

|                |                         |
|----------------|-------------------------|
| type of report | <b>Current report</b>   |
| number         | 63/2014                 |
| company        | Pharmena Spółka Akcyjna |

#### **November 2014 monthly report**

The Management Board of Pharmena S.A. hereby presents its monthly report for November 2014.

1. Information on trends and events occurring in the Issuer's market environment  
To the best knowledge of the Management Board, in November 2014 no trends or events occurred in the Issuer's market environment, which could significantly influence financial results of the company.

In November 2014, Pharmena accomplished sales revenue from its dermatological cosmetics in the amount of over 1,700,000 PLN. Obtained revenue was 47% higher when compared to the revenue achieved in an analogous period of the previous year. This was mainly associated with promotions of products for pharmacy chains.

During the said period, Pharmena S.A. enhanced the availability of its products and carried out marketing actions in order to increase sales profit from marketed products.

On 14<sup>th</sup> November 2014 the Issuer published the report covering the III quarter of the year 2014, which included selected financial data, both separate and consolidated.

In March 2014, the Issuer published a Separate Annual Report for 2013 (annual report No. 12/2014 of 14<sup>th</sup> March 2014) and Consolidated Annual Report for 2013 (annual report No. 13/2014 of 14<sup>th</sup> March 2014), which summarised the achievements of the Issuer's Capital Group and presented financial results (on separate and consolidated levels) for 2013, together with opinions and reports of statutory auditors from these financial reports.

Since 2014 the Issuer has altered the presentation of revenues and costs associated with selling dermatological cosmetics, which resulted in changing the allocation of a certain part of sales costs and general management costs.

Currently all costs associated with selling dermatological cosmetics (including remunerations for medical representatives) shall be presented in the profit and loss account under the selling costs. Whereas the position covering the general management costs shall only include costs related with remuneration for the management board, costs associated with leasing and maintaining the office, patent fees, costs related with other business lines (namely the project covering the 1-MNA anti-atherosclerosis medicinal product and 1-MNA dietary supplement), as well as other costs relating the overall activity of the Issuer. The new manner of presentation aims to present financial outcomes with emphasis on individual business lines held by the Issuer.

On the separate level the Issuer observed a decrease in revenue in the III quarter of the year 2014 (by 10.48% when compared to the III quarter of the year 2013). The decrease in revenues, as well as remaining positions within the profit and loss account, next to the drop in profitability of the conducted operational activity were mostly influenced by the following factors:

- 1) intensive advertising campaigns realised by competitive brands,
- 2) lack of possibility to repeat the September promotional and advertising campaign in pharmacies for the Dermena Complex brand, which posed a significant influence on the revenue obtained in the III quarter of the year 2013. Whereas the increased profitability observed in the III quarter of the year 2014 on the level of net and gross profit resulted from exchange gains.

The aim of the Company is to recreate the growth reported for the Dermena brand, and that is why the Company conducts marketing and sales actions covering the whole line of Dermena products.

The activity of the Issuer's Capital Group within the scope of dermatological cosmetics is profitable within all levels of the profit and loss account. Whereas the activity undertaken by the Group within the scope of clinical researches concerning the innovative 1-MNA anti-atherosclerosis medicinal product as well as in the area related with implementing the diet supplement (based on 1-MNA) currently generates only costs. These costs stand as a significant expenditure as far as the financial position of the Capital Group is concerned, and therefore the Capital Group reveals negative profitability within the consolidated level.

In the III quarter of the year 2014 the following factors posed the greatest influence on the loss of revenue achieved by the Capital Group of the Issuer:

- 1) intensive advertising campaigns realised by competitive brands,
- 2) lack of possibility to repeat the September promotional and advertising campaign in pharmacies for the Dermena Complex brand, which posed a significant influence on the revenue obtained in the III quarter of the year 2013. Simultaneously, when compared with the previous year, expenditures associated with conducting tests on the 1-MNA anti-atherosclerosis medicinal product and costs related with conducting tests within the scope of toxicity tests within

the project of the 1-MNA dietary supplement, which posed a considerable influence on the increased loss within the remaining specific positions of the profit and loss account.

Detailed financial data with Management's comments can be found in the report covering the III quarter of the years 2014.

