongoing Phase IIIb clinical study, which had been initiated in February 2011 based on previous discussions with the FDA. In addition, the FDA requested that the results of the Phase IIIb clinical study be included in any future BLA submission for Rhucin.

On 31 March 2011, Pharming and Santarus met with the FDA to discuss the FDA refusal to file letter received in February 2011 and to gain further clarification on the protocol for the ongoing study to support the Rhucin BLA. Based on input from the FDA and from the FDA meeting minutes, on 5 May 2011 Pharming and Santarus submitted an amendment to the protocol, including an increase of the number of patients from 50 to approximately 75 and a modification to the manner in which the primary endpoint will be assessed. This modification eliminates the need for further validation of the visual analog scale. On 4 August 2011, Pharming and Santarus announced that they had reached agreement with the FDA under the SPA process under which the FDA confirmed that Pharming's proposed trial design, clinical endpoints and statistical analyses of the Phase III protocol required to obtain regulatory approval in the USA are acceptable to the FDA.

The USA pivotal trial (Study 1310) completed recruitment in July 2012 but due to an internal oversight the unblinding of the top-line data was delayed by up to three months in order to complete the statistical package required by the FDA.

End of September 2012 the Company announced that Study 1310 was completed and that over the subsequent weeks, as usual in the conduct of clinical trials, the trial database would be finalised and locked; subsequently, the results are analysed and subsequently announced. Positive results of Study 1310 will trigger a US\$10.0 million milestone payment from Santarus.

The Company continues to explore other therapeutic applications of Rhucin (rhC1INH) beyond HAE. rhC1INH is currently in clinical development for the treatment of ischemic reperfusion injury.

Both SOBI and Santarus have the right to participate in the future development and distribution of Ruconest/Rhucin in the agreed countries for additional indications beyond HAE. If either SOBI and/or Santarus decide to participate in such development projects, development costs for such projects are shared with Pharming. To date Santarus have opted in for the development of the first project (AMR, discontinued in February 2012) and as such is sharing in the ongoing development costs.

#### **Other Products**

Pharming in February 2012 announced that the Company and Santarus have discontinued a proof-of concept (**POC**) Phase II study in antibody-mediated rejection (**AMR**) after kidney transplantation since improvements in clinical practice that significantly reduced the apparent incidence of AMR in renal transplant had decreased the need for therapeutic intervention, making patient recruitment for the clinical study difficult.

Pharming has decided that rhFIB and rhCOL are no longer core to its strategy and both assets are being discontinued. The Company is continuing in exploratory talks with third parties evaluating possibilities for commercialisation of hLF as a food additive in certain parts of the world.

# Transgenic Platform

Pharming seeks various partnerships to generate additional income through expanding the geographical reach of its Rhucin franchise and out-licensing of its transgenic platform.

# **Intellectual Property**

## **Patents**

Patents and other proprietary rights are critical to Pharming's business. Pharming's policy is to file patent applications to protect technology, including production processes, products (or composition of matter) and use of products, and improvements thereto that are of potential interest to the development of its business. Pharming's policy is to extend patent coverage to countries that represent a market opportunity for its products, its technology or both, in order to be able to sell licenses or form partnering alliances for joint development of its technologies in related fields. The Company also relies on confidentiality agreements and other measures to protect its proprietary technology, drug candidates and products.

In seeking to obtain the most extensive patent protection possible, Pharming generally starts by filing an initial patent application with the European Patent Office (**EPO**) and a provisional patent application with the United States Patent and Trademark Office, which fixes the relevant priority date. Within one year of these initial filings, the Company files an application under the Patent Cooperation Treaty (**PCT**) and in relevant non-PCT contracting states, e.g. in Taiwan. Usually, within 30 months of the PCT filing and after the PCT examination, the Company files patent applications with the EPO, in the USA, Japan and other important countries, including Australia, Canada and New Zealand. Patents granted by the EPO may

cover all European Patent Convention contracting states and are generally validated in most countries. Without regarding national European patents as separate patents, the Company's patent portfolio includes around 120 issued patents worldwide, of which around 60 in the USA.

Pharming owns a number of patents and several patent applications worldwide relating to expression systems for the expression of compounds in the milk of non-human transgenic animals. In addition, the Company owns patents and several applications worldwide on transgenic cattle. These patents contribute to the Company's role as an important player in the field of the production of recombinant proteins in the milk of transgenic cattle. Other patents and patent applications are product related and cover the transgenic human proteins lactoferrin, C1 inhibitor, fibrinogen and collagen.

In 2004, the Company acquired the patent portfolio of PPL Therapeutics Ltd (Scotland). This portfolio covers various aspects of transgenic technology, including expression systems, purification methods, and specific transgenically expressed recombinant human proteins.

Late 2011, Pharming was granted U.S. Patent 8,071,532, covering a method of preventing, reducing or treating an ischaemia and/or reperfusion injury by administering recombinant C1 inhibitor (Ruconest®/Rhucin®). The broad claims in the patent provide protection until 2028.

#### Licenses

#### Out-licensed by Pharming

Pharming granted Collagen Corporation (now called: Cohesion Technologies Inc) by agreement of May 1993, amended February 1996, a license under Pharming's patents relating to the use and sale of transgenically produced human collagen.

Under a cross-license agreement of July 1996 with Genpharm International (**GPI**), a subsidiary of Medarex, Inc, as amended in November 1996, Pharming granted to GPI a non-exclusive license to certain USA patents and corresponding non-USA applications for the use in production of immunoglobulins.

In 2000, Pharming granted to Genencor International, Inc a non-exclusive license to USA patents covering the use of transgenes longer than 50 kb in transgenic mice.

Under a cross-license of June 2002, Pharming granted a non-exclusive worldwide license under specific USA and non-USA patents to GTC, covering the production of proteins in the milk of certain transgenic animals, provided GTC does not manufacture, use and sell any of the products currently being developed by the Company.

Under a settlement agreement of August 2002 between Genzyme Corporation and the Company, an exclusive, worldwide license was granted to Genzyme under the Company's patents and patent applications in the field of transgenic technology, solely for the production of human alpha-glucosidase.

In July 2004, Pharming provided a license to Esteve for the marketing, distribution and selling of Rhucin in Spain, Andorra, Portugal, and Greece.

In March 2008, Pharming also provided a license to EIP for the marketing, distribution and selling of Rhucin in Turkey.

In April 2010, Pharming provided a license to SOBI for the marketing, distribution and selling of Rhucin/rhC1INH in Iceland, Norway, Switzerland and all territories of the EU, except Greece, Portugal, Andorra and Spain.

In September 2010, Pharming provided a license to Santarus for the marketing, distribution and selling of Rhucin/rhC1INH in Canada, Mexico and the USA.

In June 2011, Pharming provided a license to MegaPharm for the marketing, distribution and selling of Rhucin/rhC1INH in Israel.

In August 2011, Pharming and SOBI agreed to extend the 2010 agreement with territories in the Balkans, North Africa, and the Middle East.

In August 2011, Esteve returned the rights to market Ruconest in Spain, Portugal, Andorra and Greece. These rights were subsequently granted to SOBI.

In February 2012, Pharming entered into a commercialisation partnership with Transmedic for the commercialisation of Ruconest in Brunei, Indonesia, Malaysia, Philippines, Singapore, and Thailand for the treatment of acute HAE attacks in patients.

In March 2012, the Company entered into an agreement with Hyupjin to commercialise Ruconest for the treatment of acute attacks of HAE in the Republic of Korea.

#### In-licensed by Pharming

The Company holds licenses for intellectual property that have been developed by others and which can be used with the Company's platform technology to expand its potential range of products or increase its product development efficiency. Where licenses have been entered to obtain rights to the intellectual property rights of third parties, the Company has agreed to pay royalties and, in certain cases, license fees as consideration for the related rights.

In 1993, Cohesion granted Pharming an exclusive license to all production rights of collagen and its corresponding non-EP filings for the product collagen for the use in oral tolerance induction.

GPI granted Pharming a, royalty-free, perpetual sublicense, under a 1995 agreement covering a USA patent entitled 'Positive-Negative Selection Methods and Vectors' to be used exclusively for cattle, rabbits, goats and sheep.

Under a cross-license of June 2002, GTC granted Pharming a non-exclusive worldwide license under its specific USA and non-USA patents for the production of proteins in the milk of goats and to the production of monoclonal antibodies in the milk of transgenic animals, under certain conditions and for certain territories. In 2008 Pharming acquired an exclusive sub-license to key patents and technology on recombinant fibrinogen from GTC. These rights enable Pharming to accelerate pharmaceutical development of rhFIB and stimulate medical device development through its biomaterials program.

Pharming has access to the nuclear transfer technology of Infigen Inc with a worldwide, exclusive license under Infigen's intellectual property for the production of all Pharming products currently or previously in development using Infigen technology. In addition, Pharming holds a non-exclusive license to all intellectual property of Infigen in the area of nuclear transfer and associated technologies under a 2004 agreement.

Pharming holds an exclusive license to certain intellectual property of the University of Hawaii in the area of nuclear transfer and assisted reproductive technologies, which was previously owned by ProBio Inc, a company that was acquired by Pharming in 2004. The intellectual property portfolio of Infigen was acquired by Advanced Cell Technology in the first quarter of 2007. This does not affect Pharming's rights under the Infigen patents.

Pharming has exclusive rights for the production of proteins for treatment of lysosomal disorders in milk of transgenic animals under an agreement with Genzyme Corporation, entered into in 2002.

The termination of any of these licenses could have an adverse impact on the Company's ability to develop, manufacture, market or sell its product candidates. See also Chapter 1 "Risk Factors Relating to Pharming".

#### Trademarks and Patents

The Company also intends to protect its intellectual property through trademark registration and patents. To date, the Company holds several trademarks registered in or accepted in the EU and in the USA, Japan, Australia and Israel.

The testing, manufacture, packaging, labelling, distribution, sale, marketing, promotion, and advertising of products intended for therapeutic use in humans are subject to extensive and rigorous regulation in the USA by the FDA, as well as other agencies, including the US Department of Agriculture and the Federal Trade Commission, and are subject to comparable regulation by other authorities such as the EMA for the member states of the EU.

The process of undertaking and completing pre-clinical studies and clinical trials, and obtaining regulatory approvals, may take several years and requires the expenditure of substantial resources, with an uncertain outcome. There can be no assurance that any product will receive approval on a timely basis, if at all. Further, the manufacture of products through the use of transgenic animals is expected to present novel questions concerning the safety and efficacy of the products produced thereby and concerning compliance with prescribed current cyclic good manufacturing practices applicable to the Company's range of products.

The FDA and the EMA have published a number of guidance documents related to biotechnology derived products, including a "Points to Consider" document on products for human use derived from transgenic animals that contain recommendations that represent the agencies' current thinking on, among other things, the scientific rigor and data necessary to demonstrate the safety and efficacy of such products. In addition, regulations and recommendations regarding the use of species of animals, such as bovines, in which prion-mediated diseases have been reported, may impact the availability, expense, and care of certain source animals for transgenic production. The Company expects that regulatory standards will be imposed that are distinct from those currently employed in commercial animal husbandry practices.

