## ADMINISTRATOR'S REPORT January-September 2015

Quarter III report according to:	IFRS
For the financial year:	30.09.2015
Date of the report:	October 22 2015
Name of the company:	Antibiotice SA
Head office:	lasi, Strada V.Lupului nr.1
Phone number:	+40232/209000; fax: +40232/209633
Fiscal registration code:	RO1973096
Trade Register Registration Number:	J22/285/1991
The regulated market on which the iss	ued securities are traded:
	Bucharest Stock Exchange
Subscribed and paid-up share capital:	RON 67.133.804

The main characteristics of the securities issued by the company: nominative shares, nominal value: RON 0.10.

During the first 9 months of 2015, the pharmaceutical industry was heavily influenced by the announced legislative changes on how to subsidize medicines, to lower drug prices by applying the Order No.75/2009 as amended and supplemented, the progressive increase of the claw-back tax, as well as the entry into insolvency of some distributors and pharmacies.

According to analysts, so far, over 1,300 generic drugs have disappeared from the market and their number will increase, because with the fall in prices, they have become unprofitable. Also, as there will be no changes in pricing and claw-back, it is estimated that about half of the pharmacies will disappear and the companies which will not withdraw their products from the market will decide to restrict their availability on the market.

All these factors have negatively influenced the evolution of the pharmaceutical market during the first 9 months, with a decrease of 1.4% compared to the same period last year.

The main concern of Antibiotice SA between January and September 2015 was to ensure a further increase in drug consumption on the domestic market in pharmacies and hospitals, respectively from RON 184.6 million in 2014 to RON 210.4 million in 2015 (14% increase).

Simultaneously with the increase of drug consumption in patients, the achievement of the planned indicators in the Revenue and Expenditure Budget was also achieved, with a **gross profit** of RON **16.7** million, **up by 14%** compared to the estimated figures, but down by RON 6.9 million as compared to 2014, mainly due to a 33% increase in claw-back tax during the same period, and a **net profit** of RON **14.6** million, **up by 19%** compared to the planned values.

## 1. Analysis of the company's activity

Through the promotion and commercial policies, the Antibiotice sales to domestic distributors for the first 9 months of 2015 are worth **RON 199.5 million**, while the sales of the Antibiotice products in pharmacies were worth **RON 233.9 million** during the same period, while the sales of the Antibiotice products in pharmacies to patients amounted to **RON 210.4 million** (an increase of 14% compared to January - September 2014).

# The evolution of Antibiotice's sales on the Romanian pharmaceutical market during 2014-2015 (9 months).

- thousand

RON-			
Indicator	9 months 2014	9 months 2015	Variation 2015/2014 9 months
Sales from distribution - Antibiotice	213.3	233.9	+ 9.7%
Sales in pharmacies and hospitals Antibiotice	184.6	210.4	+ 14.0%
The pharmaceutical market	8.945.2	8.819.2	-1.4%

Source: sales distributors, Cegedim - expressed in sales price

During the analyzed period, Antibiotice registered 14% growth in the sales in pharmacies and hospitals compared to the pharma market, which recorded a decrease of - 1.4%.

At 9 months, Antibiotice maintains its leading position in the generic medicines marketplace in hospitals, with a market share of 18.5%, experiencing an increase compared to the same period last year (16.7%).

On the generics market, the company occupies the 4th position, with a market share of 5.6%, while on the total pharmaceutical market the company ranks13th with a market share of 2.38%.

The retail pharmacy segment holds 75.9% of the company's value (RON 159.6 million), up by 14.3% compared to 2014.

The Hospital segment is up by 12.9%, from RON 44.9 million in 2014 to RON 50.7 million in 2015 (*Cegedim data source*).

The therapeutic classes that experienced significant value increases in the market are: Anti-infective drugs for systemic use (+ RON 14 million), Dermatological preparations (+ RON 4.8 million), Digestive tract (+ RON 2.6 million), Cardiovascular system (+ RON 2.1 million), Nervous System (RON 1.8 million), Musculoskeletal System (+ RON 390 thousand), generated both by the contribution of new products and the positive evolution of the company's top products.

