

## THE ADMINISTRATOR'S REPORT FOR THE FIRST SEMESTER OF 2018

Half-yearly report according to:	IFRS
For the financial year:	30.06.2018
Report date:	August 8, 2018
Company name:	Antibiotice SA
Head office:	Iasi, Strada Valea Lupului nr.1
Phone number:	+40232/209000; fax: +40232/209633
Fiscal registration code:	RO1973096
Trade Register Registration Number:	J22/285/1991
Regulated market which trades shares:	Bucharest Stock Exchange
Subscribed and paid up capital:	RON 67.133.804
Main characteristics of the securities issued by the company:	Nominative shares, nominal value: RON 0.10

### CORPORATE GOVERNANCE

The governance system complies with the provisions of Law 24/2017 on the issuers of financial instruments and market operations, Law no. 31/1990 republished, with all subsequent amendments, of the NSC (National Securities Commission) Regulation no. 6/2009, subsequently amended and supplemented, of Law no. 111/2016 for the approval of the Government Emergency Ordinance no. 109/2011 on Corporate Governance of Public Enterprises of the BSE Code, the Corporate Governance Code of the BSE and those of the Articles of Incorporation of the Company.

Structures on which the Antibiotice governance system is based:

- The Management Board
- The Advisory Boards
- The Executive Management
- The Code of Ethics
- The Code of Corporate Governance
- Internal Audit, Management Control

### The Management Board

Antibiotice is administered by a Management Board responsible for fulfilling all the strategies necessary to achieve the performance indicators, except as provided by law for the General Meeting of Shareholders. There is a clear division of responsibilities between the Management Board and the Executive Management.

The Management Board seeks that its own decisions, those of the Company's management, the General Meeting of Shareholders, as well as the internal regulations, be lawful and properly implemented. The Board is responsible for monitoring the company's management on behalf of its shareholders.

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The tasks of the Management Board are described in the Articles of Incorporation of the Company and in the relevant internal regulations, available on the company's corporate website, at the Corporate Governance section.

**The structure of the Management Board of the Antibiotice SA Company on June 30, 2018**

**Legal adviser, IAVOR Ionuț-Sebastian, 42 years old**

**Chairman of the Board and representative of the Ministry of Health**

At the Ordinary General Meeting of Shareholders of April 30, 2015 Mr. Iavor was elected a member to the Management Board of the company and then appointed by the Board members as Chairman.

Mr. Ionuț-Sebastian Iavor is currently General Manager of the General Directorate of Human Resources and Legal Department within the Ministry of Health.

**Number of Antibiotice SA shares owned - 0\***

**Ec. Ioan NANI, 58 years old**

**Vice Chairman of the Board and CEO**

At the Ordinary General Meeting of Shareholders of April 19, 2016, Mr. Nani was reconfirmed as a member of the Management Board, for a period of four years; Mr. Nani was appointed then by the members of the Board as Vice-President. Mr. Nani is an economist specialized in management, a chartered accountant and a member of the Board since 2009 as well as CEO (1998-2008 and 2009 - present day).

**Number of Antibiotice SA shares owned - 1.513\***

**Dr. Dan Octavian ALEXANDRESCU, 44 years old**

**Provisional member of the Management Board and representative of the Ministry of Health.**

At the Ordinary General Assembly of the Shareholders of April 26, 2018, he was elected as a member of the Management Board, in accordance with the provisions of art.641<sup>1</sup> of GEO no. 109/2011.

Mr. Alexandrescu Dan-Octavian is a physician, State Secretary in the Ministry of Health, coordinator of the Medicines and Medical Devices Policy Division.

**Number of Antibiotice SA shares owned - 0\***

**Ec. Nicolae STOIAN, 61 years old**

**Member of the Board and representative of the SIF Oltenia shareholding and other corporate shareholders**

At the Ordinary General Meeting of Shareholders of April 19, 2016, Mr. Stoian was elected as a member of the Management Board for a period of four years.

Mr. Stoian is a chartered accountant, a tax consultant and financial auditor.

**Number of Antibiotice SA shares owned - 0\***

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**Eng. Elena CALIȚOIU, 55 years old**

**Member of the Board and representative of SIF the Oltenia shareholding and other corporate shareholders**

Mrs. Calițoiu was confirmed as a member of the Board during the Ordinary General Meeting of Shareholders on April 19, 2016, for a period of four years.

Mrs. Calițoiu is a mechanical engineer and Director of Investments and Risk Management Unit and has been a member of the Board since 2016.

**Number of Antibiotice SA shares owned - 0\***

### **The advisory committees**

During the year 2018, the specialized advisory committees had the following membership:

- *the Audit Committee*: Mr. Ionuț Sebastian IAVOR and Mr. Nicolae STOIAN and Mrs. Elena CALIȚOIU;

- *the Nomination and Remuneration Committee*: Mrs. Elena CALIȚOIU and Mr. Ionuț Sebastian IAVOR

- *the Trade Policies Committee*: Mr. Dan Octavian ALEXANDRESCU and Mr. Nicolae STOIAN.

The advisory committees have conducted investigations, analyzes and have developed recommendations for the Management Board in specific areas and submitted periodic reports upon their activity.

### **The risk management**

Within Antibiotice SA, the risk management is a continuous process that involves the identification of significant risks that may affect the company or a component structure, their assessment, ranking and prioritization, as well as the establishment of measures to mitigate the exposure in accordance with the limits of risk tolerance, in order to provide a reasonable assurance that the objectives and activities are being met.

The main categories of risks that may arise in the company's activity are: financial risks, image risks and legislative risks.

The Company is exposed through its operations to the following financial risks:

- The foreign Exchange Risk;
- The liquidity risk;
- The commercial risk/default risk.

*The foreign exchange risk*, a component of the financial risks, occurs frequently in the current market economy where monetary rates fluctuate under the supply and demand rule. Another factor also causing the occurrence of the currency risk is the national and international political context.

The exchange rate fluctuations are reflected both in the costs of imported raw materials, as well as in the prices of the finished goods for export.

The company's strategy of the risk management involves: synchronizing the import activity with the export activity by correlating the payment and collection deadlines and correlating the weight of the currencies so that the moments in which the payments are to

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be made are as close or even simultaneous as possible to the proceeds from export; anticipating or delaying the payment or cashing by the due matching of the date and introducing insurance margins into price, correlated with forecasts for the currency of the payment; covering the gap between earnings and credit payments in the transaction currency.

*The liquidity risk* results from the company's failure to honor the short-term payment obligations at any time.

The circumstances of the occurrence of liquidity risk: the collection of receivables at terms exceeding 300 days; the increased tax/lack of predictability (claw-back tax); the insolvency of some clients; the increasing of the price of utilities, raw materials and services.

For the risk management, the following measures have been proposed: an accurate estimate of payments and receipts; the business internationalization; the assessing of customer creditworthiness; the monitoring of receivables; reducing the debt collection period on the domestic market; the increasing of the payment period for suppliers; covering the gap between short-term credits and payments.

*The commercial (non-payment) risk* - is defined as the risk of loss or the nonachievement of estimated earnings due to lack of financial liquidity of the debtor and the non-fulfillment of the payment obligation at the end of its maturity.

The circumstances of non-payment risk: large exposures to major distributors, long payment periods, plus re-allocations, the insolvency of pharmacies and distributors and the withdrawal of distribution authorization.

In order to manage the commercial (non-payment) risk, the following measures were taken: the assessment of the creditworthiness of commercial partners by checking, before the conclusion of the contract, by multiple methods; the monitoring of receivables through control and permanent risk assessment; developing a customer loyalty relationship through regular meetings for their knowledge and addressing a constructive attitude; solicitation of guarantees (insurance policies, collateral security agreements, cheque filings, guaranteed promissory notes, bank guarantee letters); stopping deliveries until the liquidation of outstanding amounts; diversifying the client portfolios to reduce the exposure to large clients; the provisioning of expenses to cover the risk of non-payment.

The legislative changes aimed at the pharmaceutical market lead to the emergence of a *legislative risk*, which must be continuously managed.

The pharmaceutical market is a regulated market, with clear legislative provisions, designed to control the quality and therapeutical efficiency of medicines present on the market, as well as to avoid counterfeiting.

The adaptation to these provisions is reflected both in additional costs related to updating the documentation of compliance with the latest quality standards, in terms of the impact on the maximum sales prices and on the delays in the marketing of the products.

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The company's strategy for managing these risks involves a permanent concern for obtaining international certifications of the manufacturing lines, updating the authorization documentation for portfolio products, undertaking bioequivalence and stability studies and continuously pursuing international legislative changes.

The image risk is defined as the current or future risk of negative profits and capital damage caused by the unfavorable perception of the company's image and reputation. In order to prevent and manage efficiently the events that can generate image risks, the following measures are envisaged: monitoring the way in which the media reflect the company's activity, the constant communication to the media of the performances of the company as well as the projects related to the involvement in the life of the community, the continuous development of relations with the press and target audiences, the control of the risks that can affect the image of the company.