The Company expects that products from its current development portfolio will mostly fall under regulations in effect for pharmaceutical or biological products. The primary regulatory activities required to be successfully completed before a new human pharmaceutical or biological product may be marketed in the USA include (i) pre-clinical laboratory and animal testing, (ii) the submission to the FDA of an Investigational New Drug (IND) application, (iii) adequate and well controlled human clinical trials to establish the safety and efficacy of the drug, (iv) the submission of a New Drug Application (NDA) or a BLA to the FDA, and (v) FDA approval of the NDA or BLA prior to any commercial promotion, sale, or shipment of the product. Once approved, any changes in the manufacturing of the product that have substantial potential to adversely affect its safety or efficacy will require supplemental approval by the FDA as well as the EMA, as may changes in labelling or promotional materials, or in formulation, route of administration, or dosage form.

Sponsors of and investigators in clinical trials in the USA and Europe are subject to numerous regulations, including those relating to Good Laboratory Practices, informed consent of human patients, and welfare of animals used in pre-clinical trials. Accordingly, depending on the requirements of any particular jurisdiction, data from clinical trials may be useful in the registration and/or approval processes in various jurisdictions.

Pre-clinical studies are conducted in the laboratory and in animal models to gain preliminary information about the presence of any significant safety issues and product feasibility. In the USA, the results are submitted to the FDA as part of the IND application. Testing in humans may not commence until the IND becomes effective. Human clinical trials are conducted in phases and are designed to collect additional

data relating to the safety, dosage and side effects of the new product, and to the product's efficacy. Phase I clinical trials are usually conducted with a small number of healthy individuals to determine the metabolic and pharmacological activities of the product, to test its safety and, if possible, to obtain early evidence of efficacy. Phase II clinical trials usually involve studies in a limited patient population to determine the efficacy of the product for specific indications and to determine dosage tolerances and optimal dosage. Phase III clinical trials usually are conducted to evaluate clinical efficacy and to test safety within an expanded patient population.

There can be no assurance that submission of an IND to the FDA will result in the IND becoming effective so that clinical trials may commence. In addition, each clinical trial must be conducted under the auspices of an Institutional Review Board (IRB), which considers, among other things, ethical issues, the safety of human subjects, the adequacy of patient informed consent, and the potential liability of the institution. Further, the FDA may, for a number of reasons, impose a clinical hold on ongoing clinical trials, or the IRB or the applicant may suspend clinical trials at any time if it is felt that the participants are being exposed to an unanticipated or unacceptable health risk. If a clinical hold is imposed by the FDA, trials may not recommence without prior FDA authorisation, which may require changes to, among other things, clinical trial protocols. The results of a products pre-clinical studies, clinical studies, chemistry and manufacturing data, and proposed labelling, among other things, are submitted to the FDA in the form of an NDA or BLA for approval of the marketing and commercial shipment of the product. The FDA may refuse to accept the NDA or BLA for filing if administrative content criteria are not satisfied, and even after accepting an application for review, the FDA may require additional testing or information before making a decision to approve or deny an application. The FDA must deny an application if applicable regulatory requirements are not ultimately satisfied. Moreover, if regulatory approval of a product is granted, such approval may be conditioned on post-market testing and surveillance to monitor the safety of the product and may entail limitations on the indicated uses for which the product may be marketed. Finally, product approvals may be suspended or withdrawn if, among other reasons, compliance with regulatory requirements is not maintained, new information raises safety or efficacy questions, or problems occur following initial marketing.

# **Trends**

Product sales are related to Ruconest exclusively and are realised through Pharming's commercialisation partners, of which currently only SOBI has generated substantial sales in the EU. Reimbursement procedures in the various EU member states vary considerably and have become more onerous over the recent years; also, additional regional and local hurdles for acceptance of new products exist in several markets, hence why the roll- out across the EU still continues. The actual selling prices vary across the EU, depending on the reimbursement system, and on the local distribution channels and margins involved. The selling price to Pharming's commercialisation partners is either fixed per unit or defined as percentage of the net selling price in the market; in certain contracts, additional royalties are paid to Pharming upon exceeding pre-defined sales levels by the partner.

Most of Pharming's inventories of €6.6 million at 31 December 2011 have originally been produced as preparation for an early 2008 launch (which did not materialise as result of a rejection by the EU authorities in late 2007). These inventories will be gradually approaching their expiry date prior to sales and/or use in (pre)clinical activities. Following an internal review of the overall inventory position, the Company incurred non-cash impairment charges of €2.8 million in the first half year of 2012 while also expensing €0.8 million of inventories sold and expensing €0.3 million in (pre)clinical activities; due to €1.5 million of investments, the inventories as per 30 June 2012 amounted to €4.2 million. The downstream production (purification of milk into drug substance and subsequent fill and finish of the drug substance into drug product) has been outsourced to third parties. New purification production at the Sanofi site, on a larger scale but against a decreased cost of production compared to previous outsourced manufacturers, is starting up, such that sufficient quantities for the EU market remain available and adequate amounts for launching the product in new markets, including but not limited to the USA, is safeguarded. New production processes and sites are subject to formal approval by the respective regulatory authorities.

## Competition

The pharmaceutical and biotechnology industries are highly competitive and subject to rapid technological change. Any products that Pharming successfully may develop will compete with existing and future therapies. There are many organisations, including pharmaceutical companies, biotechnology companies, academic laboratories, research institutions, governmental agencies and public and private universities, which are actively engaged in developing products that target the same markets as the product candidates of Pharming. Many of these entities have financial and other resources substantially greater than those of the Company. In addition, many of Pharming's competitors have significantly greater experience in manufacturing, pre-clinical testing, conducting clinical trials, obtaining regulatory approvals and marketing than the Company does. These entities also compete with Pharming in recruiting and retaining qualified scientific and management personnel, as well as in acquiring products and technologies complementary to, or necessary for, Pharming's product candidates. Moreover, there can be no assurance that such competitors will not obtain patent protection or other intellectual property rights that would make it difficult or impossible to market the product candidates of Pharming. As a result, there can be no assurance that the Company will be able to compete effectively against these companies or their products.

For the treatment of acute attacks of HAE the competition can be divided into C1 inhibitors and alternative therapies targeting different effector mechanisms. Currently, Pharming is the sole provider of a recombinant version of C1 inhibitor and the other C1 inhibitors mentioned below are derived from human plasma. Other providers of C1 inhibitors include:

- CSL Behring with an approved product in several countries in the EU and in the USA;
- ViroPharma with an approved product for preventive use in the USA and both preventative and acute
  use in the EU; and
- Sanquin with the same approved product in some countries in the EU.

Competitive drugs targeting different mechanisms to treat acute attacks of HAE include:

- Shire Pharmaceuticals with an approved product in the EU and the USA; and
- Dyax with an approved product in the USA.

#### **Facilities**

Pharming's administrative, R&D and clinical development departments are located in the research facility rented in Leiden, the Netherlands.

The Company has a facility for breeding and milking transgenic rabbits in the Netherlands, including approximately 0.2 hectares of land (upstream manufacturing). This state of the art facility is dedicated to the generation and milking of transgenic rabbits, producing recombinant proteins in their milk. The facility is fully licensed for the housing, breeding and milking of rabbits to produce therapeutic proteins.

Pharming through its wholly-owned subsidiary Pharming Healthcare, Inc. has a farm facility in the USA which was specifically built and designed for the generation and housing of transgenic cattle capable of producing pharmaceutical proteins in their milk. The facility includes approximately 9.3 hectares of land owned by the Company and consists of a number of buildings, each with its own specific purpose and biosecurity level. Following Pharming's announcement in June 2012 to close the facility, the Company in

July 2012 entered into an agreement to sell the land and buildings to a US-based private entity, Sexing Technologies, Inc. This transaction was completed in September 2012.

# **Employees**

The weighted average number of employees of Pharming for each of the years ended 31 December 2010 and 2011 per functional category was as follows:

	2011	2010
Research and development	60	73
General and administrative	15	17
Total	<u>75</u>	<u>89</u>

The decrease in weighted average number of employees from 89 in 2010 to 75 in 2011 primarily reflects the termination of labour agreements following the liquidation of DNage in the beginning of 2011.

The total number of full-time and part-time employees as per 30 September 2012 is 65, which equals 59 Full Time Equivalents. The decrease in number of employees compared to 31 December 2011 primarily reflects the termination of labour agreements with employees following the second quarter 2012 decision to discontinue the Company's cattle operations. The Company announced a strategic restructuring plan of its Dutch operations, which includes a request to make more than 20 employees redundant. Reference is made to Chapter 5 "Business – History".

#### 6. MANAGEMENT, SUPERVISION AND REMUNERATION

Set out below is a summary of certain significant provisions of Dutch corporate law and the Articles of Association in respect of the Management Board and the Supervisory Board and a summary of relevant information concerning the Management Board, Supervisory Board, senior management and other employees of Pharming.

## **Management Structure**

Pharming has a two-tier board structure, consisting of a Management Board (Raad van Bestuur) and a Supervisory Board (Raad van Commissarissen).

#### **Management Board and Supervisory Board**

#### Powers, Composition and Function

The Management Board 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 Supervisory Board. The Management Board is authorised to bind the Company towards third parties. On 22 April 2005, the Management Board adopted the current management board regulations which provide for certain duties, composition, procedures and decision-making of the Management Board.

The Supervisory Board is charged with supervising the policy of the Management Board and the general course of the Company's affairs and the enterprise connected therewith. The Supervisory Board assists the Management Board by rendering advice. In performing their duties, the members of the Supervisory Board are obliged to act in the best interests of the Company and the enterprise connected therewith. On 14 October 2004, the Supervisory Board adopted the current supervisory board regulations, which provide for certain duties, composition, procedures and decision-making of the Supervisory Board.

The members of the Management Board and the members of the Supervisory Board are appointed at a general meeting of shareholders from nominations made by the Supervisory Board. If the nomination comprises two or more persons for each vacancy, the nomination shall be binding. In addition, the Supervisory Board is authorised to make a non-binding nomination for a vacancy, consisting of one person. If the Supervisory Board 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 Management Board and the members of the Supervisory Board 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 Management Board may also be suspended or dismissed by a resolution of the Supervisory Board.

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.

The general meeting of shareholders shall adopt the remuneration policy in respect of remuneration of the Management Board. The remuneration and other terms and conditions of employment of each of the members of the Management Board is determined by the Supervisory Board taking into account the remuneration policy. The remuneration of each of the members of the Supervisory Board is determined by the general meeting of shareholders.

# Members of the Management Board

The Management Board is composed of the following members:

Name	Position	Member Since	Term
Bruno Giannetti	Chief Operations Officer	1 December 2006	Up to AGM in 2015
Sijmen de Vries	Chief Executive Officer	13 October 2008	Up to AGM in 2013

The business address of the members of the Management Board is Darwinweg 24, 2333 CR Leiden, the Netherlands.