Among these are products with a contribution of more than RON 1 million: Cefort® injectable range (value input of RON 3.5 million), Eficef® capsules range (+ RON 3.4 million), Meropenem Atb® injectable range (+ RON 2.2 million), Nidoflor® cream (+ RON1.6 million), Colistina Atb® injectable 1mU (+ RON 1.4 million), Ampiplus® injectable (+ RON 1.3 million), Amoxicillin Antibiotice capules 500mg (+ RON 1.3 million), Novocalmin® suppositories (+ RON 1.2 million), Omeprazol Atb® capsules (+ RON 1.2 million) and Ceftamil® injectable 1g (+ RON 1.1 million).

Significant increases both in consumption and in terms of value generated were also registered by other products to be promoted in 2015: Nolet® (nebivololum), Silithor® capsules (silymarin + methionine + cysteine), Almacor® tablets range (amlodipine), Zolpidem Atb® tablets (zolpidem) and Nobixal® tablets (tianeptine).

Antibiotice maintains its leading position in terms of the units capitalized on the ointment segment with a market share of 27.8%, on the suppositories segment with a market share of 43% and on the segment of injectable powders with a market share of 75.4%. Compared to last year, the company has reached a top position on the capsule segment, ranked second in terms of quantity with a market share of 7.6%.

The new products launched by the company during the first 9 months of 2015 are part of the following therapeutic classes:

Central Nervous System: completing the Memantina Atb® range with the 20mg dose

Anti-infective products for systemic use: Imipenem/Cilastatin Atb® injectable 500mg/500mg.

## Developing strategic partnerships on foreign markets

The business internationalization is one of the main pillars in the company's mediumand long-term strategy of development.

The main development directions envisaged are the following:

- strengthening the world leader position for Nystatin active substance;
- establishing a portfolio of Antibiotice products to be promoted as international brands in a defined number of territories;
- the development of complex cooperation, out-licensing, co-development and co-marketing partnerships, in order to capitalize on the potential for development upon certain external markets.

The exports during the first 9 months of 2015 amounted to RON 63.853.927 experiencing an increase of 10% during the first nine months of 2015 compared to the similar period of 2014.

The evolution of exports during the first nine months of 2015 took place in the context of a prudent company policy on the exposure to foreign markets, given the unstable political situation in the Arab world and the economic crisis in Russia, CIS and Latin America.

For the year 2016, as a result of new projects that will result in sales over the next period, an increase in export turnover is projected. Thus, a superior utilization of the

Nystatin active substance is envisaged by increasing the share of US clients in the total export of active substances as a result of obtaining new authorizations on this market.

The main projects for the export of finished products, which will bring additional value in turnover relate to the export of injectable products to the US and the UK, the export of capsules to France and the Netherlands, as well as to South East Asia and the export of ointments and pessaries in the CIS.

# Certified quality

The increase of the confidence in the quality, efficiency and safety of the company's products is achieved daily by keeping under control and improving the Integrated Management System, attested by the results obtained following the inspections/audits during the first nine months of 2015:

## 1. Inspections/Audits by the authorities

**1.1.** During the period 20 - 22.01.2015 the NAMMD inspection, for the re-authorization of the partial manufacture of medicinal products for human use for clinical investigation (secondary packaging line - labeling of primary and secondary containers) was carried out at the Center for Drug Evaluation. The inspection was carried out by 3 NAMMD inspectors on the compliance with the GCP, GLP and GMP requirements applicable to the human medicinal product manufacturing line for clinical investigation. Following the inspection, the GLP (Laboratory Good Practice Certificate) was issued.

**1.2.** For the **GMP** approval of reception, sampling and storage of raw materials and packaging materials in the new warehouse, building code P33-D, the NAMMD was submitted in December 2014, the company's standard inspection and inspection dossier. Following the evaluation of the submitted documentation, the agency requested the completion of the company's certificate. It has been completed as requested by the testing activities and clinical trials, as well as the activities that take place at the headquarters and at the secondary office.

**1.3.** Between June 2 and 10 2015, an **FDA inspection** was carried out to verify the quality system that provides the legal/regulatory framework for the manufacture of products that are marketed on the United States market.

Following the inspection, the FDA 483 (Inspectional observations) form was issued in which three non-compliances were recorded. According to the FDA investigator, this result allows us to continue delivering finished products and Nystatin to the United States market.