### **The executive management**

Antibiotice is represented by the General Manager, according to the prerogatives established by the law and the Articles of Incorporation of the company. The Management Board maintains the company's attribution in relation to the directors whom it has appointed.

The executive management of Antibiotice is ensured by nine directors, one of whom is the General Manager and he is Vice-Chairman of the Management Board, and eight specialty directors.

### **Structure of the Executive Leadership of Antibiotice SA on June 30, 2018**

#### **Ec. Ioan NANI, 58 years old**

##### **General Manager and Vice-Chairman of the Management Board**

Mr. NANI, a graduate of the Faculty of Economic Sciences of the „Alexandru Ioan Cuza” University of Iasi, is an economist specialized in management and is also an accounting expert.

Mr. NANI began his activity as an economist at Antibiotice in 1987. Between 1991 and 1993 he was a financial control inspector at the General Public Finance Department of Iasi and then at the Romanian Court of Accounts. In 1994 he has returned to Antibiotice as Chief Financial Officer, and in 1998 he became General Manager. In February 2009 he was appointed Vice-President of the Authority for State Assets Recovery (AVAS), and in June of that year, General Manager of Antibiotice.

Mr. Nani has been holding the position of General Manager since 2009.

**Number of Antibiotice SA shares owned - 1.513\***

#### **Eng. Cornelia MORARU, 52 years old**

##### **Technical and Production Director**

Mrs. Moraru graduated from the Faculty of Chemical Technology, the Technical University “Gheorghe Asachi” of Iași. After graduation Mrs. Moraru worked as a chemical engineer at the Fălticeni Chemical Factory. Mrs. Moraru has been working at Antibiotice since 1990. Until 1998 Mrs. Moraru has worked at the Penicillin II Plant and then at the Biosynthesis

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compartment for a year. From July 1999 until January 2001 Mrs. Moraru has worked as a biosynthesis technologist at the Penicillin II Plant. In January 2001 she became Head of the Tablets Plant and in May 2003 Mrs. Moraru was appointed Director of the Pharmaceutical Division.

Mrs. Moraru has been the Technical and Production Director since 2005.

**Number of Antibiotice SA shares owned - 1.513\***

### **Ec. Paula Luminița COMAN, 50 years old**

#### **Economic Director**

Mrs. Coman has graduated from the Faculty of Economics and Business Administration of the "Alexandru Ioan Cuza" University of Iași and has been a Chartered Accountant since 2006 and a tax consultant since 2007.

After graduation Mrs. Coman has worked as an economist at the County Iași Tourism Office.

Mrs. Coman has been working at Antibiotice SA since 1991 as an economist in the Rates Efficiency Office. In 1998 Mrs. Coman has become Head of the Economic Analysis Compartment and in 2003 Head of the Financial-Accounting Department.

Mrs. Coman has been the Economic Manager since 2011.

**Number of Antibiotice SA shares owned - 0\***

### **Ec. Vasile CHEBAC, 63 years old**

#### **Commercial and Logistics Director**

Mr. Chebac has graduated from the Faculty of Economics of the "Alexandru Ioan Cuza" University of Iași and has been an active member of the Body of Chartered Accountants, Iași Branch since 1993 and a financial auditor and a member of the Chamber of Auditors of Romania since 2008.

Mr. Chebac has started working at Antibiotice SA in 1972. In 1987 Mr. Chebac became an economist at the Planning and Development Department within the Investment Compartment. In February 1991 Mr. Chebac has worked as a financial controller at the Directorate General of Public Finance and in July 1993 Mr. Chebac has worked as a financial controller at the Chamber of Accounts Iași. In January 1998 Mr. Chebac was appointed Chief Commissioner at the Fraud Squad of Iași. In September 2001 Mr. Chebac returned to Antibiotice SA to the position of Chief Commercial Officer and General Services.

Mr. Chebac has been the Commercial and Logistics Director since 2005.

**Number of Antibiotice SA shares owned - 0\***

### **Eng. Cristina Lavinia DIMITRIU, 60 years old**

#### **Strategic Development Director**

Mrs. Dimitriu, a graduate of the "Gheorghe Asachi" Technical University of Iași, the Faculty of Chemical Technology was granted in 2000 a Master's Degree in Management and Business Administration by the same university. Mrs. Dimitriu has been the holder of a Master's Degree Diploma in Management and Marketing granted by the Faculty of Pharmacy, the "Grigore T. Popa" University of Medicine and Pharmacy since 2007. During the same year, Mrs. Dimitriu became a PhD student of the Faculty of Pharmacy of Iași.

After graduation, Mrs. Dimitriu worked as a chemical engineer at the Făgăraș Chemical Plant. Mrs. Dimitriu has been working at Antibiotice SA since 1987, when she has worked at

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the Lysine -Biosynthesis Plant. In 1990 Mrs. Dimitriu has become a Production Manager at the Parenteral Plant and in 2000 she has held the position of Quality Control Manager for Physico-chemical and Microbiological Analysis. Since 2007 Mrs. Dimitriu has become a qualified person for the manufacture/import of medicinal products for human use and a Management Representative for the Integrated Management System.

Mrs. Dimitriu has been the Quality Manager from 2003 until 2018.

**Number of Antibiotice SA shares owned - 0\***

**Ec. Gica RUSU, 54 years old**

**Human Resources Director**

Mrs. Rusu, a graduate of the "Alexandru Ioan Cuza" University of Iași, the Faculty of Economics, was granted in 2003 a master's degree in management and business administration by the same university.

Mrs. Rusu has been working at Antibiotice since 1981. In 1986 Mrs. Rusu was an economist at the Penicillin Plant and in 1996 she was working in the Financial Department. In 1999 Mrs. Rusu has become the Head of the Human Resources Department.

Mrs. Rusu has been the Human Resources Director since 2004.

**Number of Antibiotice SA shares owned - 1.510\***

**Ec. Ovidiu BĂȚAGA, 40 years old**

**Domestic Sales and Marketing Director**

Mr. Bățaga, a graduate of the Faculty of Economics and Business Administration (FEAA) of the "Alexandru Ioan Cuza" University of Iași holds three titles of Masters in Financial Management (awarded by the same university in 2001), Pharmaceutical Marketing (from the "Grigore T. Popa" University of Medicine and Pharmacy in 2003) and Project Management (awarded by the "Gheorghe Asachi" Technical University in 2007).

After graduation, Mr. Bățaga worked as a junior in the Currency and Credit Chair, Finance specialty, within the FEAA. Mr. Bățaga has been working at Antibiotice SA since February 2001 as an economist in the Economic Analysis, Accounting and Marketing Department. In January 2006 Mr. Bățaga was appointed Head of Market Analysis and Strategic Planning Department.

Mr. Bățaga has been the Domestic Sales and Marketing Director since 2010.

**Number of Antibiotice SA shares owned - 0\***

**Dr. Mihaela MOSNEGUTU, 48 years old**

**Medical Director**

A graduate of the Faculty of Medicine, the "Grigore T. Popa" University of Medicine and Pharmacy, Dr. Moșneguțu is a specialist in family medicine.

Dr. Moșneguțu began work as a doctor working in County Iași. Dr. Moșneguțu has been working at Antibiotice since 2000. In 2000 she was working at the Promotion Office and in 2001 Dr. Moșneguțu became the Head thereof. In 2005 Dr. Moșneguțu became the Head of the Pharmacovigilance and Medical Consultancy Department and in 2009 she was appointed Medical and Retail Promotion Manager.

Dr. Moșneguțu has been Medical Director since 2011.

**Number of Antibiotice SA shares owned - 0\***

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### **Ec. Mihai STOIAN, 43 years old International Business Director**

A Graduate of the Faculty of Economic Sciences at the "Alexandru Ioan Cuza" University of Iasi, with a specialization in International Economic Relations.

Mr. Stoian has been working at Antibiotice SA since May 2005 as Export Area Sales Manager for active substances.

In July 2008 Mr. Stoian was appointed Head of Intracommunity Deliveries and Export, within the Marketing and International Relations.

Since August 2009 Mr. Stoian was appointed Export Manager and June 2011 he was appointed Business Development Manager.

Mr. Stoian has been an International Business Director since 2012.

### **Number of Antibiotice SA shares owned - 0\***

*\* Number of Antibiotice Company shares (ATB) owned on September 11 2017 according to the latest database held by Antibiotice on the year 2017.*

### **The General Meeting of Shareholders**

The executive management of the company coordinates the strategic development of the company, in close cooperation with the Management Board. Periodically, the two bodies analyze the results obtained in implementing the strategy according to the business plan, the performance criteria and the revenue and expenditure budget. In this regard, the Management of the Company informed the Management Board in five meetings during the first half of 2018 on all significant aspects of the activity carried out and its evolution in relation to the previous forecast, presenting reports according to the agenda of the meetings. These reports were analyzed by the members of the Management Board and upon their basis, as well as on other information, decisions were made with effects on the company's activities.

The Management Board retains the Company's representation attribution in relation to the directors whom it has appointed.