### B.M.L. (Bruno) Giannetti, MD PhD – Chief Operations Officer

Bruno Giannetti (1952) is responsible for the Company's operations and research & development activities. He has more than 25 years of experience in the pharmaceutical and biotech industry. Previously, he was CEO of AM-Pharma B.V. in the Netherlands and President and CEO of Verigen AG in Germany. He has served as senior management consultant for pharmaceutical R&D projects at Coopers & Lybrand in Switzerland and the UK. Bruno Giannetti was also worldwide Vice-President Marketing and Medical Information at Immuno in Austria and Head of Clinical Research at Madaus AG in Germany. He is the founder and president of CRM GmbH, a well established European Clinical Research Organisation specialising in international pharmaceutical clinical research. He holds a PhD in Chemistry and a MD PhD degree in Medicine from the University of Bonn.

#### S. (Sijmen) de Vries, MD MBA – Chief Executive Officer

Sijmen de Vries (1959) is responsible for the overall management of the Company and also acts as Pharming's Chief Financial Officer. He has extensive senior level experience in both the pharmaceutical and biotechnology industries and joined Pharming in 2008, leaving 4-Antibody AG where he was CEO. He 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. He also holds non-executive directorships in two private life science companies, Midatech Group Ltd and Sylus Pharma Ltd. Sijmen de Vries holds a Medical Degree from the University of Amsterdam and an MBA in General Management from Ashridge Management College (UK).

#### Members of the Supervisory Board

The Supervisory Board is composed of the following members:

Name	Position	Member Since	Term
Jaap Blaak	Chairman	23 May 2007	Up to AGM in 2015
Jurgen Ernst	Vice Chairman	15 April 2009	Up to AGM in 2013
Barrie Ward	Member	23 May 2007	Up to AGM in 2015
Aad de Winter	Member	15 April 2009	Up to AGM in 2013

The business address of all members of the Supervisory Board is Darwinweg 24, 2333 CR Leiden, the Netherlands.

#### J. (Jaap) Blaak, MSc - Chairman

Jaap Blaak (1941) held managerial positions with Hoogovens, Indivers N.V. and Interturbine Holding B.V. in the Netherlands, the USA, Germany and Singapore. In 1983, he was involved with the foundation of the MIP Equity Fund, one of the largest venture capital groups in Europe, and was appointed CEO in 1986. During the lifetime of the fund, MIP invested in several life sciences companies that became active in the Netherlands, including Centocor, Mogen and EuroCetus/Chiron. In several of the companies MIP

invested in, he was a board member. MIP merged with the ABN-AMRO Venture Capital Group to form AlpInvest. Since 1989, Jaap Blaak is president and owner of Tailwind B.V., a company investing mainly in early stage life science companies. He also holds board positions in non-listed companies in the life science industry, including FlexGen Holding B.V. and to-BBB Holding B.V. and is a partner/shareholder in VenGen Holding B.V. Furthermore, he is an advisor to the Dutch Ministry of Economic Affairs for the Technopartner program and other innovative projects related to Entrepreneurship and Innovation. Jaap Blaak studied physics, mathematics and business economics at the Free University of Amsterdam and followed the Advanced Management Program of the Harvard Business School (AMP '81).

# J.H.L. (Jurgen) Ernst, MBA - Vice Chairman

Jurgen Ernst (1939) 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, he continued his career at Solvay and held several positions until he retired in 2004. Amongst other, he was member of the board of Pharmaceutical Division, CEO of Health Divisions, General Manager Pharmaceutical Sector and supervisory director and member of the Executive Committee. Jurgen Ernst is currently chairman of the supervisory board of Aeterna Zentaris Inc. He holds an ISMP Degree from Harvard University and an MBA from the University of Cologne.

# J.B. (Barrie) Ward, PhD - Member

Barrie Ward (1938) has a broad international network and experience in managing and financing biopharmaceutical companies. He has held senior management positions in the UK, the USA and Singapore at several pharmaceutical and biotechnology companies, including Glaxo Group Research Ltd, Virus Research Institute Inc, Avant Immunotherapeutics Inc, KuDOS Pharmaceuticals Ltd, Immunobiology Ltd, a vaccine company in Cambridge, UK and his most recent position was CEO of KuDOS Pharmaceuticals Ltd, which was sold to Astra-Zeneca in 2006. Currently, he is chairman of Spirogen Ltd, Cellcentric Ltd, a member of the board of Cancer Research Technology Ltd and a director of BergenBio. Barrie Ward holds a PhD in Microbiology from the University of Bath (UK).

# A. (Aad) de Winter, LLM – Member

Aad de Winter (1953) 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, he became senior Advisor Corporate and Institutional Finance at NIBC (formerly 'De Nationale Investerings Bank'). As from 1998, Aad de Winter was at NYSE Euronext, Amsterdam responsible for advising and admitting companies to the stock exchange in Amsterdam as Director Listing & Issuer Relations. As from January 2009, he is an Associate Partner of First Dutch Capital, Amsterdam and since 2008 a member of the China and India working group at the Holland Financial Centre which is, *inter alia*, focused on attracting Chinese and Indian companies to a (cross) listing on the Euronext Amsterdam. As from February 2010, he is also an Associate Partner at Nederlandsche Participatie Exchange (NPEX), an innovative online trading platform for less liquid securities. Aad 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.

## **Senior Management**

The Management Board is supported by the following members of the executive group, composing the senior management (the **Senior Management**):

# H.A.M. (Dic) Geuens, LLM - General Counsel & Company Secretary

Dic Geuens (1964) joined Pharming in 2007 and is currently responsible for granting legal advice and support to the Management Board and communication with the Supervisory Board. He previously held positions at Solvay Pharma S.A. and Solvay Healthcare Ltd/Solvay Chemicals Ltd, Yamanouchi Europe B.V. and Aon Holding B.V. Dic Geuens received his LLM from Leiden University and holds a post-doctoral title in company law.

### A. (Arthur) de Hey, MSc – Group Controller & Compliance Officer

Arthur de Hey (1970) is responsible for the management reporting, financial reporting and internal control policies. In addition he serves as the Company's Compliance Officer. He joined Pharming in 2003 after working as an auditor in the eight years prior to that, of which more than six years for the multinational practice of Ernst & Young. Arthur de Hey holds an MSc in Controlling from Nyenrode Business University.

J.L.M. (Jos) van der Lubbe, MSc, PhD – Senior Director Quality Assurance and Archive & Documentation / Qualified Person

Jos van der Lubbe (1954) joined Pharming in 2012 and is currently responsible for developing, implementing and managing Pharming's global quality strategy and quality system and ensuring compliance of Pharming's business units and external partners with the applicable international quality expectations and Pharming's quality strategy for outsourced quality activities. He previously held several positions at Xendo Pharma Services B.V., Pharmachemie B.V., two Bloodbanks and Centocor B.V. in the Netherlands. Jos van der Lubbe received his PhD in medical biochemistry from Leiden University.

# A.C.P. (Sander) Mathôt, MSc - Senior Director Supply Chain Management

Sander Mathôt (1967) joined Pharming in 2009 as Director Quality Assurance/Quality Control and is currently responsible for developing, implementing and managing Pharming's Supply Chain. This includes Quality Control activities, Manufacturing Development, Supply Chain Planning and all Pharming's Production activities. He previously held several positions at Solvay Pharmaceuticals B.V. and Katwijk Pharma/Apotex B.V. in the Netherlands. Sander Mathôt received his MSc from Utrecht University.

#### A. (Anurag) Relan, MD MPH - Medical Director

Anurag Relan (1972) joined Pharming in 2006 and is responsible for the management of clinical operations, including CRO activities for trials, investigator/site support, protocol development, patient group interactions, managing regulatory affairs operations and strategic planning. He has more than ten years of experience in the clinical and medical industry. Previously, he held positions at the University of California, Los Angeles, School of Medicine, Providence Medical Institute, Zynx Health Inc and MedFirst Healthcare Inc. Anurag Relan holds an MD and an MPH from UCLA and a BA in Economics from University of California at Berkeley, USA.

# M. (Mourad) Salaheddine, DVM PhD - Senior Director Animal Health

Mourad Salaheddine (1964) joined Pharming in 1994 as a veterinary scientist and contributed to the development of all Pharming's transgenic animal lines. He has been responsible for the Company's transgenic rabbit facility and the development of the Company's upstream production for Rhucin. Furthermore he has been coordinating the cattle operations in the research and development farm in the USA. He is currently responsible for the health, breeding and welfare of the animals. Furthermore he is the Company's expert on the transgenic animal platform and associated strategies. Mourad Salaheddine holds a PhD from the University of Glasgow in veterinary reproductive physiology.

The business address of all members of the Senior Management is Darwinweg 24, 2333 CR Leiden, the Netherlands.

## **Supervisory Board Committees**

The Supervisory Board has appointed from among its members an audit committee (the **Audit Committee**), a remuneration committee (the **Remuneration Committee**) and a corporate governance committee (the **Corporate Governance Committee**).

#### **Audit Committee**

The Audit Committee consists of Aad de Winter (chairman), Jurgen Ernst and Barrie Ward. The tasks performed by the Audit Committee include reviewing the scope of internal controls and reviewing the implementation by the Management Board of recommendations made by the external auditors of Pharming.

#### Remuneration Committee

The Remuneration Committee consists of Barrie Ward (chairman), Jurgen Ernst and Jaap Blaak. The Remuneration Committee advises the Supervisory Board with regard to salaries, grants and awards under incentive plans, benefits and overall compensation for officers of the Company. Ultimately the Supervisory Board decides upon remuneration of the Management Board.

#### **Corporate Governance Committee**

The Corporate Governance Committee consists of Barrie Ward (chairman), Jurgen Ernst and Aad de Winter. The Corporate Governance Committee is responsible for monitoring for compliance with the Dutch Corporate Governance Code.

# **Remuneration Policy**

The remuneration policy was approved in the annual general meeting of 14 May 2012. Reference is made to the report of the Remuneration Committee in the annual report 2011, pages 34-38, available on Pharming's website.

#### Management Board

The total remuneration Pharming paid to or for the benefit of members of the Management Board in 2011 amounted to €2,545,000.

Each member of the Management Board is entitled to a bonus of up to 40% of his gross annual salary in the event he has achieved certain pre-defined milestones which are a combination of corporate and personal targets. Payment of the 2012 bonus will be settled in cash and/or Shares valued at the volume weighted average price measured over the 20 trading days prior to 31 January 2013, such at the option of the Supervisory Board.

The following table denotes the breakdown in remuneration of members of the Management Board in 2011 (amounts in €'000):

	Periodic remuneration		Share- based	Post- employment	Other <sup>2</sup>	
Name	1	Bonus	payment	benefits	(2)	Total
Bruno Giannetti	266	64	199	64	15	608
Karl Keegan	213	68	204	20	15	520
Rienk Pijpstra	221	53	193	26	18	511
Sijmen de Vries	396	111	299	64	36	906
Total	<u>1,096</u>	<u>296</u>	<u>895</u>	<u>174</u>	<u>84</u>	<u>2,545</u>

<sup>&</sup>lt;sup>1</sup> As of 1 January 2012 the periodical remuneration of Karl Keegan increased from €213,000 to €253,000; the periodic remuneration of the other members of the Management Board has not changed.

