

type of report	Current report
number	57/2014
company	Pharmena Spółka Akcyjna

October 2014 monthly report

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

1. Information on trends and events occurring in the Issuer's market environment

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

In October 2014, Pharmena accomplished sales revenue from its dermatological cosmetics in the amount of over 1,088,000 PLN, which constitutes an increase by 10%, when compared to the revenue achieved in an analogical period of the previous year. This result was mainly achieved thanks to higher sales of Dermena products.

In 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.

Within the above measures, the Company undertook direct cooperation with a pharmaceutical wholesaler Lubfarm S.A. on 28th October 2014. Lubfarm has 20 years of experience in distribution of pharmaceutical products in South-Eastern Poland. It covers the area of the following voivodeships: lubelskie, podkarpackie, świętokrzyskie, małopolskie, eastern part of the mazowieckie and śląskie, as well as southern part of the podlaskie.

The Management Board of Pharmena S.A. estimates that the cooperation with the pharmaceutical wholesaler Lubfarm will have a beneficial influence on the availability of PHARMENA products in South-Eastern Poland and will, over the next few years, significantly contribute to the increase of the Company's revenue. Terms of cooperation were established on the market conditions.

The objective of the cooperation is to execute one of the constituents of the Company's updated Strategy for 2012-2015 that has been adopted by the Issuer. The part of the strategy related to dermatological cosmetics includes enhancement of distribution of the Issuer's products by new wholesale companies that operate on the pharmaceutical market. The Issuer informed about the assumptions of the updated Strategy in current report no. 16/2012 of 13th April 2012.

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

1) On 3rd October 2014, the Company PHARMENA received a report from pathological analysis within subchronic (90 days) toxicity test on animal models. The analysis covered macroscopic and microscopic analysis, as well the evaluation of internal organs. The performed analysis did not demonstrate any lesions depending on the tested substance, i.e. 1-MNA, the results of which are compliant with the Company's expectations. The report that the company received today constitutes yet another part of the full toxicity report that is being drawn up by the study centre.

Subchronic (90 days) toxicity test on animal models has been ordered in March 2014 in order to complete the application for authorisation of 1-MNA as new food ingredient (dietary supplement) pursuant to Art. 4 of Regulation (EC) No. 258/97. After obtaining the test report, the Issuer plans to immediately present test results to Advisory Committee on Novel Foods and Processes (ACNFP), which will conduct assessment concerning authorisation of 1-MNA as a new food ingredient in cooperation with Food Standards Agency (FSA).

The procedure stipulated in the provisions of Art. 4 of Regulation (EC) no. 258/97 of the European Parliament and of the Council of 27th 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 15th May 1997 in any EU Member State. The goal of subjecting 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 European level may appear necessary. In such case, it will be performed by European Food Safety Authority. 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.

2) On 20th October 2014, the Company PHARMENA received a report from densitometric analysis (bone density) within subchronic (90 days) toxicity test on animal models. The analysis demonstrates no influence of the tested substance, i.e. 1-MNA, on bone mineral density, the results of which are compliant with the Company's expectations. The report that the company received today constitutes yet another part of the full toxicity report that is being drawn up by the study centre.

3) On 31st October 2014, the Management Board of PHARMENA S.A. informed that toxicity tests within the project of 1-MNA dietary supplement were successfully completed.

The analysis of the toxicity tests results demonstrated very good tolerance as well as high safety of use of the tested substance, i.e. 1-MNA. The tests showed no adverse effects depending on the tested substance. The assessment covered clinical observations, physical activity, body mass, food intake, ophthalmological and haematological assessment, clinical chemistry, evaluation of blood clotting parameters, evaluation of internal organ masses, macroscopic and microscopic analysis of internal organs, and bone density analysis (DXA densitometry). The study included 124 animals in total. 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 results of the tests are compliant with the Company's expectations.

The Issuer will immediately present the test results to Advisory Committee on Novel Foods and Processes (ACNFP), which conducts assessment concerning the authorisation of 1-MNA as a new food ingredient (dietary supplement) in cooperation with Food Standards Agency (FSA), pursuant to Art. 4 of Regulation (EC) No. 258/97 of the European Parliament and of the Council of 27th January 1997.

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

1) The Management Board of PHARMENA S.A. informed that on 30th October 2014, the Issuer increased share capital of subsidiary company Cortria Corporation by 1,000,000 USD (through the issue of 10,000 new shares). The share capital increase is financed from the Issuer's own funds obtained from the issue of series D shares.

The funds from the share capital increase will be allocated to further financing of phase II clinical trials of innovative anti-atherosclerosis medicinal product (1-MNA).

Cortria Corporation is a private pharmaceutical company with registered headquarters in Boston, Massachusetts, USA, which conducts clinical trials focusing on developing safe and well-tolerated medicinal products for the treatment of cardiovascular diseases, particularly atherosclerosis.

Moreover in October 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.

2. Achievement of the goals of an issue

In October 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 mainly on phase II clinical trials over the 1-MNA anti-atherosclerosis medicinal product.

3. A list of all information published by the Issuer in the form of current reports in the reporting period from 01.10.2014 to 31.10.2014.

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

- Current report no. 48/2014 of 03-10-2014 – Information on the progress in toxicity tests within the project of 1-MNA dietary supplement
- Current report no. 49/2014 of 14-10-2014 – September 2014 monthly report
- Current report no. 50/2014 of 21-10-2014 – Information on the progress in toxicity tests within the project of 1-MNA dietary supplement
- Current report no. 51/2014 of 23-10-2014 – Appointment of the President of the Supervisory Board
- Current report no. 52/2014 of 29-10-2014 – Commencing cooperation with LUBFARM S.A.
- Current report no. 53/2014 of 30-10-2014 – Share capital increase of Cortria Corporation
- Current report no. 54/2014 of 31-10-2014 – Toxicity tests within the project of 1-MNA dietary supplement successfully completed

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

- Current report no. 3/2014 of 17-10-2014 – Information on transactions in financial instruments of the Issuer
- Current report no. 4/2014 of 21-10-2014 – Disclosure of shareholding – increasing of the share held by a shareholder over 5% of the total number of votes
- Current report no. 5/2014 of 29-10-2014 – Information on transactions in financial instruments of the Issuer

4. Investor's calendar for November 2014.

14.11.2014 - publication of Q3 2014 quarterly report

Until 14.11.2014 – publication of October 2014 monthly report.

Legal basis: Resolution No. 795/2008 of the Warsaw Stock Exchange Management Board dated 31st 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 Wieczorkowska - Vice President of the Board