The President coordinates the activity of the Management Board and reports on this to the General Meeting of Shareholders. He oversees the proper functioning of the internal structures of the company.

The President represents the Management Board in relations with third parties. Other powers may be delegated to him by the Management Board.

The Vice-President replaces de jure the Chairman of the Management Board when he/she is missing (according to Article 29, Chapter V, Articles of Incorporation of the Antibiotice Trade Company - S.A., Iasi).

The executive management of Antibiotice Iasi is ensured by executive directors, one of whom is the General Manager and the Vice-President of the Management Board.

The General Meeting of Shareholders is the company's highest decision-making body, where shareholders participate directly and make decisions. Among other attributions, it



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decides on the distribution of profits, chooses the Management Board, appoints the auditors and establishes the remuneration of the Management Board.

During the first half of 2018, the Management Board convened a General Assembly of Ordinary Shareholders and an Extraordinary General Meeting on **March 5, 2018**.

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.

The **Ordinary Shareholders' General Assembly** approved:

- The income and expenditure budget for 2018 and
- The increase of fixed indemnity and monthly gross variables of the members of the Management Board and of the General Manager and the conclusion of the additional acts according to this approval, in view of the application of GEO no. 79/2017 for amending and completing the Law no. 227/2015 regarding the Fiscal Code and GEO no. 90/2017 regarding some fiscal-budgetary measures, amending and completing some normative acts and extending some deadlines.

During the **General Extraordinary Meeting of Shareholders**, the establishment of two representatives of the company, one in the Republic of Moldova and the second in Ukraine was approved, the date for identifying the shareholders on whom the effects of the adopted decisions are reflected, according to the provisions of art. 238, par. 1 of the Law no. 297/2004 regarding the capital market, modified and completed by the provisions of L10/2015, was 20.03.2018, establishing ex-date for 19.03.2018.

**On April 26, 2018**, the Management Board of the company convened an Ordinary Meeting of Shareholders and an Extraordinary General Meeting of Shareholders, as well as two General Meetings of Shareholders.

The **Ordinary General Meeting of the Shareholders** approved:

- The financial statements of the company for the financial year 2017, based upon the Administrators' Report and the Financial Auditor's Report.

IFRS

• Sales income	RON	336.904.666
• Gross profit	RON	35.361.430
• Net profit	RON	33.558.354

- the distribution of the net profit for 2017, the fixing of the gross dividend amounting to RON 0.026552598 per share and the establishment of the payment date as of 14.09.2018.

- Net profit to be distributed: RON  
33.558.354

- legal reserve	0
- other earnings reserves provided by law	15.732.585
- dividends of which:	17.825.769
- dividends to the majority shareholder	9.450.737
- dividends due to other legal entities and individuals	8.375.032

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- the income registration of unclaimed and not collected dividends for the 2013 financial year.
- the achievement of the objectives and performance criteria for the year 2017 for the members of the Management Board.
- the discharge from the administration for the activity carried out in the financial year 2017, based on the reports submitted.
- the objectives of the management plan for the members of the Management Board for 2018.
- the remuneration of the members of the Management Board according to the provisions of Law no. 111/2016 for the approval of the Government Emergency Ordinance no. 109/2011 on Corporate Governance of Public Enterprises.
- the election of Mr. Dan-Octavian ALEXANDRESCU as interim administrator of the Management Board, according to the provisions of art. 64<sup>1</sup> of GEO no. 109/2011, following the termination of the mandate contract of Ms. Adela-Petria NEAGOE;
- the registration date **31.08.2018**, in order to identify the shareholders on whom the effects of the adopted decisions are reflected, according to the provisions of art. 86, par. 1 of Law 24/2017 on issuers of financial instruments and market operations, and setting ex-date for **30.08.2018**.

### **The Extraordinary Shareholders' General Assembly approved:**

- the extension of the validity of the multi-volume multi-product limit of RON 30 million contracted by SC Antibiotice SA from the Export Import Bank of Romania - EximBank SA for a period of 12 months.
- the maintaining of the guarantees for multiproduct multipurpose limit of RON 30 million for the entire validity period resulting from the extension under point 1 of the Agenda of the Meeting.
- the issuance of a decision-making commitment of SC Antibiotice SA not to divide, not to merge and not to decide on the early dissolution during the validity period of the multiproduct multipurpose limit without the prior agreement of the Export Import Bank of Romania - EximBank SA.
- the empowerment of the General Manager Ioan NANI and the Economic Director Paula COMAN to sign on behalf of the company all the documents related to the extension, according to the 1st and 2nd point of the Agenda of the Meeting, as well as the documents related to the obligations assumed by the company according to point 3 of the Agenda of the Meeting.
- contracting a long-term investment facility (10 years) in the amount of EUR 15.406.300 from UniCredit Bank.
- guaranteeing the investment credit facility amounting to EUR 15.406.300 to be contracted from UniCredit Bank with:
  - the mortgage, the mortgage of the financier, the prohibition of alienation, encumbrance, renting, dismantling, joining, demolition, restructuring, improvement and construction, as well as the mortgage on the present and future rents and rents on the land consisting of land in surface of 5.075 sqm and building C1 with a 421 sq m built-up area, with a spread area of 1.263 sqm, built from the ground floor with a surface of 351.44 sqm, 1st floor with a surface of 354.16 sqm and 2nd floor with a

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surface of 347.745 sqm. Cadastral identification for land, cadastral no. 133207 and for construction, cadastral no. 133207;

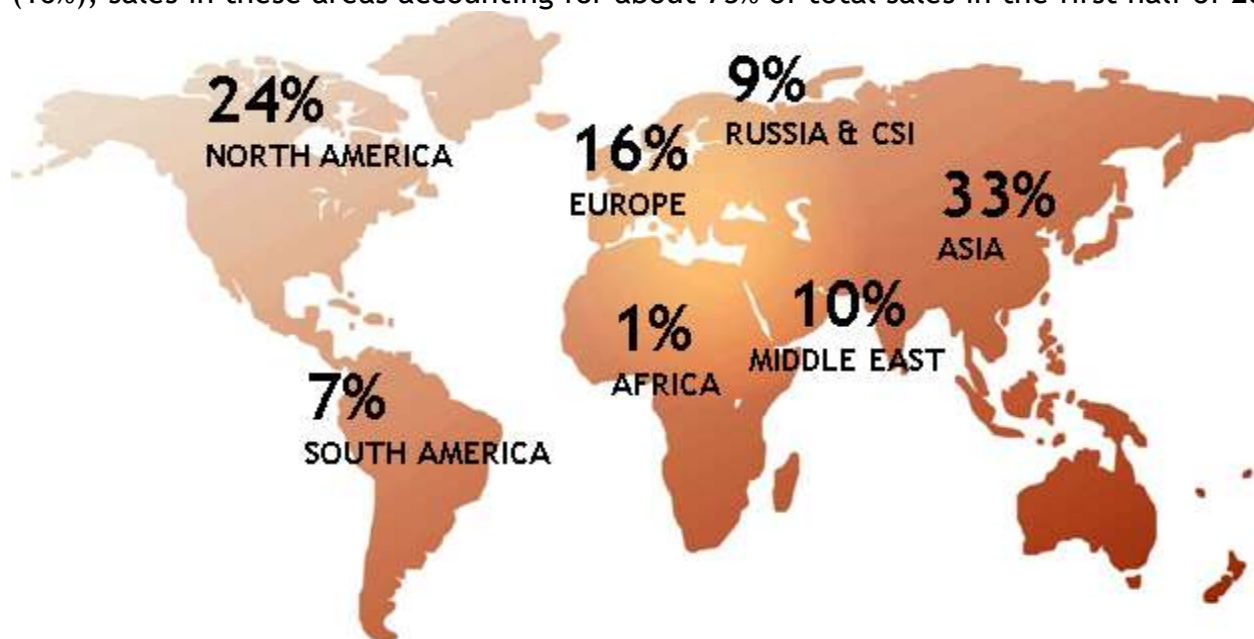
### **Activity analysis**

In order to meet the expectations of its shareholders - to increase confidence in Antibiotice and stock market capitalization - the priority actions of the management were grouped on the following strategic directions:

- I. Developing the international business component;
- II. Ensure a sustainable and sellable portfolio by increasing the degree of innovation;
- III. Optimizing operating costs and increasing operating efficiency
- IV. Adapting the human resource and providing the necessary skills to achieve strategic direction;
- V. Quality management for compliance with the legal, national and international requirements specific to the pharmaceutical industry.

### **I Developing the international business component**

Exports of US \$ 17.65 million in the first half of 2018 were 9.8% higher than in the first half of 2017, when sales were \$ 16.08 million. The main destinations for Antibiotic products (Finished Products and Nystatin) were Asia (33%), North America (24%) and Europe (16%), sales in these areas accounting for about 73% of total sales in the first half of 2018.