As decided by the Supervisory Board, bonuses incurred for the Management Board in 2011 were fully settled in Shares and based on the volume weighted average price measured over the five trading days prior to 31 January 2012. Bruno Giannetti received 583,366 Shares, Karl Keegan received 622,841 Shares, Rienk Pijpstra received 484,676 Shares and Sijmen de Vries received 940,567 Shares. All these Shares were transferred to the recipients in the first quarter of 2012.

Effective as of 19 June 2012 the Company entered into an agreement with Rienk Pijpstra, former Chief Medical Officer, as a result of which he resigned from the Management Board with immediate effect and as an employee as of 1 September 2012; reference is made to Chapter 6 "Management, Supervision and Remuneration – Employment Agreements".

K.D. (Karl) Keegan, former Chief Financial Officer, left Pharming as per 1 September 2012.

# Share Ownership

As per the date of this Registration Document, the number of Shares held by the members of the Management Board and Senior Management are set out below:

Name	Shares held
Bruno Giannetti Sijmen de Vries	771,461 1,192,638
Total Management Board	<u>1,964,099</u>
Total Senior Management	<u>1,314,385</u>
Total general	<u>3,932,694</u>

#### Supervisory Board

The total remuneration paid to or for the benefit of members of the Supervisory Board in 2011 amounted to €174,000.

Other compensation items include (lease) car compensation and, for Sijmen de Vries, contributions to other expenses.

The remuneration of the members of the Supervisory Board is determined by the general meeting of shareholders. The annual general meeting held on 11 May 2011 approved the following compensation structure effective as of 1 January 2011:

- the chairman of the Supervisory Board receives €44,000 per annum and the other members of the Supervisory Board receive €31,000 per annum;
- the chairman of the Audit Committee is paid an additional fee of €9,000 per year and the chairman of the Remuneration Committee receives an additional fee of €6,000 per annum;
- the other members of the Audit Committee and Remuneration Committee receive an additional fee of €3,000 per annum; and
- an additional compensation of up to €1,000 per day is paid in case of extraordinary activities.

This compensation structure has not changed in 2012.

The following table denotes the breakdown in remuneration of members of the Supervisory Board in 2011 (amounts in €'000):

Name	Supervisory Board	Audit Committee	Remune- ration Committee	Share- based payment	Total
Jaap Blaak	44	<u> </u>	3	3	50
Jurgen Ernst	31	3	3	2	39
Barrie Ward	31	3	6	3	43
Aad de Winter	31	9	-	2	42
Total	<u>137</u>	<u>15</u>	<u>12</u>	<u>10</u>	<u>174</u>

Members of the Supervisory Board do not participate in an option plan and are not eligible to receive Shares under the Long Term Incentive Plan for the years 2011 and further. None of the Supervisory Board members hold Shares, options or warrants in the Company.

#### Senior Management

The total remuneration which Pharming paid to or for the benefit of the Senior Management in 2011 amounted to €812,000.

#### **Other Information**

Save as set out below, none of the members of the Management Board, Supervisory Board and Senior Management is, or has been, (i) subject to any convictions in relation to fraudulent offences in the last five years, (ii) in the last five years associated with any bankruptcies, receiverships or liquidations of any entities in which such members held any office, directorships or senior management positions, or (iii) subject to any official public incrimination and/or sanctions of such person by statutory or regulatory authorities (including designated professional bodies), or disqualification by a court from acting as a member of the administrative, management or supervisory bodies of an issuer or from acting in the management or conduct of the affairs of any issuer for at least the previous five years.

Barrie Ward was a non-executive chairman of the management board of Onyvax Ltd in February/March 2009 when Onyvax Ltd became subject to administration proceedings.

## Administrative, Management and Supervisory Bodies Conflicts of Interest

Pharming is not aware of any potential conflict of interest between the private interests or other duties of the members of the Management Board, Supervisory Board or Senior Management and their duties and responsibilities to the Company.

No family ties exist among the members of the Management Board, Supervisory Board and Senior Management.

# **Option Plans**

The Company has a Long Term Incentive Plan and two option plans in place, one for the Management Board and one for employees. In addition, option arrangements have been made with individual consultants. All these plans or arrangements are equity settled.

### Long Term Incentive Plan

At the annual general meeting of 16 April 2008 a Long Term Incentive Plan (the LTIP) was approved with an effective date of 1 January 2008. The LTIP is applicable to the Management Board, the Supervisory Board (only for 2008 up to and including 2010) and a selected number of members of the Senior Management. Participants leaving the Company within three years after the grant date, either voluntarily or upon request of the Company (including through a court settlement), are immediately excluded from the LTIP and grants under the LTIP will automatically be cancelled. Under the LTIP, Shares are granted conditionally each year with a target value of 30% of annual compensation. Shares will vest after three years provided that the share price has increased. The number of Shares to vest will be based on the performance of Pharming compared to a peer group of 35 other European Small Cap (< €500 million) listed companies active in Life Sciences. Upon a change of control, all LTIP Shares will vest automatically.

None of the LTIP Shares granted in 2008 and 2009 have ultimately vested since the conditions were not met.

At the AGM of 27 May 2010, the shareholders approved the granting of conditional Shares for 2010, applying the same criteria as for the 2009 LTIP, as follows: Supervisory Board 30,000 per member; Management Board 100,000 per member; Senior Managers 400,000 in total with a maximum of 40,000 per Senior Manager.

At the AGM of 11 May 2011, the shareholders approved an amount of conditional Shares under the LTIP based on the closing price of 31 December 2010 (€0.207) and 30% of the Management Board member's 2011 base salaries. This resulted in the following maximum allocations of LTIP Shares: Sijmen de Vries 573,913, Karl Keegan 308,695, Bruno Giannetti 384,057 and Rienk Pijpstra 320,289. For a selected group of four members of the Senior Management a maximum of 125,000 conditional Shares each were made available.

At the AGM of 14 May 2012, the maximum number of LTIP Shares approved by the shareholders for 2012 (provided Pharming ranks in the top 5% of the peer group or upon a change of control) was based on 30% of the base salary for members of the Management Board and the closing price of the Shares as per 31 December 2011 (€0.082), thereby granting a maximum number of LTIP Shares to Sijmen de Vries of 1,448,780, to Karl Keegan of 925,610, to Bruno Giannetti of 973,170 and to Rienk Pijpstra of 808,537. In addition to these 4,156,097 Shares available for the members of the Management Board, another 1,000,000 LTIP Shares are available for Senior Managers (maximum of 200,000 Shares per Senior Manager). All 1,234,305 LTIP Shares for Karl Keegan as well as all 1,228,826 LTIP Shares for Rienk Pijpstra were forfeited following discontinuation of their employment agreements as of 1 September 2012.

The allocations under the 2010, 2011 and 2012 LTIP end as per 31 December of 2012, 2013 and 2014 respectively.

In 2010, in line with corporate governance guidelines, the Supervisory Board has decided to withdraw their participation in the LTIP as of 2011.

As per the date of this Registration Document, the remaining maximum number of conditional Shares awarded under the LTIP is 5,479,920 (2010: 600,000; 2011: 1,457,970; 2012: 3,421,950).

#### Main Characteristics of the Option Plans

The total number of Shares with respect to which options may be granted pursuant to the option plans, shall be determined by Pharming, but shall not exceed 10% of all issued and outstanding Shares on a fully diluted basis. Shares issuable upon exercise of options shall reduce the maximum number of Shares available for use under the plans. Unexercised options can be re-used for granting of options under the option plans.

Pharming may grant options to members of the Management Board and employees: (i) at the time of a performance review; (ii) only in relation to an individual: a date within the first month of his or her employment; (iii) in case of an extraordinary achievement; and (iv) in case of a promotion to a new function within Pharming.

The option exercise price is the price of the Shares on Euronext Amsterdam on the trading day prior to the date of grant or on the trading day prior to the meeting of the Supervisory Board during which it was resolved to grant options. Options can be exercised at any time within five years following the date of grant. Unexercised options shall be deemed cancelled and shall cease to exist automatically after five years. Exercise of options is subject to compliance with laws and regulations in the Netherlands.

### Option Plan Management Board

Pursuant to the option plan for the Management Board, the Supervisory Board may, at its sole discretion, grant to a member of the Management Board the right to acquire Shares for a pre-determined exercise price during a certain period. On the basis of certain guidelines provided by the Remuneration Committee, the Supervisory Board determines the conditions and the criteria for the options to be granted to the members of the Management Board. 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.

Furthermore, the option plan for the Management Board states that in case of resignation or dismissal of a member of the Management Board, except for retirement and death, Pharming, at its sole discretion, is entitled to decide that the options of such member of the Management Board shall lapse if the conditions set out in the letter pursuant to which the options are granted have not been fulfilled at the time of the resignation or dismissal of the membership of the Management Board.

The number of options granted to the Management Board in 2012 is as follows: Sijmen de Vries 3,750,000, Karl Keegan 2,812,500, Bruno Giannetti 2,437,500 and Rienk Pijpstra 2,437,500. These options for the Management Board will vest on 1 January 2013, provided that the relevant member of the Management Board is in service by that date. The 2,437,500 options granted to Rienk Pijpstra as well as the 2,812,500 options granted to Karl Keegan were forfeited following discontinuation of their employment as of 1 September 2012.

#### Option Plan Employees

Pursuant to the option plan for employees Pharming may grant options to its employees. The criteria for granting of the options will be determined by the Supervisory Board, at its sole discretion. The Management Board submit a proposal to the Supervisory Board, indicating the criteria for the granting of

options which have been met and the number of options to be granted. Furthermore, the option plan for employees states that in case of a termination of the employment, except for retirement and death, Pharming at its sole discretion is entitled to decide that the options of the relevant employee shall lapse.

# Option Movements and Option Positions Management Board, Senior Management and Others

An overview of activity in the number of options for the years 2010, 2011 and 2012 is presented in the following table. For practical reasons, the activity in 2012 is up to and inclusive 31 August 2012; no material adjustments have taken place between 1 September 2012 and the date of this Registration Document nor related these movements to the Management Board or Senior Management. Certain option series granted have a weighted average exercise price of four or more digits; for practical reasons the exercise prices in this table have been rounded to three digits.

	<u>2012</u>			<u>2011</u>		<u>2010</u>	
	<u>Number</u>	Weighted  average exercise price (€)	<u>Number</u>	Weighted average exercise price (€)	<u>Number</u>	Weighted  average exercise price (€)	
Balance at 1 January	19,424,643	0.314	6,673,077	0.844	5,172,391	1.439	
Granted to Management Board	11,437,500	0.056	10,550,000	0.154	1,600,000	0.350	
Granted to employees	422,725	0.082	2,862,600	0.088	765,125	0.272	
Expired	(464,075)	2.940	(363,175)	3.635	(831,082)	3.074	
Forfeited	(5,363,421)	0.058	(297,859)	0.279	(33,357)	0.616	
Balance at 31 August (2012) and 31 December (2011 and 2010)	25,457,372	0.200	19,424,643	0.314	6,673,077	0.844	

All options outstanding are exercisable with the exception of those options under the option plan for the Management Board that have not vested (see below); for employees the subsequent sale of the Shares is subject to the vesting conditions of the option. The weighted average remaining contractual life in years of the outstanding options at 31 August 2012 is 3.6 years with exercise prices ranging from €0.056-€2.64.