**1.4. The NAMMD inspection** - in order to prepare the GMP re-certification inspection of the secondary cephalosporin packaging line from the Non-Penicillin Capsule Plant, the company's Standard File for GMP re-certification of the partial manufacturing line - secondary packaging and product labeling sterile cephalosporin vials; the secondary packaging cephalosporin vials + solvent vials; batch testing and release was drafted, approved and sent to NAMM.

**1.5.** The ANSVSA (National Sanitary Veterinary and Food Safety Authority) inspection - In order to prepare the GMP re-certification inspection of the manufacturing lines for

veterinary products - injectable products, ointments, feed-grade nystatin, the standard GMP Recertification File of the manufacture of veterinary products - injectable products, ointments, feed-grade nystatin was drafted, approved and sent to ANSVSA. The file will be evaluated for approval and the setting of the recertification inspection date.

**1.6.** The supervision audit - On 29.07.2015 the surveillance audit carried out by the SRAC CERTSERV certification body was carried out in order to verify the observance and maintenance of the conditions that led to the issue of certificates of conformity with the current product specifications for products (aluminum tubes, staples, thread caps). No non-compliances were identified, and it is recommended to maintain the certifications.

## 2. Audits from contract suppliers (contract manufacturing)

**2.1.** Between January 22 and 23 2015, **DSM Netherlands**, conducted the audit of Antibiotice as a beneficiary under contract for Amoxicillin Capsules, 250 and 500 mg. The audit was conducted by Senior Quality Assurance Manager DSM. No non-compliances have been identified and Antibiotice was proposed to qualify as a contract beneficiary.

## 3. Audits to raw material/primary packaging/finished products suppliers

Between September 04-29 2015 audits were carried out to verify the compliance of the quality management system with the GMP requirements at a number of manufacturers of active substances/finished product manufacturers for contract manufacturing in China.

The 2015 audit plan for auditing some manufacturers of active substances/finished product manufacturers for contract manufacturing in India has been established and approved. The scheduled audits will be conducted by two (Qualified Personnel) teams within the Quality Unit to verify the compliance of the quality management system with the GMP requirements.

# The employee development - a guarantee for performance

The performance orientation of the whole activity led to the completion of the structures with the necessary staff through:

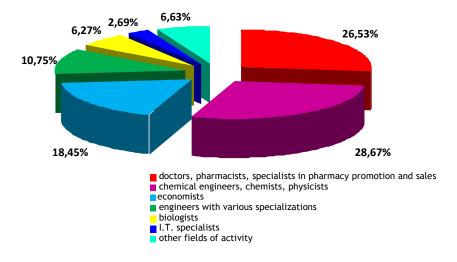
- the redistribution from the surplus staff to vacant positions, depending on their ability of adapting to specific requirements;

- attracting staff to complete teams with 21 people with higher education in the fields of commercial and promotion, marketing, pharmaceutical development, export, production and engineering.

Staff structure on September 30, 2015:

Total employees 1465, out of which:

- higher education staff 638 (43.5% of total staff)
- secondary education staff 827 (56.5 % of total staff)



In order to achieve professional performance - the premise for increasing the competitiveness and the quality of our business, our concerns have resulted in employee career development projects, with training programs in each direction, according to the needs identified for each organizational structure and in close correlation with the changes applicable to the European Union legislation and the domestic legislation.

- The progress of the training sessions in accordance with the "Annual Training Plan with External Lecturers" for 2015;
- The completion of the courses organized by the 6th edition of the "Summer School a+", which aimed to familiarize and train the graduates in the fields of pharmacy, chemistry, biology and chemical engineering with the working environment, the concepts and regulations in the pharmaceutical industry in to attract specialists for vacancies in the fields of Pharmaceutical Development, Quality Assurance, Quality Control and Production. Following the sixth edition of the "Summer School a+", a number of 38 students and graduates became familiar with the concepts and notions specific to the pharmaceutical industry.

# 2. The economic and financial Results for the first 9 months of 2015

The sales revenues are worth RON 216.3 million, reaching the same level as in 2014, by the end of the year, reaching a budget target of RON 326 million, of which 28-30% export.