These results were possible by applying the strategies from the international markets as it follows:

- strengthening the world leader position for Nystatin active substance by maintaining traditional markets and increasing exports on regulated markets, especially in the US;
- exporting finished products under Antibiotice brand to foreign markets through partnerships with local distributors, partnerships that allow stable long-term development of exports;

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- the opening of representative offices in certain territories on the basis of the potential assessment in terms of: market characteristics, compatibility of the company's portfolio with consumption in the evaluated markets, economic and political-social environment, etc.

On the U.S. market **Nystatin exports have grown with 52%** in terms of value compared with the similar period of 2017. US Market represents the largest and most valuable market for Nystatin and the increase of its presence on this market was a strategic objective of Antibiotice company. During this year, strategic parities with the most important Nystatin end-users have been strengthened on this market in order to create the premises for business stability developed for this product in the U.S.

In South East Asia, the main market that will generate increases in the coming years is Vietnam. The sales of finished products on this market increased by 31% compared to the first half of 2017. The opening of the Vietnam representation aims at the strategic development of this market by registering new products, developing appropriate commercial policies and addressing all sales channels. Other markets in South East Asia, such as the Philippines, Thailand and Hong Kong, are also targeted.

On the South American market has recorded a doubling of Nystatin's export value, mainly due to the Brazilian market growth, the most important South American market for this product and one of the largest in the world.

On the European market there was an increase of 6.6%, mainly due to the export of finished products, which was by 14% bigger than in the previous year. In European area, the development strategy targets both countries in Central and Eastern Europe (Serbia, Albania, the Baltic States) and Western Europe, particularly through licensing partnerships with local firms, especially for injectable and dermatological products.

Exports from Russia & C.I.S. registered an increase of 9.4% especially due to the Ukrainian market. In the first semester of 2018, the procedures for registering the Antibiotice's own Antibiotice were initiated considering the potential of the market and the growth prospects. The opening of the representative office is aimed at registering the product portfolio, promoting the Antibiotice brand and developing its own sales team for the development of long-term exports.

### **II. Ensure a sustainable and sellable portfolio by increasing the degree of innovation**

The Romanian pharmaceutical market recorded an increase of 16.8% in the first half of 2018 compared to the same period of the previous year, reaching 7.6 billion lei compared to 6.51 billion lei made in the first half of 2017. The positive evolution is also recorded at the level of physical consumption of drugs, increasing it by 377 million physical units, from 6.16 billion units in I semester of 2017 to 6.54 billion in I semester of 2018.

The market is continuously sustained by the value of national programs for hepatitis and the products recently introduced in the cost-volume contracts/ cost-volume results. If we relate to the pharmaceutical market excepting the value of these contracts, during the first semester of 2018 a value growth of 8,9% was registered from RON 6.38 million (first semester of 2017) to RON 6.94 million (in the first semester of 2018). As much as the drug

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consumption is concerned, it grew by 6% reaching 6.54 million units compared to 6.16 million units registered during the same period of the previous year.

The Hospital market (the one without cost-volume contracts/ cost-volume result) registered a slightly growth of 2,72% compared to the interval January-June 2017, while the Retail market (without cost-volume contracts/cost-volume results) registered a value growth of 9,8% compared to the anterior period.

In the context of the pharmaceutical market from Romania, the activity on the internal market developed taking into account the following risks:

- progressive growth of clawback tax which has come to represent in the first quarter of 2018: 24,13%, from 19,86% in the similar period 2017 and 15,62% in the first quarter of 2016;

- increasing of the manufacturing costs as a result of the increase in the costs of raw materials;

- recast on pharmaceutical categories (chain pharmacies, minichains, and independent pharmacies), which attracted the allocation of more important budgets on segments of pharmaceutical chains and minichains by adjusting sales policy of minichain and independent pharmacies to the implemented policies of the chain pharmacies (molecule negotiations, portofolio negotiations, promoting the products by diseases, providing a zero coplanar level for patient);

- the lists of compensated medicines have seen updates on introducing new molecules such that the Romania patients to have acces to last generation therapies;

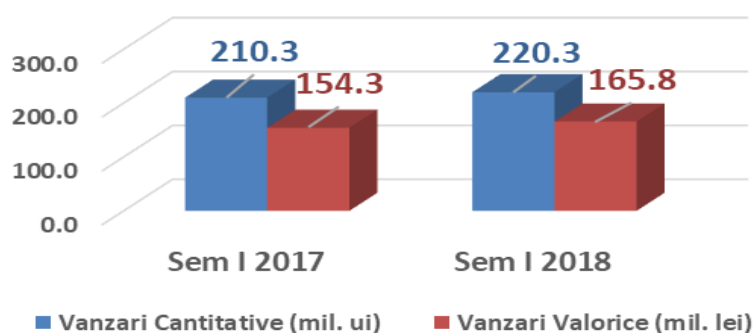
- centralised auctions for medicine acquisitions, antibiotics and oncological drugs wich will have as a result the rationalizing of resources consumption in 2018 from the health budget;

- the premises of lowering the prices of inovative medicines that come out of the patent protection affect the drug manufacturers by embittering the competitive enviroment, and the patients that will be confrunted with the dissapereance of the products from the market, in this way limitting the acces to medicinal products.

In this context, Antibiotice company register a sales growing from pharmacies and hospitals with 7,5% compared to the first semester of 2017, while sales in therapeutic units registered a growing by 4,8%.

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### The evolution of Antibiotic's sales in pharmacies and hospitales (sell out)



Data sources: Sales Cagedim January-June 2018

With a sales value of 165,8 million lei, the company keeps the 4<sup>th</sup> place in the line of generic medicines producers of over the counter medicines.

The retail pharmacy segment is growing by + 5.6% compared to the first semester of 2017, from 116.4 million lei to 122.9 million lei, while the Hospital segment registered an increase of + 13.1%, from 37,95 million lei in 2017 to 42,94 million lei in 2018.

The main therapeutic classes with significant increase in value compared to the first half of 2017 are: Cardiovascular system (+6.3 million lei), Antiinfectious (+3.6 million lei) and Central Nervous System (+1.9 million lei) generated both the contribution of new products and the positive evolution of the company's top products.

Products with a contribution of more than 1 million lei are: Fluxiv® (+ 2.8 million lei), Meropenem® injectable products (+2 million lei), Indapamida Atb® tablets (+1.7 million lei), Cefort® injectables 1gr (1.15 million lei) and Nolet® tablets (+1.14 million lei).

In the first half of 2018, Antibiotice company maintains its leading position in the generic and OTC drug market, marketed in hospitals, with a market share of 18.8%.

On the generic and OTC segment, the company occupies the 4<sup>th</sup> position, with a market share of 5,13%, while in the total pharmaceutical market occupies 16<sup>th</sup> place, climbing a position compared to the same period of the previous year, with a market share of 2.18%.

At the level of the first semester of 2018, Antibiotice maintains its leading position in terms of value ounces with a market share of 26.7%, suppositories with a market share of 41.8% and injectable powders with a market share of 72.4%.

During the analyzed period, Antibiotice Iași generated net sales on the internal market (ATB outputs) of 89.91 million lei, while in the sale from the distribution of See IN it amounted to 156.72 million lei, and in the pharmacies and hospitals at 165.8 million lei (estimate, source of data: Cegedim Romania).

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(million lei)

Indicator name	I Sem 2017	I Sem 2018	I Δ Sem 2018/2017
Net sales (domestic market)	79,70	89,91	+12,8%
Distribution Sell INN	149,98	156,72	+4,5%
Sell OUT (Pharmacy and hospital)	154,31	165,8	+7,4%

### **PRODUCT STRATEGY**

The entire activity of the company - from research, production to the sales - is structured on a portfolio of generic drugs, ranging from pharmaceutical forms and therapeutic classes.

The portfolio of 141 medicines (finished products marketed at the exit of Antibiotice in 2018) covering 12 therapeutic classes confirms that Antibiotice's strategy is the permanent orientation towards the renewal of the product portfolio and the manufacture of bioequivalent generic therapeutics with the original products while maintaining the high standards of quality.

The new products assimilated to the company's portfolio in the first half of 2018 are:

- Tinero® cream - Cosmetic product for acne skin care, imperfections with excess sebum, redness, itching, dilated pores, black dots; the product has begun to be rolled out since April 2018;

- Fluxiv® cream - a cosmetic product of which ingredients help maintain elasticity, hydration and skin tonicity, provide skin softening, protects microcirculation from its level providing comfort and relaxation for the feet; this product has begun to be harnessed since April 2018 and together with the oral form provides a complete therapeutic option for the health of vascular circulation;

- Perasin® - powder for solution for infusion - medicine used to treat bacterial infections such as those affecting the lower respiratory tract (lungs), urinary tract (kidney and bladder), abdomen, skin or blood. In the first half of 2018, the Marketing Authorization was obtained;

In the same period, first half of 2018, variations were made regarding the packaging form for the following products: Clafen® gel 1%, Clafen® gel 5% and Cutaden Bebe® - packaging form: 100 g tube and Saliform forte® - the form of newly introduced packaging: 50 g and 100 g, respectively.