Total options which have been granted as per 31 August 2012 can be presented as follows:

Options held by	<u>Number</u>	Weighted average exercise price (€)
Management Board	14,504,167	0.174
Senior Management	3,105,000	0.180
Others	7,848,205	0.256
Total	<u>25,457,372</u>	<u>0.200</u>

The following table provides an overview of outstanding option holdings of the Management Board as per the date of this Registration Document.

		Vested at the date of this	(Weighted average) exercise price of options	<b>Expiration</b>
		Registration	granted	date
<u>Name</u>	<u>Granted</u>	Document	<u>(€)</u>	<u></u>
Bruno Giannetti	41,667	41,667	1.120	15 April 2013
Brano Claimetti	250,000	250,000	0.620	12 October 2013
	250,000	250,000	0.500	14 April 2014
	250,000	250,000	0.401	26 May 2015
	2,275,000	2,275,000	0.154	10 May 2016
	2,437,500	-	0.056	13 May 2017
Sijmen de Vries	500,000	500,000	0.620	12 October 2013
eymen de viide	500,000	500,000	0.500	14 April 2014
	750,000	750,000	0.401	26 May 2015
	3,500,000	3,500,000	0.154	10 May 2016
	3,750,000	-	0.056	13 May 2017
Total Management Board	<u>14,504,167</u>	<u>8,316,667</u>	<u>0.174</u>	

# **Employment Agreements**

Pharming entered into employment agreements with each of the members of the Management Board. These employment agreements have an indefinite term and can be terminated, subject to a statutory notice period, which is one month for the employee and two months for the employer.

In the event of termination of an employment agreement with a member of the Management Board for other reasons than (i) immediate dismissal (ontslag) of the relevant member of the Management Board on the basis of an urgent reason as defined in Article 7:678 of the Dutch Civil Code (including but not limited to wilful misconduct, gross negligence and bad faith) or (ii) non compliance by the relevant member of the Management Board with Article 2:9 of the Dutch Civil Code, and the same has been acknowledged by judgement of a competent court of law or lawful arbitral award which is not or no longer subject to appeal (in kracht van gewijsde) or by deed of settlement between the parties, the relevant member of the Management Board shall be entitled to a one-time severance pay in cash that (a) equals 50% of gross salary that the member of the Management Board enjoyed during a period of 12 months prior to the month in which the dismissal has come into effect, in the event the day of dismissal lies in the period of 2 years calculated from and including the first day in office, or (b) equals 100% of gross salary that the member of the Management Board enjoyed during a period of 12 months prior to the month in which the dismissal has come into effect, in the event the day of his dismissal lies after the period of 2 years calculated from and including the first day in office.

Effective 19 June 2012 the Company entered into an agreement with Rienk Pijpstra, former Chief Medical Officer, as a result of which he resigned from the Management Board with immediate effect and as an employee as of 1 September 2012; base salary until such date remained €17,000 gross per month. The agreement entitles Rienk Pijpstra to receive a maximum gross amount of €177,000, to be paid out as follows:

- (1) €29,000 is paid upon termination of the employment as per 1 September 2012;
- (2) €74,000 is paid upon receipt of US\$10.0 million from Santarus following achievement of the milestone related to successful completion of Study 1310; and
- (3) €74,000 is paid upon receipt of US\$5.0 million from Santarus following acceptance of the BLA for review by the FDA.

In the event Pharming is acquired by a third party or enters into a partnership with a third party, the amounts under item (2) and (3) are paid out irrespective of any payment by Santarus to Pharming.

Pharming did not enter into (service) agreements with members of the Supervisory Board providing for benefit upon termination of such agreement.

#### **Directors Indemnification and Insurance**

In order to attract and retain qualified and talented persons to serve as members of the Management Board or the Supervisory Board, in respect of a sector, region, product group or other internal company structure or segment, Pharming provides such persons with protection through a directors' and officers' insurance policy.

Pharming holds harmless and indemnifies the members of the Management Board against third party claims made against such member of the Management Board as a result of damages (allegedly incurred) caused by acts or omissions of Pharming while being in function, provided that such member of the Management Board (i) notifies Pharming immediately when facts or circumstances have occurred that may result in such third party claim and forthwith upon receipt of such claim(s) and (ii) provides all supports and assistance that Pharming may reasonable require. Nonetheless, Pharming may withdraw the aforementioned indemnity in certain circumstances such as gross negligence, or criminal acts.

### **Pension Plan**

For all Dutch employees as of age 21, 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 USA are enabled to participate in a separate plan, which also qualifies as a defined contribution plan. To become an eligible participant, an employee must complete six months of service and attain the age of 21 years.

# **Works Council**

As required by Dutch law, Pharming has established a works council. Works councils in the Netherlands have the authority to advise on certain company decisions proposed by the general meeting of shareholders or the management board, including but not limited to a change of control. Employers are also required to submit certain statutory defined matters that are viewed as 'social policy' (affecting employment terms and conditions) to the works council for prior approval.

#### 7. DESCRIPTION OF SHARE CAPITAL AND CORPORATE GOVERNANCE

#### General

Pharming's business was commenced by a company incorporated under Dutch law as a private company with limited liability (besloten vennootschap met beperkte aansprakelijkheid), by deed executed on 11 November 1988 under the name GENFARM B.V. GENFARM B.V. was ultimately renamed to Pharming Group B.V. On 29 May 1997 Pharming was converted from a private company with limited liability (besloten vennootschap met beperkte aansprakelijkheid) into a public company with limited liability (naamloze vennootschap). Pharming trades under the name Pharming and is registered with the Chamber of Commerce of The Hague under number 28048592. The corporate seat of the Company is in Leiden, the Netherlands. The Articles of Association were last amended on 15 May 2012 before D.F.M.M. Zaman, civil law notary in the Netherlands.

Set out below is an overview of outstanding Shares, options and warrants as well as a brief summary of certain provisions of the Articles of Association and a description of Pharming's compliance with the Dutch corporate governance code. The summary does not purport to give a complete overview and should be read in conjunction with the Articles of Association, together with relevant provisions of Dutch law, and does not constitute legal advice regarding these matters and should not be considered as such.

### **Corporate Objects**

Pursuant to Article 3 of the Articles of Association, the corporate objects of the Company are:

- to incorporate, to participate in, to manage and to take part financially in any way whatsoever, in other companies and enterprises;
- to render services to other companies, persons and enterprises in the administrative, technical, financial, economic and managerial fields;
- to develop and trade in patents, trade marks, licenses, know-how and other industrial property and intellectual rights;
- to obtain, alienate, manage and exploit registered property, securities, and items of property in general; and
- to borrow, to lend and to raise funds, including to act as guarantor or as severally-liable co-debtor, or to bind itself as a security for a debt of a third party,

and furthermore, to do everything that is connected therewith or may be conducive thereto, all this to be interpreted in the widest sense of the word.

# **Share Capital**

# Authorised and Issued Share Capital

At the date of this Registration Document, the authorised share capital of Pharming amounts to €13.0 million, divided into 1,300 million ordinary shares, with a nominal value of €0.01 each. There are currently 909,143,756 ordinary shares (in this Registration Document referred to as Shares) issued and outstanding.

Currently, neither the Company nor any of its subsidiaries hold any Shares in Pharming's capital. All Shares that are outstanding as of the date of this Registration Document are fully paid up.

The following table sets forth information about the issued share capital including the outstanding options, LTIP Shares and entitlements to Shares under warrants granted or issued by Pharming as of the date of this Registration Document.

Shares	909,143,756
Full-diluted shares	1,011,221,738
Options <sup>1</sup>	25,457,372
LTIP	5,479,920
2010 Warrants	5,208,333
2011 Warrants	20,300,000
2012-I Warrants	25,759,226
2012-II Warrants	19,873,131

For an overview of the development in the share capital in the past two financial years, reference is made to note 8 of the company financial statements in the annual report 2010 and note 8 of the company financial statements in the annual report 2011, which are included by reference.

## No Major Shareholders

Pharming is not aware of any person who, as of the date of this Registration Document, directly or indirectly, has a beneficial interest in 5% or more of the Shares.

# **Options and LTIP**

Since 1995, there have been stock option plans for the Company's employees and members of the Management Board, which have been slightly revised, effective as of 1 January 1999. Furthermore options are granted to consultants. In 2008, the Company implemented a Long Term Incentive Plan in addition to the option plans pursuant to which entitlements to Shares are granted subject to the financial performance of Pharming. Reference is made to Chapter 6 "Management, Supervision and Remuneration – Option Plans".

## 2010 Warrants

The 2010 Warrants may be exercised until 31 December 2012 by means of a cashless exercise, which means that the Shares to be issued upon exercise will be paid up by means of set off against the reduction of such number of Shares equal to the quotient obtained by dividing (x) the aggregate exercise price of the 2010 Warrants to be paid (if the exercise price were to be paid in cash), by (y) the volume weighted average price (**VWAP**) on the business day immediately preceding the day of the exercise of the 2010 Warrants. The exercise price of the 5,208,333 remaining 2010 Warrants at the date of this Registration Document has decreased from 0.12 to 0.013878. On the expiration date, the 2010 Warrants shall be automatically exercised in full via cashless exercise if the VWAP on the trading day immediately preceding the expiration date is greater than the applicable exercise price of the 2010 Warrants.

#### 2011 Warrants

The 2011 Warrants are exercisable until 15 July 2017 at an exercise price of €0.013878 per warrant (subject to adjustment).

# 2012-I Warrants

The 2012-I Warrants are exercisable until 7 February 2017 at an exercise price of €0.013878 per warrant (subject to adjustment).

<sup>&</sup>lt;sup>1</sup> The options to be granted to employees for 2012 are not included in this table.

#### 2012-II Warrants

The 2012-II Warrants are exercisable until 10 September 2017 at an exercise price of € 0.0233 per warrant (subject to adjustment).

# **Summary of the Articles of Association**

The following description summarises certain provisions of the Articles of Association, as currently in force. This summary does not purport to be complete, and is subject to, and qualified in its entirety by reference to the Articles of Association, as well as to the relevant provisions of Dutch law.

### General Meeting of Shareholders

An AGM is to be held within six months after the end of each financial year in Leiden, Amsterdam, Rotterdam or The Hague. The matters considered at the AGM include: (a) the annual report; (b) the adoption of the annual accounts; (c) discharge of members of the Management Board and members of the Supervisory Board; (d) notification of intended appointments of members of the Supervisory Board and members of the Management Board and of anticipated vacancies in the Supervisory Board; (e) instruct an auditor to verify the annual accounts and (f) any other proposals put forward by the Supervisory Board or the Management Board. Extraordinary general meetings of shareholders will be held (i) as often as the Management Board or the Supervisory Board deems necessary or (ii) upon the written request of those persons entitled to attend the general meetings of shareholders who represent at least one tenth of the Company's issued share capital, which request must be submitted to the Management Board and/or the Supervisory Board and set out in detail the matters to be considered.