The gross profit of the fiscal year during the first nine months of the year is worth RON 16.7 million, up by 14% compared to the figures for the Income and Expenditure Budget.

The **net profit** of RON **14.6 million** increased by 19% compared to the budgeted values.

				LEI
	No.	IEB approved 9 months 2015	30.09.2014	30.09.2015
Α	В	1	2	3
Revenue from sales	1	215.144.000	217.193.201	216.292.531
Other operating revenues	2	3.168.000	9.804.563	11.919.130
Income related to product stock costs	3	-1.404.000	5.934.261	12.656.986
Income from the activity of the entity and capitalized	4	1.340.000	1.912.544	1.907.578
Expenditure on raw materials and consumables	5	69.809.000	70.833.065	82.867.694
Staff expenditure	6	53.727.000	53.862.145	52.917.398
Expenses with amortization and depreciation	7	12.854.000	13.004.124	11.186.851
Other operating expenditure	8	60.158.000	64.767.577	76.091.471
Profit from exploitation	9	21.700.000	32.377.657	19.712.810
Net financial income	10	-7.080.000	-8.794.204	-2.999.851
Profit before tax	11	14.620.000	23.583.453	16.712.959
Profit tax expense	12	2.339.000	3.305.949	2.148.666
Profit	13	12.281.000	20.277.504	14.564.293

## a) The overall result

In the structure, the main expenditures have evolved as follows:

- the increase in raw materials and consumables is determined by the manufacturing structure, the increase in production value and the influence of the USD growth;
- the staff expenditure decreased by 2% compared to the first 9 months of 2014;
- other operating expenses registered a value of RON 76.1 million, up by 17% compared to the same period last year. The increase is due mostly to the increase of the claw-back tax by 33% compared to the same period of the previous year, but also to the provision for the uncertain receivable of the drug distributor A&G Med Trading SRL Bucharest.

The fact that Antibiotice achieved the budgeted figures for the period from January to September and also achieved the pharmacies' destocking provides a favorable situation for the realization of the indicators from the Revenue and Expenditure Budget by the end of the year, i.e. the sales revenues of RON 326 million and the gross profit of RON 26.1 million.

# b) The situation of the financial position

The value of the assets for the first 9 months of the year (RON 529.5 million) registered an increase compared to January 1 2015 by 5%.

The stocks increased by 19% in order to start production after the revision period;

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- The receivables registered a 13% increase compared to the beginning of the year, with a decrease in value of 2% compared to the first nine months of 2014;
- The equity experiences a constant value comparative to the beginning of the year;
- The increase of trade debts by 29% compared to the beginning of the year, lower by 4% compared to the same period last year;
- The increase of the current debts by 23% as compared to January 1 2015, but decreased by 3% compared to 2014.

ASSETS	30.09.2014	01.01.2015	LEI 30.09.2015
Fixed assets	196.309.552	196.493.836	196.975.907
Tangible assets Real estate investments	189.058.183	188.576.994	187.643.908
Intangible assets Investments in equity instruments	7.251.369	7.916.842	9.331.999
Current assets	333.656.596	307.152.860	332.575.565
Stocks	62.682.415	57.284.464	68.302.769
Commercial receivables	266.359.839	232.062.022	262.353.596
Financial assets for sale	140	140	220
Cash and cash equivalents	4.614.202	17.806.234	1.918.980
TOTAL ASSETS	529.966.148	503.646.697	529.551.472
EQUITY AND LIABILITIES			
Equity	353.469.766	364.331.001	363.148.585
Subscribed share capital	263.790.495	264.835.156	264.835.156
Revaluation reserves	5.501.611	4.158.471	3.298.428
Legal reserves	13.189.007		13.426.761
Other reserves	118.149.425	118.149.425	133.303.701
Reported result	(47.160.772)	(67,139,797)	(66.279.754)
Current result		31,138,739	14.564.293
Long-term debt	24.416.475	20.158.444	19.620.686
Investment grants	3.615.188	3.521.762	3.266.659
Deferred tax	16.740.110	16.636.682	16.354.027
Long-term provisions	4.061.177	-	
Current debts	152.079.907	119.157.252	146.782.201
Commercial and other debts	63.195.108	46.916.170	60.676.596
Short-term loans	83.865.239		76.625.090
Tax and current tax liabilities	5,019.560	12.436.407	7.059.370
Short-term provisions	0	5.021.334	2.421.145
Total debt	176.496.382	139.315.696	166.402.887
Total equity and debt	529.966.148	503.646.697	529.551.472

From the analysis of the equilibrium indicators we can see that the current liquidity is increasing compared to 30.09.2014, the debt ratio (total debt/total assets) has decreased compared to the first nine months of 2014, falling within the historical trend of this indicator.