### **PRICE STRATEGY**

Price strategies have consistently pursued the correlation between the maximum level required by law, increasing of profitability and ensuring competitiveness compared to other players from the market (positioning as the first generic, positioning as the reference medicine, best price / quality ratio).

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On the Hospitals segment, the average price of the products in the Antibiotice portfolio was RON 2.503/therapeutic unit, representing 37.8% of the average market price (RON 6.733/therapeutic unit);

On the retail segment - prescription medicinal products, Antibiotice recorded an average price of RON 0.548 / therapeutic unit, representing 48.9% of the average market price (RON 1.122/therapeutic unit), according to the Cegedim Romania reporting source. with the legislation in force regulating the prices for prescription products (maximum 65% of the price of the innovator).

On the OTC segment - products without prescription, Antibiotice recorded an average price of RON 0.888/therapeutic unit, being positioned at the same level as the market price of non-prescription medicines (RON 0.890/therapeutic unit), according to the Cegedim Romania source, being constantly adapted to positioning strategies in the pharmaceutical market.

In the first half of 2018, the non-prescription drug portfolio (11 OTC products) recorded a price increase, aiming both at a competitive market positioning and optimizing the profit margin.

Also, in the first semester 2018 the price order for the product Perasin® injectable products was obtained.

### **DISTRIBUTION STRATEGY**

The primary objective of 2018 is to strengthen partnerships with major national distributors through which significant sales growth has been planned.

The product portfolio was supported in the first semester by distribution (monthly offer, periodic campaigns, promotion and merchandising on OTC products) as well as through its own business team and Call Center team by specific actions.

Monthly, an offer calendar has been prepared to support profitable products with significant weightings in the planned figures as well as those that represent a significant share in the stock of distributors.

Actions carried out in the first semester 2018:

- Establishment of monthly / quarterly sales shares with each partner so as to generate sales growth in the market as compared to 2017;
- scrolling actions for stock diminishing - monthly stock analysis on each partner in terms of products representing 80% of the value stock, products with high storage times (over 2.5 months) and the validity terms;
- setting additional monthly bids on BBD products under one year following stock analysis of each partner or products where the product's life is longer than the storage life;
- keeping offers with constant business conditions for specified periods. Antibiotic portfolio products have been delivered to partner and pharmacies and hospitals in continuity, by providing optimal stocks to provide for any possible consumption.

### **THE MARKETING STRATEGY**

Marketing actions carried out in the first semester 2018:

- Direct promote to healthcare professionals (doctors, pharmacists)



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- participation in events organized by student societies to promote the brand among future specialists;
  - Participation in national events to increase the brand awareness of the company brand and product brands;
  - Organizing Interdisciplinary Antibiotic Events to increase Nutriensa brand awareness of food supplements;
  - media projects to make known the product brands;
  - actions to promote to the general public;
  - shelf products marketing campaigns in open-circuit pharmacies.
- Events with regional and national coverage attended by Antibiotice in 2018:
- Alphega Conference, Farmexpert: January-Constanta, February-Sibiu, March-Timisoara; April Craiova;
  - Beneficia course, Farmexim: "The role of the pharmacies manager" - for the pharmaceutical professionals: February-Brasov, Sibiu; March Timisoara; April Cluj;
  - Mediplus Conference - June: Galati, Braila, Vrancea, Buzau;
  - National Congress of Pharmacist Students, March-Iasi;
  - Dermatology Conference "Gheorghe Nastase Days" April 26-28, 2018, Iasi;
  - National Conference "Critical Patient Management in Infectious Pathology", 25-27 April 2018, Targu-Mures;
  - National Conference "Medical Days Vasile Dobrovici" 19-21 April 2018, Iasi;
  - The XVIth Congress of the Romanian Society of Neurology 08-12 May 2018, Bucharest;
  - National Conference on Psychiatry on "Mental Health, Person and Society" 16-19 May 2018, Timisoara;
  - The Infectious Diseases Conference, Timisoara 23-25 May;
  - National Conference with International Participation Problems of Infectious Pathology at the Border, 7-9 June 2018, Galati;
  - The 44th Congress of the Romanian Society of Anesthesia and Intensive Care under the aegis of the Romanian Society of Intensive Care Anesthesia, 9-13 May 2018, in Sinaia;
  - "Spring Dermatological Ieseana" - 7th edition, 23-27 May 2018 - launch of cosmetic product, Tinero® gel;
  - Suceava Medical Days, 24-26 May 2018;
  - National Conference of Otolaryngology and Cervico-Facial Surgery - 6-9 June 2018, Arad;
  - "National Conference of Infectious Diseases" - Infectious pathology problems at the borders "07-09 June 2018, Galati;
  - Interdisciplinary Symposium Antibiotice - We Know a Life, 14 June 2018, Galati, 26 June 2018, Ploiesti, 29 June - 1 July 2018, Paltinis
  - Jubilee Conference of the Association of Traumatologists and Orthopedists from Moldova, June 14-16, 2018;
  - National Conference of Hospital Pharmacists - 5th edition, Bucharest, 14-16 June 2018;
  - Conference on Infectious Pathology, June 21-23, 2018, Iasi
  - Days of Anesthesia Cluj, June 21 - 23, 2018, Cluj Napoca;
  - Ginecofocus - June 22-24, 2018, Campulung Moldovenesc;

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Media communication projects for the OTC category and food supplements:

- Spaverin® radio campaign.
- Facebook Sprinten® Campaign.
- Sprinten® radio campaign.
- Radio and Facebook Fezivit C® campaign.
- Promoting Equilibra®, Silithor®, Fluxiv®, Soriso®, Sprinten®, Cutaden Bebe®, Tintero® in the Food Supply Chain

Promotions to the general public:

- further branding project of RATP lasi stations (company of local public transport)
- Car Fleet Adhesive coating for Distributor Partners.

The shelf products marketing campaigns in open-circuit pharmacies:

Non-prescription products were present on the pharmacy shelves, displayed by categories of affections. The projects aimed to increase brand awareness. The products involved in this project were: Equilibra® (x60cps, x120cps), Ibufen®, Spaverin®, Paracetamol suppository, Silithor®, Fluxiv®, Cicatrol®, Sprinten®, Fezivit®, Tintero®. Through these projects, the products have been promoted in printed materials, promotion in the online environment (banners on specialized sites, discount products in the product presentation section).

### **Development of research and development structures for the sustainable adaptation and consolidation of the company portfolio**

The development activity has as main objective the development, optimization and maintenance of the portfolio of over 150 products (injectables, topical application forms, ova, suppositories, tablets, capsules). Strategic therapeutic areas (antiinfectives, cardiovascular, dermatology, women's health products) are strengthened by national and international authorization of new prescription drugs, OTCs, cosmetics, or dietary supplements.

The international expansion took place in the first half of 2018, with the acquisition of 22 new Antibiotic Marking Authorizations in three Asian and European countries.

For the consolidation of the non-prescription product portfolio, the notification to the Ministry of Health of two new cosmetic products was made.

In order to maintain the current portfolio, it was intended to align with the current pharmacopoeial changes for a number of 4 products.

The research product pipeline includes 33 projects at different stages of development, from the therapeutic classes that define the company: oral antiinfectives, injectable antiinfectives, dermatological products, cardiovascular, non-steroidal anti-inflammatory drugs, digestive tract and medication for women's health.

Within the Centre for Drug Evaluation, two bioequivalence clinical trials were conducted between January and June 2018. Also, the stage of documenting and drawing up clinical trial protocols for three other new products has been completed, and they will be submitted for approval to the authorities.

## ***The Administrator's Report for the first semester of 2018***

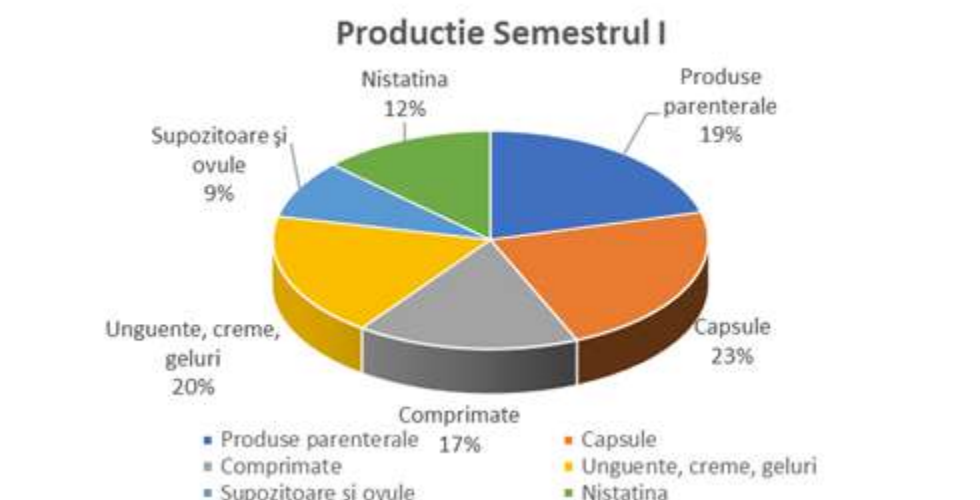
Permanent monitoring of efficacy and safety in the management of Antibiotic drugs is being conducted through the Pharmacovigilance Department, linked to the European Medicines Data Processing Network - EudraVigilance.