Shareholders who are entitled to attend the general meetings of shareholders of the Company and who represent at least a percentage of the issued share capital of the Company or represent Shares with at least a market value as prescribed by Dutch law have the right to initiate proposals for consideration at a general meeting of shareholders (*recht van initiatief*), provided that they submit their proposal to the Management Board or the Supervisory Board by registered letter.

The Company will provide notice of each meeting of shareholders in accordance with the provisions of the Dutch Civil Code, i.e. by publishing a notice on its website and - as long as legally required - in at least one national daily newspaper distributed in the Netherlands. Pursuant to Dutch company law, such notice will be given no later than 42 days before the day of the meeting.

# Right of Attendance and Voting Rights

With respect to the right to attend general meetings of shareholders and the right to exercise voting rights in such meetings, the Company shall consider as shareholders holders of Shares named in a written statement of a financial institution in which statement the financial institution states (i) the number of Shares held by such shareholder (ii) that the Shares form part of the collective depot of such financial institution, (iii) that the shareholder named in the statement is a participant in the collective depot to the extent of the number of Shares stated and (iv) that the shareholder named in the statement shall keep such capacity at least until after the meeting, provided that this statement is deposited at the offices of the Company prior to the meeting. The convocation notice for a general meeting of shareholders shall state the date on which the statement must ultimately be deposited. Subject date cannot be a date prior to the seventh day prior to the date of the meeting.

Pursuant to Dutch company law, the Management Board shall set a registration date (the **Registration Date**), on the 28<sup>th</sup> day before the day of the meeting. If the Management Board has determined a Registration Date, the statement of the financial institution referred to above shall only have to include that the Shares mentioned in the statement formed part of the collective depot of the financial institution involved at the Registration Date and that the person mentioned in the statement was a participant in that collective depot at the Registration Date for the number of Shares mentioned.

Holders of registered Shares that do not form part of a *girodepot* or collective depot must inform the Company in writing of their intention to attend the general meeting of shareholders at the place referred to in the convocation notice, at the latest seven days prior to the date of the meeting. Unless a Registration Date has been determined, they can exercise the rights in question at the meeting only in respect of registered Shares which are registered in their names both on the day referred to above and on the day of the meeting.

Those entitled to attend general meetings of shareholders shall only be authorised to attend and to address the general meetings of shareholders, either in person or by proxy authorised in writing, if they have announced to the Management Board in writing at least four days prior to the meeting, that they intend to attend the meeting in person, or that they shall be represented by proxy. The convocation notice shall state such requirement.

Each Share confers the right to cast one vote.

### **Annual Report and Annual Accounts**

The Company's financial year is the calendar year. The Management Board must prepare the Company's annual accounts (consisting of the balance sheet and profit and loss account with explanatory notes thereto) and the annual report within four months after the end of the preceding financial year. Within this same period, the Management Board must prepare the Company's annual report.

The general meeting of shareholders selects an independent auditor who is responsible for auditing the annual accounts, reporting to the Supervisory Board and the Management Board on the audit, and issuing an auditor's opinion with respect thereto. If the general meeting of shareholders fails to select an auditor, the Supervisory Board is authorised to do so, and, if this body also fails to do so, the Management Board is then authorised to select the auditor.

The annual accounts of the Company must be submitted to the shareholders at a general meeting of shareholders for adoption. Copies of the annual accounts and annual report must be available to the shareholders for inspection at the offices of the Company from the date on which the notice of the meeting at which they are to be considered is given. The shareholders will be informed about the availability of the annual accounts and the annual report through the notice for the general meeting of shareholders in which the annual accounts are to be adopted. Upon request, those entitled to attend such meeting can receive copies of the annual accounts and the annual report free of charge. Within eight days after the adoption of the annual accounts by the general meeting of shareholders, the annual accounts and the annual report must be filed with the Chamber of Commerce of The Hague.

The general meeting of shareholders may resolve to discharge the members of the Management Board and the Supervisory Board from any liability with respect to the conduct of their duties during the financial year concerned. Under Netherlands law, this discharge is not absolute and is not effective with regard to matters not disclosed to the shareholders.

#### **Dividends**

The Company may distribute dividends only in so far as its 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 Netherlands company law. Under the Articles of Association, the Management Board, subject to the approval of the Supervisory Board, may annually determine to set aside as reserves part or all of the distributable profit of the Company with respect to the preceding financial year. To the extent that the annual profit has not been reserved, it will be distributed as a dividend on the Shares. Upon receipt of a proposal from the Management Board, which has been approved by the Supervisory Board, the general meeting of shareholders may resolve to make a dividend payment in whole or in part in Shares instead of in cash.

At a general meeting of shareholders, the shareholders may also resolve to make payments out of the distributable reserves of the Company upon receipt of a proposal thereto from the Management Board, which is subject to approval by the Supervisory Board.

The Management Board may, upon the approval of the Supervisory Board, distribute interim dividends.

The right of any shareholder to receive dividends shall be terminated if such dividends are not claimed within five years from the date on which this dividend became payable.

# Amendment of the Articles of Association, Dissolution and Liquidation

A resolution of the general meeting of shareholders to amend the Articles of Association or to dissolve the Company may only be adopted upon a proposal of the Management Board which has been approved by the Supervisory Board.

In the event of dissolution of the Company pursuant to a resolution of the general meeting of shareholders, the members of the Management Board will be responsible for the liquidation of the business of the Company and the Supervisory Board will be responsible for supervision thereof.

In the event of the dissolution and liquidation of the Company, the assets remaining after payment of all debts and liquidation expenses will be distributed pro rata (based on the nominal amount of the Shares held) to the holders of Shares.

### Issuance of Shares and Rights to subscribe for Shares

The Management Board has the authority to issue Shares or grant rights to subscribe for Shares if and insofar as the Management Board has been designated by the general meeting of shareholders as the authorised corporate body for this purpose and subject to the approval of the Supervisory Board. Such a designation may be effective for a specified period of up to five years and may be renewed for additional periods not exceeding five years. As per 14 May 2012, the Management Board has been granted such a designation concerning all the authorised and issued share capital of the Company until 26 May 2013. This period may be extended by an amendment of the Articles of Association, or by a resolution of the general meeting of shareholders for a period not exceeding five years in each case.

Upon expiration of this authority of the Management Board, the issuance of Shares or the granting of rights to subscribe for Shares shall require a resolution of the general meeting of shareholders (unless another corporate body has been designated by the general meeting of shareholders). A resolution by the general meeting of shareholders to issue Shares or to grant rights to subscribe for Shares or to designate another corporate body as being competent to do so may only be adopted upon a proposal of the Management Board, which proposal is subject to the approval of the Supervisory Board.

## Pre-Emptive Rights

Under the Articles of Association, each holder of Shares generally has a pre-emptive right to subscribe to its pro rata portion of any issue of Shares or grant of rights to subscribe for Shares, except for certain issuances to employees and issuances for non-cash consideration. The Management Board has the authority to restrict or exclude the rights of pre-emption for a period not exceeding five years, if and insofar as the Management Board has been designated by the general meeting of shareholders as the authorised corporate body for this purpose and subject to the approval of the Supervisory Board. The Management Board has been granted such authorisation until 26 May 2013. This period may be extended by an amendment of the Articles of Association, or by a resolution of the general meeting of shareholders for a period not exceeding five years in each case.

Upon expiration of this authority of the Management Board, the right to restrict or exclude pre-emptive rights shall require a resolution of the general meeting of shareholders (unless another corporate body

has been designated by the general meeting of shareholders). A resolution by the general meeting of shareholders to restrict or exclude pre-emptive rights or to designate another corporate body as being competent to do so may only be adopted upon a proposal of the Management Board, which proposal is subject to the approval of the Supervisory Board.

# Reduction of Share Capital

Upon a proposal by the Management Board, which has been approved by the Supervisory Board, the general meeting of shareholders may reduce the issued share capital of the Company by cancellation of Shares held by the Company or by reducing the nominal value of Shares, subject to certain statutory provisions.

#### Acquisition of Shares by the Company

Subject to the authorisation of the general meeting of shareholders and the approval of the Supervisory Board and subject to certain conditions imposed by Dutch company law, the Company may acquire fully paid-up Shares in its own share capital for consideration if: (i) the distributable equity is at least equal to the purchase price; and (ii) the nominal value of the Shares or depository receipts thereof which the Company acquires, holds or holds on lien or which are held by a subsidiary does not exceed one-tenth of the issued capital.

The Management Board has been granted such authorisation until 26 May 2013.

No voting rights may be exercised on Shares held by the Company. The Management Board may decide to transfer such Shares. The shareholders of the Company do not have a pre-emptive right on such transfers.

#### **Corporate Governance Code**

On 10 December 2009, the Dutch Corporate Governance Code (as initially released on 9 December 2003) has been amended and restated, with retroactive effect per 1 January 2009. This amended and restated Corporate Governance Code (the **Code**) contains principles and best practice provisions for the management board, the supervisory board, shareholders and the general meeting of shareholders and audit and financial reporting. The Code *inter alia* applies to all companies whose registered offices are in the Netherlands and whose shares or depositary receipts for shares have been admitted to listing and to trading on a regulated market.

Companies to which the code applies are required to disclose in their annual reports whether or not they apply the provisions of the corporate governance code that relate to the management board or supervisory board and, if they do not apply, to explain the reasons why. The corporate governance code provides that if a company's general meeting of shareholders explicitly approves the corporate governance structure and policy and endorses the explanation for any deviation from the best practice provisions, such company will be deemed to have applied the corporate governance code.

Pharming acknowledges the importance of good corporate governance and generally agrees with its basic provisions.

Pharming fully supports the principles and best practice provisions of the corporate governance code and applies with the relevant best practice provisions of the corporate governance code, subject to the exceptions set out below.

#### Non-Compliance with the Corporate Governance Code

The practices where the Company is not in compliance with the Code are the following:

Options for the Management Board (section II.2.4 of the Code)

With respect to section II.2.4 of the Code, the Company believes that its future success will depend in large part on the continued services of its members of the Management Board and key employees. The Company believes it is essential that it can offer internationally competitive remuneration packages to qualified members of the Management Board. In line with the recommendations of the Remuneration Committee and in line with industry practice, the options granted to members of the Management Board to acquire shares in the capital of the Company will be a conditional remuneration component which becomes unconditional when a member of the Management Board is still in the service of the Company at the end of the year. These options may be exercised within the first five years of granting, provided that these options have vested in line with conditions set by the Supervisory Board and approved by the shareholders. The Company considers the total compensation of the members of the Management Board is in line with international industry practice and significantly driven by long-term incentives, the potential values of which are fully dependent on value creation for all shareholders.