Name of indicator	Calculation method	30.09.2014	30.09.2015
1. Current liquidity indicator	Current assets/Current liabilities	=333.656.596/152.079.907=2.19	=332.575.565/146.782.201 =2.27
2. Indicator of indebtedness	(Total Debt/Total Assets)	=(176.496.382/529.966.148)*100 =33.3%	=(166.402.887/529.551.472)*100= =31.4%
3. Rotation speed of customer flows	(Average Customer Balance/Sales income)*270	(263.042.576/217.193.201)*270= 327 days	(256.452.655/216.292.531)*270= 320 days
4. Rotation speed of fixed assets	Sales income/Fixed Assets	=217.193.201/196.309.552=1.10	=216.292.531/196.975.907=1.1

#### b) Cash-flow

The level of cash and cash equivalents at the beginning of the period was RON 17.8 million. The cash receipts from operating activities for January - September 2015 amounted to RON 174.05 million. The cash payments to the suppliers of goods and services amounted to RON 109.66 million, and those to and on behalf of employees in relation to staff of RON 51.5 million.

At the same time, the cash payments of RON 31.9 million were made, representing the value added tax, profit tax, local taxes, bank interest and claw-back tax.

There were no receipts from the investment activity, but payments for tangible and intangible assets of RON 10.3 million were made.

From the financing activity there were receipts from short-term loans of RON 21.8 million, the payment of dividends amounting to RON 8.5 million was made.

At the end of the period the level of cash and cash equivalents amounted to RON 1.9 million.

#### Administration of the company

During the first 9 months of 2015, the Management Board convened a General Assembly of Ordinary Shareholders and an Extraordinary General Meeting on *April 30, 2015*, namely an Ordinary General Assembly and an Extraordinary General Assembly on *August 13, 2015*.

All the necessary documents related to the smooth running of the General Assemblies were published in due time and according to the legislation in force.

In the Ordinary Shareholders General Assembly dated April 30, 2015, the modification of the Management Board's structure was approved by the revocation of Mr. RADU Valentin as a result of retirement and the election of Mr. IAVOR Ionut Sebastian.

Also the financial results of the company for the year 2014 were approved, the results that were drafted in accordance with the Order of the Minister of Public Finance No. 881/25.06.2012, the Order of the Minister of Public Finance no.1286/2012 for the approval of the accounting regulations complying with the international standards of financial reporting applicable to companies whose securities are admitted to trading on a regulated market, the Order of the Minister of Public Finance no. 1690/2012 regarding the modification and completion of accounting regulations, the Order of the Minister of Public Finance no.65 / 2015 on the main aspects regarding the drawing up and submission of the annual financial statements and of the annual accounting reports of the economic operators to the territorial units of the Ministry of Public Finance.

During the same meeting, the following decisions were taken:

- The approval of the distribution of the net profit for the year 2014 in the amount of RON 31.138.739, the fixing of the gross dividend per share of RON 0.02345571 and the payment of the dividends starting with 01.10.2015;
- The approval of the discharge of the administrators for the activity carried out during the financial year 2014, upon the basis of the submitted reports;
- The approval of the Income and Expense Budget for 2015;
- The approval of the achievement of the objectives and performance criteria for the year 2014 for the members of the Management Board;
- The approval of the extension of the financial audit contract with "B.D.O. Audit" SRL, for a period of two years.
- The approval of the objectives included in the management plan for the members of the Management Board for 2015;
- The approval of the remuneration of the of the Management Board members according to the provisions of the Government Emergency Ordinance no. 51/2013, regarding the modification and completion of the Government Emergency Ordinance no. 109/2011 on the Corporate Governance of Public Enterprises;
- The approval of rental to S.C. Apa Vital S.A. Iasi of a land with an area of 345 sqm, within the lot no. cadastral no. 133178, on which a nitrogen plant was placed, for the operation by S.C. Apa Vital S.A. Iasi of a drinking water supply area, funded by European funds.