Production activity - Modernizing and streamlining manufacturing flows

Antibiotics produced in the first semester 2018:

- 343 million pharmaceutical units in the form of tablets, capsules, parenteral products, ointments, creams, gels, suppositories and ovules;
- bulk active substance (Nystatin) in a quantity comparable to that of the previous year;

The value of manufactured goods for export (Nystatin and finished products) represents 26% of the total value of production made in the first half of 2018.



**Objectives of Antibiotics in the first semester of 2018 in the field of pharmaceuticals manufacturing:**

- Manufacture of parenteral products for foreign companies based on manufacturing and control contracts. Production for export of parenteral products accounted for 35% of the total value of products destined for foreign markets;
- Reduce raw material costs by optimizing manufacturing formulations and identifying new sources for excipients used in conditioned products technology;
- Reduction of utilities consumption, through careful management, in all manufacturing areas;
- Efforts to implement the environmental protection program on volatile organic emissions during the Nystatin extraction phase and reduction of solvent consumption in the specific technological process have continued.

**Investment policy - Medium and long-term development by investing in new facilities**

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The planned value for investments for the year 2018 is 116,280,727 lei. From this value, up to 30.06.2017 were realized investments of 30,170,162 lei, representing 26% of the total programmed.

The total value of the contracts concluded for investments is 96,532,862 lei, representing 83%.

At this time, the realization percentage is relatively small, because in the first part of the year, for many of the investment objectives, the activities prior to the contracting are carried out in accordance with the internal procedures, consisting in: the realization of projects (when applicable) technical, obtaining opinions, authorizations; requesting and analyzing offers; negotiation of contracts, and in the second part of the year, the acquisitions and settlements to the suppliers will actually take place.

	Objectives of Investments (thousands of lei)	Approved 2018	Accomplished by 30.06.2018
	<b>Investment Expenditure as follows:</b>	<b>116.280.727</b>	<b>30.170.162</b>
<b>1</b>	<b>Ongoing investment as follows:</b>	<b>59.484.987</b>	<b>16.371.840</b>
	Set up of an Ointment and Suppositories production Capacity	44.814.272	9.086.585
	Equipment for the manufacturing plants, Quality Division, Medical Division	9.245.476	4.740.411
	Infrastructure Modernization of Utilities	3.769.240	2.137.784
	Set up a storage of pharmaceutical alcohol	1.656.000	407.060
<b>2</b>	<b>New investments as follows:</b>	<b>56.795.740</b>	<b>13.798.321</b>
	Serialisation Equipment (Parenteral products Plant, Capsules Plant, Tablets Plant, Ointments and Suppositories Plant, Finished Product Storage)	17.250.000	4.872.357
	Smart Energy Monitoring System of the company	1.081.000	357.241
	Feasibility and design study to increase the production capacity of nystatin	92.000	3.000
	Rehabilitation of façades of the Parenteral Products Plant	46.000	0.000
	Tablets Plant investments	11.676.640	2.616.504
	Biosynthesis investments	2.950.900	509.091
	Parenteral Products Plant investments	1.127.460	35.903
	Capsules Plant investments	2.680.880	886.264
	Ointment and Suppositories Plant investments	89.240	18.374
	Medical Division -Acquisition of new licenses for new products and research projects	4.140.000	1.336.018
	Laboratory equipment for Medical Division	2.848.550	611.550
	Laboratory equipment for Quality Division	3.663.440	372.326

## *The Administrator's Report for the first semester of 2018*

Economic Division- Achizitie de tehnica de calcul	92.000	82.578
Commercial Division- Equipment and installation acquisition, refurbishments, rehabilitations	3.402.390	1.280.211
Achieving a roundabout on access from gate 2 of the company in DN (national roads) (Iasi-Pascani) Realizarea unui sens giratoriu la accesul de la poarta nr.2 a societatii in DN (Iasi-Pascani)	92.000	0.000
Parking lot	920.00	0.000
Engineering and Investment Division - Equipment and installation acquisition, refurbishments, rehabilitations	4.229.240	498.192
Marketing Division	0.000	276.106
Main Division/General Division	0.000	34.562

The objectives of the investments included in the program are:

- achieving a new, high performance capacity, equipped with modern production facilities for the manufacture of ointments and suppositories, that can receive the GMP and FDA approval;
- modernization and refurbishment of existing production flows to increase production capacities, product quality and reduce production costs;
- modernization of installations that provide utilities for the entire platform;
- achieving objectives that are in line with the strategy for pollution reduction and environmental protection;
- to consolidate the integrated management system, create new production facilities to reduce costs, utilities consumption and increase work productivity, constant compliance with GMP Good Manufacturing Practice, as well as with Work and Protection environment rules and practices;
- increasing the storage capacity for raw materials corresponding to the increase of the production capacity.

### **I. ONGOING INVESTMENTS**

#### **1. Creating a Production Capacity for Ointments and Suppositories**

The aim of the project is creating a new production facility for the manufacturing of semi-solid pharmaceutical products divided into tubes and suppositories in order to increase the turnover and the capacity of Antibiotice S.A. to register, produce and market qualitative Romanian medicines on all regulated pharmaceutical markets (Europe, USA and Canada) by investing in a new plant that can receive GMP approval.

#### **Investment Objectives**

- construction and proper equipping of an Ointment and Suppository Plant that can receive the EU-GMP and FDA approval
- GMP Certification of the newly developed Ointments and Suppositories Plant by the national regulatory authority in the field (National Agency for Medicines and Medical Devices)

## *The Administrator's Report for the first semester of 2018*

- appropriate conditions for the manufacture of medicines in compliance with legislative and pharmacopoeial requirements and their registration and marketing on all regulated markets, especially in Europe, USA and Canada.

### **Justification of the investment**

The establishment of a modern plant for the manufacture of semisolid medicinal products divided into tubes (ointments, creams, gels) and suppositories is a guarantee of a long-term business development for Antibiotice S.A.

The company's development strategy focuses on maintaining and expanding the portfolio of semisolid products divided into tubes and suppositories.

The strategy focuses on the development of the portfolio for the domestic market, but also on the diversification and penetration of new important foreign markets in Europe, North America, Asia and Africa.

In order to ensure the main characteristics of the medicines (quality, efficiency, safety), their manufacture must be carried out in facilities equipped with performant equipment and critical utilities that meet the requirements of Good Manufacturing Practice (GMP).

For the second stage of this important investment project which is the development of the clean rooms and the related installations, the selection procedure of a specialized company for the contracting of turnkey works was carried out.

In February of 2018, a team of specialists of the company, together with the designer's representative for the company evaluation, carried out a reference visit to determine the capacity and capability to develop clean rooms and related facilities, specific to the pharmaceutical industry.

Following the reference visit, the following conclusions were drawn:

- the selected company has proven to have experience, logistics, trained and dedicated personnel for each component of such a complex project (design specialists, engineers of execution on specialties, engineers specialized in qualifications, etc.);
- the selected company has carried out manufacturing flows for the pharmaceutical industry of a complexity similar to our investment and at a very good quality level;
- the company owns production capacities for making the vast majority of the clean room components: partition elements (walls, doors, glazing, ceilings), ventilation plants, accessories for ventilation installations, etc. which can have an important contribution to quality, performance speed and flexibility of the Antibiotice S.A. project;
- an important asset is the fact that they have their own specialists for the necessary qualification and validation activities and a project manager will be appointed for this project only, a project which is considered large and complex.
- during the discussions regarding our project, they were willing to fully collaborate with the other suppliers (the technological equipment supplier, the supplier of the purified water system, the compressed air supplier, etc.) in order to avoid delays or damage to clean room furnishings or installations and to optimize installations and correlation of utility routes so that no intersections will occur.

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Currently the contract was signed and the design phase is in progress. Technical meetings were held during which technical details were set regarding: ventilation-air-conditioning installations, clean room partitioning system, installations, etc.

### **2. Equipment for production plants, Quality Division, Medical Division**

Laboratory equipment and apparatus were contracted in 2017 for the purpose of refurbishing production flows and quality control and research laboratories for which payments will be made in 2018. Both manufacturing equipment and laboratory equipment, are the latest generation, with high productivity, low energy consumption, and high operational safety. The manufacturing equipment is designed to replace equipment with significant physical wear, which generates high maintenance costs and low productivity. Acquisition of modern laboratory equipment is necessary due to continuous revision of pharmacopoeial monographs and increased precision of analytical methods in the pharm industry laboratories.

### **3. Investments aimed at modernizing the infrastructure of utilities**

Investments aimed at modernizing the infrastructure for the production, transport and distribution of utilities (technological steam, drinking water, district heating, demineralized water, power supply, sewage treatment) were started in 2017 and will be completed in 2018.