Profile Supervisory Board (section III.3.1 of the Code)

The current Supervisory Board profile was adopted under and in compliance with the previously prevailing Corporate Governance Code. This profile has not been aligned with the more detailed requirements of this provision under the currently prevailing Corporate Governance Code.

Regulations governing ownership of and transactions in securities, other than issued by the Company, by the Management Board or the members of the Supervisory Board (section III.6.5 of the Code)

The Company believes that the members of the Management Board and the members of the Supervisory Board should not be further limited by regulations in addition to commitments which are already applicable pursuant to Dutch law and regulations.

Granting of Shares or Rights to Shares to members of the Supervisory Board (section III.7.1 of the Code)

From 2008 the members of the Supervisory Board could participate in the LTIP, but as of 2011 the members of the Supervisory Board decided to withdraw their participation in the LTIP. The allocations of the conditional shares in the capital of the Company under the 2010 LTIP will end on 31 December 2012.

Follow in real time all the meetings (section IV.3.1 of the Code)

Considering the Company's size, it would create an excessive burden to provide facilities that enable shareholders to follow in real time all the meetings with analysts, presentations to analysts, presentations to investors referred to in the best practice provision. However, the Company ensures that presentations are posted on the website immediately after the meetings in question. Meetings discussing financial results and other significant news will be announced and conducted in accordance with this provision.

Independent third party to hold proxies (section IV.3.12 of the Code)

Given its size, the Company does not believe it is appropriate at this time to appoint an independent third party to hold proxies. The Company does allow for shareholders to appoint their own independent third party proxies.

Outline policy on bilateral contacts with the shareholders (section IV.3.13 of the Code)

This is a requirement, introduced only by the implementation of the currently prevailing Code. The Company has not historically felt the requirement for such a policy and therefore did not comply.

Internal Auditor (sections III.5.4c-III.5.4d and V.3.1-V.3.3 of the Code)

Due to the size of the Company, Pharming has not 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 the Group Controller, who is also the Company's Compliance Officer.

#### **Disclosure of Information**

As a Dutch company listed on Euronext Amsterdam, pursuant to the AFS, Pharming is required to publish its annual accounts within four months after the end of each financial year and its half-yearly figures within two months after the end of the first six months of each financial year. In addition, Pharming is obliged to publish interim management statements (*inter alia* containing an overview of important transactions and their financial consequences) in the period starting ten weeks after and six weeks before the first and second half of each financial year, or, alternatively, to publish quarterly financial statements.

Pharming must also make public certain inside information by means of a press release. Pursuant to the AFS, inside information is knowledge of concrete information directly or indirectly relating to the issuer or the trade in its securities which has not been made public and publication of which could significantly affect the trading price of the securities. The AFS contains specific rules intended to prevent insider trading.

### **Notification of Holdings of Voting Rights and Capital Interest**

Pursuant to the AFS, certain notification requirements apply to the Company as well as to holders of its shares due to the fact that Pharming is a listed company. The notification requirements are summarised below. Pursuant to the AFS, each person whose holding of voting rights and/or capital interest, directly or indirectly, amounts to 5% or more must notify the AFM without delay by means of a standard form or through the automated notification system of the AFM. Any person who, directly or indirectly, acquires or disposes of an interest in the Company's share capital or voting rights must without delay give written notice to the AFM, if, as a result of such acquisition or disposal, the percentage of capital interest or voting rights held by such person, directly or indirectly, reaches, exceeds or falls below the following thresholds: 5%, 10%, 15%, 20%, 25%, 30%, 40%, 50%, 60%, 75% and 95%.

Pharming is required to notify the AFM of any changes in its share capital and voting rights. More specifically, Pharming is required to notify the AFM without delay of any changes in its share capital if Pharming's share capital has changed by 1% or more compared to the previous disclosure in respect of its share capital. Pharming is also required to notify the AFM without delay of any changes in the voting rights, insofar as it has not already been notified at the same time as a related change in its share capital.

Changes in Pharming's share capital and voting rights of less than 1% must also be notified; these changes can be notified at any time but at the latest within eight days after the end of each calendar quarter. The AFM will publish such notifications in a public register. If, as a result of such change, a person's direct or indirect interest in Pharming's share capital or voting rights passively reaches, exceeds or falls below the abovementioned thresholds, the person in question must give notice to the AFM no later than the fourth trading day after the AFM has published the change in Pharming's share capital and/or voting rights in the public register.

In addition, annually within four weeks after the end of the calendar year, every holder of 5% or more of Pharming's shares or voting rights whose interest has changed in the period after his most recent notification to the AFM, which change relates to the composition of the notification as a result of certain acts (e.g., the exchange of shares (an actual interest) for depositary receipts for shares (which is a potential interest) or the exercise of a right to acquire shares (pursuant to which the potential interest becomes an actual interest)) must notify the AFM of such changes.

A person is deemed to hold the interest in Pharming's share capital or voting rights that is held by its controlled undertakings as defined in the AFS. The controlled undertaking does not have a duty to notify the AFM because the interest is attributed to the undertaking in control, which as a result has to notify the

interest as an indirect interest. Any person, including an individual, may qualify as an undertaking in control for the purposes of the AFS. A person who has a 5% or larger interest in Pharming's share capital or voting rights and who ceases to be a controlled undertaking for purposes of the AFS must without delay notify the AFM. As of that moment, all notification obligations under the AFS will become applicable to the former controlled undertaking.

For the purpose of calculating the percentage of capital interest or voting rights, amongst others, the following interests must be taken into account: (i) shares or depositary receipts for shares or voting rights directly held (or acquired or disposed of) by any person, (ii) shares or depositary receipts for shares or voting rights held (or acquired or disposed of) by such person's controlled undertakings or by a third party for such person's account or by a third party with whom such person has concluded an oral or written voting agreement (including a discretionary power of attorney), and (iii) shares or depositary receipts for shares or voting rights which such person, or any controlled undertaking or third party referred to above, may acquire pursuant to any option or other right held by such person (including, but not limited to, on the basis of convertible bonds). As a consequence, the notification should indicate whether the interest is held directly or indirectly, and whether the interest is an actual or a potential interest.

In addition, a notification obligation for certain cash settled instruments has been introduced. As a result hereof the notification is extended to holders of financial instruments where the increase in value of the instruments is dependent on the increase in value of the (underlying) shares of related dividends.

A holder of a pledge or right of usufruct in respect of shares or depositary receipts for shares can also be subject to the reporting obligations of the AFS, if such person has, or can acquire, the right to vote on the shares or, in the case of depositary receipts for shares, the underlying shares. If a pledgee or usufructuary acquires the voting rights on the shares or depositary receipts for shares, this may trigger a corresponding reporting obligation for the holder of the shares or depositary receipts for shares. Special rules apply with respect to the attribution of shares or depositary receipts for shares or voting rights which are part of the property of a partnership or other community of property.

The AFS contains detailed rules that set out how its requirements apply to certain categories of holders, including but not limited to (managers of) investment funds, investment managers, custodians, market makers, clearing and settlement institutions, brokers and credit institutions.

Pursuant to the AFS, members of the Management Board and Supervisory Board must notify the AFM of their interest in the Company's share capital and voting rights within two weeks of their appointment as a member of the Management Board or Supervisory Board. Any subsequent change of their interest in the Company's share capital and voting rights must be notified to the AFM without delay.

The notifications referred to in this paragraph should be made in writing by means of a standard form or electronically through the notification system of the AFM.

The above rules under Dutch law may change.

It is envisaged that a threshold of 3% or shareholders will be added to the above described thresholds pursuant to a bill on the amendment of the AFS. Further, listed companies such as Pharming would be obliged to publish their strategy on their website. In connection therewith, shareholders with an interest of 3% or more will have to disclose whether they have any objections against the published strategy.

There is another draft bill, also amending the AFS, which includes an extension of the notification obligations in respect of substantial holdings on the basis of economic long positions. Pursuant to the proposal the notification obligations would be extended to voting rights and capital holdings in financial instruments of which the value depends on the increase in value of the shares or dividend rights and which will be settled other than in those shares. On the basis of this proposal, (legal) persons which / who hold certain financial instruments such as contracts for differences and total return equity swaps should notify their interest as of 3%.

However, it is unclear if and when the above described proposed legislation will become effective.

### Market Abuse Regime

The rules on preventing market abuse set out in the AFS are applicable to Pharming, the members of the Management Board and Supervisory Board, other insiders and persons performing or conducting transactions in the Company's securities. Certain important market abuse rules set out in the AFS that are relevant for investors are described hereunder.

Pharming is required to make inside information public. Inside information is information that is specific and pertains directly or indirectly to Pharming or its shares or the trading thereof: (a) which information has not been made public and (b) where disclosure of such information could have a significant effect on the price of its shares or derivatives of its shares. Pharming must also provide the AFM with this inside information at the time of publication. Furthermore, Pharming must without delay publish the inside information on its website and keep it available on its website for at least one year.

It is prohibited for any person to make use of inside information within or from the Netherlands or a non-EU member state by conducting or effecting a transaction in Pharming's shares. In addition, it is prohibited for any person to pass on inside information to a third party or to recommend or induce, on the basis of inside information, any person to conduct a transaction. Furthermore, it is prohibited for any person to manipulate the market, for instance by conducting transactions which could lead to an incorrect or misleading signal of the supply of, the demand for or the price of the securities.

Pharming's insiders within the meaning of the AFS are obliged to notify the AFM when they carry out or cause to be carried out, for their own account, a transaction in the Company's shares or in securities the value of which is at least in part determined by the value of the Company's shares. Insiders within the meaning of the AFS in this respect are: (i) members of the Management Board and Supervisory Board, (ii) other persons who have a managerial position and in that capacity are authorised to make decisions which have consequences for the Company's future development and business prospects and who, on a regular basis, can have access to inside information relating, directly or indirectly, to Pharming, and (iii) certain persons closely associated with the persons mentioned under (i) and (ii) designated by the Dutch Market Abuse Decree (*Besluit marktmisbruik Wft*).

This notification must be made no later than the fifth business day after the transaction date on a standard form drawn up by the AFM. This notification obligation does not apply to transactions based on a discretionary management agreement as described in Article 8 of the Dutch Market Abuse Decree. Under certain circumstances, the notification may be delayed until the date on which the value of the transactions amounts to €5,000 or more in the calendar year in question.

If a member of the Management Board or Supervisory Board has notified a transaction to the AFM under the AFS as described above under "Notification of Holdings of Voting Rights and Capital Interest", such notification is sufficient for purposes of the AFS as described in this paragraph.

Pharming has adopted an internal code on inside information in respect of the holding of and carrying out of transactions in the Company's shares by the members of the Management Board and Supervisory Board and its employees. Further, Pharming has drawn up a list of those persons working for the Company who could have access to inside information on a regular or incidental basis and Pharming has informed the persons concerned of the rules on insider trading and market manipulation including the sanctions which can be imposed in the event of a violation of those rules.