In the area of works over 1-MNA dietary supplement, the following events occurred during the period covered by this report:

1) In relation to the Strategy of the Company for the years 2012-2015 (published in the current report No. 16/2012 dated 13.04.2012), notification about the evaluation concerning the application for authorizing the 1-MNA as the new food ingredient (published in the current report No. 80/2013 dated 05.12.2013), as well as notification on completing toxicity tests within the project of 1-MNA dietary supplement (published in current report No. 54/2014 dated 31.10.2014) the Management Board of PHARMENA S.A. informed that on 6<sup>th</sup> November 2014 the Company submitted results of subchronic (90 days) toxicity test performed on animal models to Food Standard Agency and to the Advisory Committee on Novel Foods and Processes (ACNFP), as these documents complemented the motion to authorize the 1-MNA as a new food ingredient pursuant to art. 4 of Regulation No. 258/97. The conducted analysis concerning the results of toxicity tests demonstrated very good tolerance as well as high safety of use of the 1-MNA substance. The tests showed no adverse effects depending on the tested substance. The value of NOAEL (No Observable Adverse Effect Level) ratio has been indicated – it is 1000 mg/kg of the animal's (rat's) body mass. This value is the highest tested dose of 1-MNA substance and simultaneously constitutes the highest recommended dose of the substance (according to OECD recommendation no 408) administered within the 90-day toxicity test. It should be highlighted that the indicated NOAEL value for 1-MNA corresponds to ca. 9600 mg/day for humans, which is almost 40 times higher a dose when compared to the planned dose of 1-MNA (250 mg) in dietary supplement (based on the 1-MNA substance). The obtained results of the tests are compliant with the Company's expectations.

The procedure stipulated in the provisions of Art. 4 of the Regulation (EC) No. 258/97 of the European Parliament and of the Council of 27<sup>th</sup> January 1997, concerns foods and food ingredients that have no record of safe consumption in the Community, which means they were not used in foods before 15<sup>th</sup> May 1997 in any EU Member State. The goal of subjecting the 1-MNA to this procedure is to prove, by the use of available for PHARMENA S.A. research and scientific publications, the safety of the ingredient's use within the proposed area. Within this procedure, the entity responsible for placing on the Community market submits appropriate application to EU Member State, where the new foodstuff is to be first placed on the market. An additional scientific assessment at the European level may appear necessary, and in such case, it will be performed by the European Food Safety Authority (EFSA). Following full assessment, the European Commission grants permission for placing the new foodstuff on the market.

Successful authorisation will open EU markets for the dietary supplement.

The 1-MNA dietary supplement will be an innovative product with a capacity to influence the risk biomarkers of cardiovascular diseases and to stimulate the endogenous (natural) production of prostacyclin. Low levels of prostacyclin in human organism increase the risk of atherosclerosis. Studies have shown that the concentration of endogenous 1-MNA in human organism decreases with age. 1-MNA dietary supplement can complement 1-MNA deficiency in the organism and therefore stimulate the production of prostacyclin which reduces the risk of atherosclerosis development.

In the area of works on the innovative 1-MNA anti-atherosclerosis medicinal product, the following events occurred during the period covered by this report:

1) In relation to the Strategy of the Company for the years 2012-2015 (published in the current report No. 16/2012 dated 13.04.2012), notification on the progress of clinical tests concerning the innovative 1-MNA anti-atherosclerosis medicinal product (published in the current report No. 41/2014 dated 04.08.2014) the Management Board of PHARMENA S.A. informed that on 23<sup>rd</sup> September 2014 23 patients have been enrolled into the II phase clinical trial of the 1-MNA anti-atherosclerosis medicinal product, including 7 patients who completed the trial. The aim of phase II clinical trial of the 1-MNA anti-atherosclerosis medicinal product is to determine the effective dose of the drug and to confirm the lack of adverse effects in human, as far as tested doses of the drug are concerned. Due to restrictive criteria concerning the participation of patients in the study - among others the ones concerning lipid profile disorders, as well as the prohibition to use other therapies in dyslipidemia - the percentage of patients excluded from the trial is higher than the anticipated number. Based on the recommendations stated by the entity conducting the study, the Montreal Heart Institute, the Issuer decided to introduce certain changes within the study protocol, as far as enrolment criteria are concerned. HDL –c cholesterol shall not be included in the patient's selection criterion, however, any changes within its level will still be monitored during the study. Restrictive criterion concerning the HDL –c cholesterol was initially included in study protocol due to cognitive reasons. The implemented change shall not influence the commercialization of the project; however, it will enable to increase the pace of patient enrolment. On 28.11.2014 the Company was granted the agreement of the Health Canada (the unit supervising the realization of the II phase clinical trial of the 1-MNA anti-atherosclerosis medicinal product) to make the change in the clinical trial protocol. The Montreal Heart Institute remains to be the leading research and scientific centre in Canada, which specializes in cardiology, and it is one of the biggest institutes of this kind in the world. It is a globally renowned centre, which has introduced a multitude of innovative solutions, both international and national. More information can be found on the Internet site: [www.icm-mhi.org](http://www.icm-mhi.org).

Taking into consideration the current number of patients in the trial, as well as bearing in mind the change in study protocol concerning the HDL cholesterol, the anticipated completion of the trial is scheduled for the II quarter of the

year 2015. Prolonging the duration of the trial will not pose any significant influence on the anticipated costs related with conducting the II phase clinical trial of the 1-MNA anti-atherosclerosis medicinal product. II phase clinical trials ("Proof of Concept") are financed from funds obtained from issuing Series D shares.

2) On 08.11.2014 the Issuer received notification that the US Patent Office decided on granting a patent to patent application No. US13/083,106 concerning the use of 1-methylnicotinamide (1-MNA) in atherosclerosis treatment, related to 1-MNA's ability to increase the level of prostacyclin. The patent ensures the Company a patent protection in the abovementioned scope in the USA.

This is yet another patent (previous ones were granted among others in USA, Europe, Russia, Mexico, Canada, Australia, and China) which the Company receives within patent applications concerning the use of selected pyridinium salts in vascular protection, as in the previous years, the Company made a vast number of patent applications to ensure a worldwide protection.

Moreover in November 2014, the Issuer's Capital Group continued its research and development work on new products and searched for new applications for active substances protected by patents and patent applications owned by the Issuer's Capital Group. The Company prepares 15 brand new dermatological cosmetics, which shall be introduced on the market in the first half of the year 2015. Simultaneously, the Company conducts developmental works covering the following 17 products, which should be introduced on the market at the turn of 2015/2016.

## 2. Achievement concerning the goals of an issue

In November 2014, Pharmena S.A. did not make any money expenditure directly on issue-related purposes. However, in the reported period, a subsidiary company Cortria Corporation spent its funds to cover the costs of its everyday functioning.

## 3. A list of all information published by the Issuer in the form of current reports in the reporting period from 1<sup>st</sup> November 2014 to 30<sup>th</sup> November 2014.

During the period covered by this report, Pharmena S.A. published the following reports in EBI system:

- Current report No. 55/2014 of 06-11-2014 – Completing the application for the authorization of 1-MNA as a new food ingredient
- Current report No. 56/2014 of 06-11-2014 – Information concerning the progress of clinical research on the innovative 1-MNA anti-atherosclerosis medicinal product
- Current report No. 57/2014 of 07-11-2014 – October 2014 monthly report
- Current report No. 58/2014 of 10-11-2014 – Decision on granting a patent in the USA
- Current report No. 59/2014 of 14-11-2014 – PHARMENA S.A. – Report covering the III quarter of the year 2014
- Current report No. 60/2014 of 24-11-2014 – Concluding an agreement with the auditor

During the period covered by this report, Pharmena S.A. did not publish any reports in ESPI system.

## 4. Investor's calendar for December 2014.

Until 14.01.2015 – publication of December 2014 monthly report.

Legal basis: Resolution No. 795/2008 of the Warsaw Stock Exchange Management Board dated 31<sup>st</sup> November 2008 concerning the adoption of the codes of best practice applicable on the NewConnect market, Appendix 1, point 16.

### **Representatives of the company:**

- Konrad Palka - President of the Board
- Marzena Wiczorkowska - Vice- President of the Board