The main objectives of these investments are sizing and adapting utility routes to the current consumption of production flows, so as to save energy by reducing consumption and eliminating losses.

### **4. Set up a storage of pharmaceutical alcohol with flow sampling**

The need for such an investment has emerged as a result of the recommendations received from the Quality Assurance Structure in order to comply with the GMP standards. Also, as a result of the external audits that took place in recent years, it has become necessary to set up a storage for pharmaceutical alcohol. Since the pharmaceutical alcohol is raw material, the new storage must be organised in accordance with the GMP provisions. Alcohol being considered a solvent, the characteristics of the construction and the adjustments to be made in the new warehouse must also comply with the provisions of the Norms P118 / 1-2013 concerning the fire safety of the constructions.

## **II. NEW INVESTMENTS**

### **1. Serialisation equipment (Parenteral Products Plant, Capsules Plant, Tablets Plant, Ointments and Suppositories Plant, Finished Products Storage)**

Given that since 2019 all pharmaceutical products to be marketed both on the domestic and foreign markets (USA, EU) have to be serialized, it is also mandatory that the products that will be manufactured by Antibiotice S.A., to be serialized starting this year.

This measure becomes mandatory according to the requirements of the European Directive 2011/62 / EU and the Drug Quality and Security Act USA, concerning the policy to prevent counterfeit medicines from entering the market.

The serialisation systems will be purchased and included in the manufacturing flows within the production plants and finished products storage.

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**2. Smart Energy Monitoring System of Antibiotice S.A.** - project co-financed by European funds, through the Operational Program High Infrastructure, Axis 6.2, with the title: Monitoring of Energy Consumption in Industrial Consumers.

The overall objective of this project is to reduce the specific energy consumption (kgep / 1000 euro) within Antibiotice S.A. by an average of 1%, the period of 5 years after the implementation of the project, as a result of monitoring the consumption through the implementation of a smart metering system energy.

The specific objectives are as follows:

- monitoring and storing the consumption of electric power, natural gas in the company plants and other users where the monthly energy deduction is made;
- preparing daily reports of monitored energy consumption or, as the case may be, seasonal reports, reports on shifts and manufacturing cycles;
- conducting consumption analyses / energy costs of the consumers or installations / equipment;
- the calculation of specific consumption that allows to establish the proper measures / strategies for a better efficiency of equipment / installations, and ethnic support for future upgrading projects.

**3. Feasibility and design study to increase the production capacity of nystatin and modernize the clean area**

Creating a modern plant for the manufacture of active substance Nystatin represents the guarantee of a long-term business development for Antibiotice S.A.

The company's development strategy also focuses on maintaining and expanding of sales markets for the active substance Nystatin.

**4. Investments in manufacturing flows**

In 2018 it was proposed the acquisition of equipment, installations, various equipment and laboratory apparatus in order to refurbish the production flows. The manufacturing equipment and the installations to be purchased are the latest generation, with high productivity, low energy consumption, and high operational safety. The manufacturing equipment is designed to replace equipment with significant physical wear, which generates high maintenance costs and low productivity. It is also necessary to purchase equipment and installations to ensure environmental protection measures, to reduce energy consumption and work safety.

**5. Licensing new products and acquisition of research projects**

The new product development program has the following objectives:

- modernization of the company's product portfolio in order to provide last generation generic medicines, therapeutically effective and safe in administration for the internal market
- providing competitive pharmaceuticals on the foreign market and ensuring, in the long run, the growth of company's turnover and competitiveness
- reducing NHIH expenditures for the purchase of expensive imported medicines or under risk to be discontinued.



## **6. Research investments**

Research is one of the most dynamic activities in the company with continuous changes and an ascending evolution. Throughout the whole company, research acts as a dynamic element of the whole system, generating new products that drive growth in production. With specific use of intelligence and creativity, research contributes to product portfolio development.

Given the importance of the information obtained through the Medicines Evaluation Center, the investment program includes a range of equipment, endowments and software to support and improve research activities to obtain qualitative, valuable, competitive new products.

## **7. Quality investments**

Considering the ongoing revision of pharmacopoeial monographs and the increased accuracy of analytical methods in the pharmaceutical industry laboratories, it has become imperative to acquire the latest generation equipment to make it possible to check the quality of the products manufactured by Antibiotice S.A. according to international standards. Quality Control Laboratories have a decisive role in demonstrating the quality and compliance of the products manufactured in our company, which is why they continuously need to be equipped with the most modern and performing laboratory equipment.

## **8. Logistics investments - Commercial Division**

Investments are mainly directed towards supplying the finished product storages with equipment that improves storage conditions and working conditions and increases labor productivity. Furthermore, by making certain acquisitions. replacement of old, high-wear equipment, which is no longer safe in operation, is also our objective.

## **9. Investments for the management and transport of utilities**

Investments are mainly focused on modernization and renewal of the systems, equipment and facilities that are used to manage the utilities (steam, compressed air, water, demineralized water, methane gas, electricity, drinking water, sewerage, etc.) of the entire platform of the company, in order to size and adapt the utility routes to the current consumption of manufacturing flows, so as to save energy by reducing consumption and eliminating losses.

By making these investments there will be benefits such as:

- safety in operation;
- increasing labor productivity;
- reducing intervention times by implementing a powerful diagnosis system based on error messages that reduce maintenance and repairs;
- energy and resource savings and, implicitly, better environmental protection;
- ease of use of the equipment by the human operator.

## **I. Optimizing operating costs and increasing operating efficiency**

## *The Administrator's Report for the first semester of 2018*

### **NET PROFIT OF THE TARGET PERIOD INCREASED WITH 5% COMPARATIVE TO SEMESTER I OF 2017**

Antibiotice S.A. carried out activity during the first half of 2018 in the spirit of achieving the objectives and indicators established through the Income and Expenditure Budget.

#### **Overall result**

Sales revenues of the target period recorded 157.7 million lei, an increase of 7% compared to 2017, when 147.2 million lei were registered, as a result of the company's sustained effort to consolidate the business.

Within the structure, the main expenditures evolved as presented below:

- the increase of 12% in raw material and material expenses is determined by both the manufacturing structure and a value of 26% of the superior production compared to the same period of 2017;
- staff expenses registered an increase of 10% compared to 2017 due to the salary increases granted in May 2017, according to BVC approved in the General Meeting of Shareholders;
- Other operating expenses registered a value of 50 million lei, an increase of 5% compared to the same period of last year. These values were determined by the increase of the value of the claw back tax up to 18 million lei, higher than the planned value in BVC of 12 million lei and the value registered in the first semester of 2017 of 14 million lei. When preparing this report, the value of the claw back tax for the second quarter is at the estimated level, the final amount set by CNAS will be communicated at the beginning of August.

#### **6. Investments in Research**

Research is one of the most dynamic activities in the company, which experiences permanent changes and an ascending evolution. Throughout the whole of the company, research acts as a dynamic element of the whole system, generating new products that drive a growth in production. With specific consumption of intelligence and creativity, research contributes to product portfolio development.

Given the importance of the information generated in the Center for Drug Evaluation, the investment program includes a range of equipment, endowments and software to support and improve research activities to obtain new, quality, valuable and competitive products on the market.

#### **7. Investing in Quality**

Given the ongoing review of pharmacopoeial monographs and the increased accuracy of analytical methods in the pharmaceutical industry laboratories, it has become imperative to acquire the latest generation equipment to make it possible to check the quality of the products manufactured by Antibiotice at international standards. The Quality Control Laboratories have a decisive role in demonstrating the quality and compliance of the products manufactured in our company, which is why they need to be permanently equipped with cutting edge and performing laboratory equipment.

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### **8. Investments to ensure logistics - the Commercial Unit**

The investments are mainly directed towards the endowment of the finished product warehouses with equipment that improves the storage conditions and working conditions and increases labor productivity. Also, by making certain acquisitions, the replacement of old, high-wear equipment, which is no longer safe in operation, is being performed.

### **9. Investments for the production and transportation of utilities**

The investments are mainly focused on the modernization and upgrading of the systems, equipments and installations for producing the utilities (steam, compressed air, water, demineralized water, methane gas, electricity, drinking water, sewerage, etc.) from the entire platform of the company, in order to dimension and adapt the utility routes to the current consumption of the production lines, so as to save energy by reducing consumption and eliminating losses.

By making these investments there will be benefits such as:

- safety in operation;
- increase in labor productivity;
- a reduction of the intervention times by implementing a powerful diagnosis system based upon error messages that reduce the maintenance and repair work;
- energy and resource savings and, implicitly, a better environmental protection;
- ease of use of the equipment by the human operator.

## **I. Optimizing the operating costs and increasing the operating efficiency**

### **THE NET PROFIT OF THE PERIOD UP BY 5% COMPARED TO THE FIRST SEMESTER OF 2017**

Antibiotice carried out its activity during the first half of 2018 in the spirit of achieving the objectives and indicators established through the Income and Expenditure Budget.