#### 8. GENERAL INFORMATION

#### **Available Information**

Pharming publishes its annual accounts, accompanied by an annual report and an auditor's report, within four months after the end of each financial year and its half-yearly figures within two months after the end of the first six months of each financial year. In addition, the Company publishes quarterly financial statements.

The annual accounts must be signed by all members of the Management Board and the Supervisory Board. The annual reports (comprising the annual accounts, an annual report and an auditor's report) and the half-yearly reports and quarterly reports upon their publication can be inspected by Pharming's shareholders without charge at its head office in Leiden, during regular business hours.

Copies of the annual reports for the years ended 31 December 2010 and 2011, its (unaudited) report for the six months period ended 30 June 2012, the Articles of Association and the Prospectus may be obtained free of charge for the life of this Registration Document by sending a request in writing to Pharming at its business address: Darwinweg 24, 2333 CR Leiden, the Netherlands and are also available on <a href="https://www.pharming.com">www.pharming.com</a> for the life of this Registration Document.

The Prospectus will also be available to investors on the website of the AFM at <a href="www.afm.nl">www.afm.nl</a> and through the Euronext Amsterdam website at <a href="www.euronext.com">www.euronext.com</a>.

# **Corporate Information**

Pharming Group N.V. is a public company with limited liability, incorporated on 11 November 1988 under the laws of the Netherlands, and is registered with the Trade Register of the Chamber of Commerce of The Hague under number 28048592 and has its corporate seat in Leiden, the Netherlands. The Company's business address is Darwinweg 24, 2333 CR Leiden, the Netherlands and its website is <a href="https://www.pharming.com">www.pharming.com</a> and its telephone number is +31 (0)71 5247400.

# **Share Trading Information**

The Shares are listed and traded on Euronext Amsterdam and are cleared through the book-entry facilities of Euroclear Netherlands, only. The address of Euroclear Netherlands is: Herengracht 459-469, 1017 BS Amsterdam.

The Shares are traded under the following characteristics:

ISIN Code: NL0000377018 Common Code: 15661178

Amsterdam Security Code: 37701 Euronext Amsterdam Symbol: PHARM

# **Paying Agent**

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 1000 EA Amsterdam The Netherlands

# **Organisational Structure**

Pharming is a holding company of the following (in)directly held operating companies:

Name	Percentage	Country of Incorporation	
Broekman Instituut B.V.	100%	The Netherlands	
Pharming B.V.	100%	The Netherlands	
Pharming Healthcare, Inc	100%	USA	
Pharming Intellectual Property B.V.	100%	The Netherlands	
Pharming Technologies B.V.	100%	The Netherlands	
ProBio, Inc	100%	USA	

#### **Advisors**

Loyens & Loeff N.V. acted as Dutch counsel for Pharming in connection with this Registration Document.

# **Independent Auditors**

The consolidated financial statements of Pharming for the years ended 31 December 2010 and 2011 have been audited by PricewaterhouseCoopers Accountants N.V., Thomas R. Malthusstraat 5, 1066 JR Amsterdam, which initially has been appointed as the Company's auditors at the general meeting of shareholders held on 15 April 2009. The responsible partner of PricewaterhouseCoopers Accountants N.V. is a member of the Royal Netherlands Institute of Chartered Accountants (*Koninklijk Nederlands Instituut voor Registeraccountants*).

#### **Legal Proceedings**

There are no governmental, legal or arbitration proceedings, including any such proceedings pending or threatened of which Pharming is aware, during a period covering at least the past 12 months which may have, or have had in the recent past, significant effects on Pharming's financial position or profitability.

#### **Material Agreements**

Save for the finance agreements (described in Chapter 4 "Operating and Financial Review – Liquidity and Capital Resources"), there are no contracts (not being entered into in the ordinary course of business) which are, or may be, material and which (i) have been entered into by Pharming or any of its subsidiaries during the two years immediately preceding the date of this Registration Document or (ii) which contain a provision under which Pharming or any of its subsidiaries has any obligation or entitlement which is material to the group as at the date of this Registration Document.

# **Related Party Transactions**

Save as disclosed in Chapter 6 "Management, Supervision and Remuneration – Remuneration Policy; – Option Plans; and – Employment Agreements" no related party transactions between Pharming (including its subsidiaries) were entered into between 1 January 2012 and the date of this Registration Document.

#### 9. GLOSSARY OF SELECTED TERMS

AGM: Annual General Meeting of Shareholders.

**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 transplant because of suboptimal histocompatibility, is perceived by the recipient as a foreign body. The immune system is activated and the foreign body is attacked, which can lead to organ failure and immunological rejection of the organ.

**BLA:** In the USA, pharmaceuticals are approved for marketing under the provisions of the Public Health Service (PHS) Act. The Act requires a firm which manufactures a pharmaceutical for sale in interstate commerce to hold a license for the product. To commercialise a new biological product in the USA, 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 affects 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 amongst others monoclonal antibodies, growth factors, blood products and proteins intended for therapeutic use. The concerning FDA centre is the Center for Biologics Evaluation and Research (CBER).

**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 in the complement system (C1), which is part of the immune system. Insufficient C1 inhibitor action or amounts can cause inflammation and HAE attacks.

**CHMP**: The Committee for Medicinal Products for Human Use (CHMP) plays a vital role in the marketing procedures for medicines in the European Union. Amongst others, 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.

**CMO**: A Contract Manufacturing Organisation (CMO) is an organisation that provides clients from the pharmaceutical industry with comprehensive services from drug development through manufacture.

**DGF**: 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 ventilatory 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 are transplanted annually, including kidney, liver, lung and heart transplants.

**DNA**: DNA or deoxyribonucleic acid is a large organic molecule which contains the genetic information for the development and functioning of living organisms. The DNA holds so-called genes, each of them carrying the instructions to generally construct one specific protein. All genes together are called the genome or 'blueprint'. The proteins made from this blueprint are responsible for the biochemical activity of the cell.

**Downstream manufacturing**: Downstream manufacturing are all activities related to the purification of the C1 inhibitor protein from the milk, the fill and finish of the vials and the packaging and labelling of the vials.

**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.

**FDA**: The US Food and Drug Administration (FDA) is the regulatory office responsible for drug approval in the United States of America.

**G&A**: General & Administrative activities.

**GMP**: GMP status 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. 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, between 1 in 10,000 and 1 in 50,000 individuals suffers from HAE, having an average of 7 to 8 acute attacks per year.

**hLF**: Human lactoferrin (hLF) is a natural protein that helps to fight and prevent infections. The protein is present in substantial quantities in mother's milk and plays an important role in the defense system of infants. The protein is also present in various body fluids and continues to play an important role against a wide range of bacterial, fungal and viral pathogens in adults. Pharming produces a recombinant version of the natural lactoferrin protein.

**IFRS**: International Financial Reporting Standards (IFRS) along with International Accounting Standards (IAS) are a set of accounting standards issued by the International Accounting Standards Board (IASB).

**IND**: An Investigational New Drug Application (IND) 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 lack of oxygen due to an interruption of the blood supply (ischaemia) resulting in 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').

LTIP: Long Term Incentive Plan.

MAA: A Marketing Authorisation Application (MAA) is a request for market approval in the EU.

**NDA:** In the USA, pharmaceuticals are approved for marketing under the provisions of the Public Health Service (PHS) Act. The Act requires a firm which manufactures a pharmaceutical for sale in interstate commerce to hold a license for the product. To commercialise a new pharmaceutical drug product in the USA, the FDA needs to approve a New Drug Application (NDA). An NDA is a submission that contains specific information on the manufacturing processes, chemistry, pharmacology, clinical pharmacology and the medical effects of the pharmaceutical drug product. If the information provided meets FDA requirements, the application is approved and a license is issued allowing the company to market the pharmaceutical. The concerning FDA center is the Center for Drug Evaluation and Research (CDER).

**Orphan Drug**: A drug being developed to treat a rare 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 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 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 tenyear period.

**POC**: A Proof of Concept (POC) is a study to verify that a concept or theory has the potential of being used.

**Protein**: Proteins are large organic molecules, like C1 inhibitor, fibrinogen and collagen, and form the basis to all living organism. They are composed of one or more chains of amino acids joined together by peptide bonds. The sequence of these amino acids is defined by genes, which are present in the DNA.

**Recombinant**: Recombinant refers to the combination of genetic material (DNA) from different biological sources. Pharming, like all biotechnology firms, uses recombinant technology to produce proteins such as recombinant human C1 inhibitor.

**R&D**: Research and Development activities.

**rhC1INH**: Recombinant human C1 esterase inhibitor (rhC1INH) is the active component of Ruconest®/Rhucin®. Natural C1 inhibitor DNA from a human source is used in Pharming's protein production technology to ensure expression of the C1 inhibitor protein. This product might be useful for certain indications, such as the prevention of complications that sometimes arise after organ transplantation.

**rhCOL**: rhCOL is short for Pharming's recombinant human collagen type I. Natural human collagen is a protein found in skin, bone, blood vessels and many other tissues. Existing medical products using biomaterials are based on collagen from human plasma or animal tissues. Pharming aims to substitute these products with its recombinant human collagen.

**rhFIB**: Human fibrinogen is a natural human plasma protein involved in blot clotting. Together with thrombin it can form insoluble fibrin polymers or clots. Deficiency or low levels of fibrinogen can result in uncontrolled bleeding, as can occur in case of trauma, surgery, liver disease, sepsis and cancer. Pharming is developing recombinant human fibrinogen (rhFIB) as a replacement therapy for patients with genetic and acquired deficiencies of fibrinogen.

**Rhucin**<sup>®</sup>: Rhucin is the global trade mark for Pharming's recombinant human C1 inhibitor for the treatment of patients with acute HAE attacks. Human C1 inhibitor is a protein involved in the regulation of the first protein in the complement system (C1), which is part of the immune system. Insufficient C1 inhibitor action or amounts can cause inflammation and HAE attacks.

**Ruconest**<sup>®</sup>: Ruconest is the global registered trade mark for Pharming's recombinant human C1 inhibitor for the treatment of patients with acute HAE attacks.

**SPA**: The Special Protocol Assessment (SPA) process is a procedure by which the FDA provides official evaluation and written guidance on the design of proposed protocols that are intended to form the basis for a BLA or NDA. Final marketing approval depends on the results of efficacy, the adverse

event profile and an evaluation of the benefit/risk of treatment demonstrated in all the data contained in the BLA or NDA submission.

**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 the human recombinant gene responsible for expressing that product.

**Upstream manufacturing**: Upstream manufacturing are all activities related to the production of milk.

**VWAP**: Refers to the Volume Weighted Average Price of the Shares.

# **ISSUER**

# **Pharming Group N.V.**

Darwinweg 24 2333 CR Leiden the Netherlands

# **DUTCH COUNSEL TO THE ISSUER**

# Loyens & Loeff N.V.

Fred. Roeskestraat 100 1076 ED Amsterdam the Netherlands

# **INDEPENDENT AUDITOR**

# PricewaterhouseCoopers Accountants N.V.

Thomas R. Malthusstraat 5 1066 JR Amsterdam the Netherlands