During the Extraordinary General Meeting of Shareholders, the following was approved:

- the extension of the validity of the multi-product cap amount (multi-currency, in RON and USD) for a period of 12 months in the amount of RON 60 million contracted by SC Antibiotice SA from Eximbank Export Bank of Romania EximBank SA.
- the extension of the validity of the state guarantee amounting to RON 10 million, related to the multiproduct cap amount (multi-currency, in RON and USD) in the amount of RON 60 million contracted by Antibiotice SA from the Export Import Bank of Romania EximBank SA.
- maintaining the guarantees related to the multiproduct cap amount (multi-currency, in RON and USD) in the amount of RON 60 million, for the entire validity period resulting from the extension according to item no.1 and no. 2 of the Agenda of the Meeting.
- the issuance of a decision commitment of SC Antibiotice SA not to divide, not to merge and not to decide the early dissolution over the entire period of validity of the

multi-product cap amount (multi-currency, in RON and USD and the guarantee in name and state account issued by EximBank, without the prior consent of the Export Import Bank of Romania - EximBank SA.

- Empowering the General Manager Mr. Ioan NANI and the Economic Director Mrs. Paula COMAN to sign on behalf of the company all the documents related to the extension and transformation of the credit facility, according to item 1 and 2 of the Agenda of the Meeting, as well as the documents related to the obligations assumed by the Company under Items 3 and 4 of the Agenda of the Meeting.
- the proper modification of Annex 1 Administrators of SC Antibiotice SA lasi (company statute) according to the draft supplementary document presented in the appendix to the convocation document.
- the modification and updating of the Articles of Incorporation for the purpose of introducing in Article 6, regarding the object of activity of the company, in the category of main activities, the code of the building in which the following is carried out:
  - 1. 2110 The manufacture of basic pharmaceutical products/building code: P10-B and the introduction of the following activities and related CAEN codes into the category of secondary activities together with the code of the buildings in which the following activities are carried out:
  - 1. 2120 The manufacture of pharmaceutical products/building codes: P1-US, P9-C, P11-PP, P13-CsP, P14-Csc, P15-CsN;
  - 2. 4646 Wholesale of pharmaceuticals/building codes P7-D,
  - 3. 5210 Depot/building codes: P5-D, P28-D, P29-D, P33-D;
  - 4. 5224 Manipulations;
  - 5. 7120 Testing and technical analysis/building code: P2-CC;
  - 6. 7219 Research and development in biotechnology/building code: P21-MKP;
  - 7. 7211 Research and development in biotechnology/building code: P21-MKP;
  - 8. 8292 Packing activities/building codes: P1-US, P9-C, P11-PP, P13-CsP, P14-CsC, P15-CsN;
  - 9. 8622 Specialized nursing activities/building code: P16-CEM-RA.

Within the Ordinary General Meeting on August 13, 2015, the financial statements of the company for the first semester of 2015 were approved upon the basis of the Managers Report and the Financial Auditor's Report, and during the General Extraordinary Meeting of Shareholders, the supplementary guarantees for the multi-currency multi-product cap amount in the amount of RON 60 million, contracted by the "Antibiotice" SA trade company from the Export-Import Bank of Romania - EximBank SA, with mortgage/assignment on the receipts/receivables from the contracts concluded with Farmexpert DCI (all present and future bills).

The knowledge of the domestic and international pharmaceuticals markets, the research and assimilation of new products in the company's own portfolio, the continuous modernizing of the manufacturing lines, the improvement of the staff represent the guarantee for the economic performance of Antibiotice SA, as well as the development on the well-grounded scientific fundamentals of the future through:

- The development of new international projects through the focus on the markets with high potential for generic drug uptake;

- The achievement of professional performance, which is the premise for increasing the competitiveness and the quality of the business;

- The achievement of the economic indicators at the level of 2015 is a continuous concern.

The financial statements were not audited for the period January-September 2015.

## Vice-Chairman of the Management Board Ec.Ioan NANI

Economic Manager Ec. Paula Coman