#### **The overall result**

The sales revenues of the period amounted to RON 157.7 million, up by 7% compared to 2017, when RON 147.2 million were registered, as a result of the company's sustained effort to consolidate the business.

In the structure, the main expenditures evolved according to the table below:

## *The Administrator's Report for the first semester of 2018*

- the increase in raw material and consumable expenses is 12% and is determined by both the manufacturing structure and the value of the superior production by 26% compared to the same period of 2017;
- the staff expenses registered an increase of 10% compared to 2017 due to the salary increases granted in May 2017, according to the IEB approved in the General Meeting of Shareholders;
- other operating expenses registered a value of RON 50 million, up by 5% compared to the same period last year. These values were determined by the increase of the value of the claw-back tax to the level of RON 18 million, higher than the planned value in IEB of RON 12 million and the value registered during the first semester 2017 by RON 14 million. When drafting this report, the value of the claw-back tax for the second quarter is at the estimated level, the final amount set by NHIH will be communicated at the beginning of August.

The overall result (RON)	30.06.2017	30.06.2018	2018/2017
<b>Sales income</b>	<b>147.200.095</b>	<b>157.700.486</b>	<b>1.07</b>
Other operating revenues	13.517.588	14.810.614	1.10
Income related to product stock costs	19.038.444	23.440.792	1.23
Income from the activity of the entity and capitalized	800.167	1.549.525	1.94
Expenditure on raw materials and consumables	65.349.770	73.332.578	1.12
Staff costs	38.235.362	41.996.215	1.10
Expenses with amortization and depreciation	8.574.285	9.800.119	1.14
Other operating expenses	47.749.054	50.067.426	1.05
<b>Profit from exploitation</b>	<b>20.647.822</b>	<b>22.305.078</b>	<b>1.08</b>
Financing costs	-590.220	-1.460.910	2.48
<b>Profit before tax</b>	<b>20.057.602</b>	<b>20.844.169</b>	<b>1.04</b>
Profit before tax	861.407	741.122	0.86
<b>Profit</b>	<b>19.196.195</b>	<b>20.103.047</b>	<b>1.05</b>

The revenue and financial expenses are the income and expense with the interest of the period.

The profit before tax is for the reported period of RON 20.8 million, superior to that registered in 2017 by 4%, and 23% higher compared to the profit estimated in IEB.

The profit after tax is RON 20.1 million, higher than 2017 by 5% and to the budgeted profit by 41%.

### Situation of the financial position

## *The Administrator's Report for the first semester of 2018*

On June 30, 2018, the fixed assets of the company recorded a higher value of 3% compared to the beginning of the year. Accounting depreciation is calculated using the straight-line method according to IFRS.

	<b>01.01.2018</b>	<b>30.06.2018</b>	
<b>ASSETS</b>			
<b>FIXED ASSETS</b>			
Tangible assets	223.242.890	229.561.070	1.03
Intangible assets	13.107.622	13.412.260	1.02
<b>TOTAL FIXED ASSETS</b>	<b>236.350.512</b>	<b>242.973.330</b>	<b>1.03</b>
<b>CURRENT ASSETS</b>			
Stocks	67.264.546	103.634.791	1.54
Commercial and similar receivables	264.212.743	294.715.288	1.12
Financial assets held for sale	0	0	
Cash and cash equivalents	5.107.743	1.767.891	0.35
<b>TOTAL CURRENT ASSETS</b>	<b>336.585.032</b>	<b>400.117.970</b>	<b>1.19</b>
<b>TOTAL ASSETS</b>	<b>572.935.544</b>	<b>643.091.300</b>	<b>1.12</b>
<b>LIABILITIES</b>			
<b>CURRENT LIABILITIES</b>			
Commercial and similar debts	55.535.974	72.933.264	1.31
Amounts owed to credit institutions	69.731.310	114.081.765	1.64
Tax and current tax liabilities	9.792.887	9.064.331	0.93
Short-term provisions			
Investment grants	326.246	403.229	1.24
<b>TOTAL CURRENT LIABILITIES</b>	<b>135.386.417</b>	<b>196.482.589</b>	<b>1.45</b>
<b>LONG TERM DEBT</b>			
Investment grants	2.498.889	2.619.070	1.05
Deferred tax	18.172.398	17.924.462	0.99
Amounts owed to credit institutions	0	7.182.635	
<b>LONG TERM DEBT</b>	<b>20.671.287</b>	<b>27.726.167</b>	<b>1.34</b>
<b>TOTAL LIABILITIES</b>	<b>156.057.704</b>	<b>224.208.756</b>	<b>1.44</b>
<b>Social capital and reserves</b>			
Social capital	264.835.156	264.835.156	1.00
Revaluation reserves	14.556.141	13.569.294	0.93
Legal reserves	13.426.761	13.426.761	1.00

## The Administrator's Report for the first semester of 2018

Other reserves	162.134.513	166.884.712	1.03
Reported result	-71.633.085	-59.936.426	0.84
Current result	33.558.354	20.103.047	0.60
<b>TOTAL EQUITY</b>	<b>416.877.840</b>	<b>418.882.544</b>	<b>1.00</b>
<b>TOTAL EQUITY AND LIABILITIES</b>	<b>572.935.544</b>	<b>643.091.300</b>	<b>1.12</b>

### Current assets:

- the stocks experience a 54% higher level compared to the beginning of the year, due to the additional production achieved both for the revision period and for the period before the achievement of the new Ointments Plant;
- the total receivables amount to 12% higher due to the payment delays in the healthcare system.

For 2018, Antibiotice has proposed an ambitious Investment Plan worth RON 116.3 million approved by the GMS on 26.04.2018, supported by both the company's own resources and short-term bank loans (financing lines) and long-term loans, which led to an increase in indebtedness and a decrease in current liquidity, values that fit into the safety and economic efficiency panel.

Name of indicator	Calculation method	30.06.2017	30.06.2018
Current liquidity	Current assets/Current liabilities	2.36	2.04
Level of indebtedness	Borrowed capital/Equity x 100	17.7%	28.9%
Turnover speed, for client debit items	Average Customer Balance/Sales revenue x Time	325 days	322 days
Turnover speed for fixed assets	Sales income/Fixed assets	0.67	0.65

### Balance sheet liability items

The company records on 30 June 2018 current debts worth RON 135.4 million, increasing by 45% compared to 2017; the cash demand of the company in 2018 was higher than 2017, both for the payment of the claw-back tax, dividends to the shareholders as well as to support purchases for the Investment Plan, leading to greater use of credit lines.

### Amounts owed to credit institutions on 30.06.2018

Short-term contract no. IAS3-42-2016/17.08.2016 concluded with Unicredit Bank S.A.

Objective	Credit Line - Circulating Capital
Amount	RON 50.000.000
Maturity	16.08.2018
<b>Balance on June 30 2018</b>	<b>RON 46.623.059</b>
Guarantees	Mortgage contract for buildings, land/Contract for

## *The Administrator's Report for the first semester of 2018*

### assignment of receivables

The long-term investment credit agreement no. IAS3-20-2018/03.05.2018 concluded with Unicredit Bank S.A.

Objective	Long-term investment credit
Amount	EUR 15.406.300
Maturity	02.05.2028
<b>Balance on June 30 2018</b>	EUR 1.540.974.33 (RON 7.182.635.45)
Guarantees	Mortgage contract for buildings, land, equipment purchased under the investment project/Contract for the assignment of receivables

Short-term contract no. 12/01.07.2013 concluded with the Export Import Bank of Romania EXIMBANK S.A.

Objective	Credit Line - Circulating Capital
Amount	RON 30.000.000
Maturity	25.06.2019
<b>Balance on June 30 2018</b>	RON 29.339.449.08
Guarantees	Mortgage contract for buildings, land/Contract for assignment of receivables

Short-term contract no. 12239/22.05.2012 concluded with ING BANK N.V. AMSTERDAM - Romania Branch

Objective	Credit Line - Circulating Capital
Amount	EUR 9.500.000
Maturity	22.05.2019
<b>Balance on June 30 2018</b>	RON 14.513.695,84 EUR 5.064.375.49 (RON 23.605.560.60)
Guarantees	Mortgage contract for buildings, land/Contract for assignment of receivables

SC Antibiotice SA has not posted guarantees and has not pledged or mortgaged its own assets to guarantee obligations in favor of a third party.

### **Cash flow**

The level of cash and cash equivalents at the beginning of the period was -RON 64.6 million, representing credit lines worth RON 69.7 million, of which RON 5.1 million remained unused in accounts with banks in the same lines credit. The cash receipts from operating activities amounted to RON 151 million. The cash payments to suppliers of goods and services amounted to RON 106.3 million, and those to and on behalf of employees of RON 40.5 million.

At the same time, payments of RON 3.2 million, representing corporate tax, VAT, local taxes and bank interest, were made and payments were made for the purchase of

## *The Administrator's Report for the first semester of 2018*

fixed assets of RON 26.9 million. Contributions were paid to the Ministry of Health (claw-back tax) worth RON 19.1 million.

Regarding the financing activity, the long-term bank credits worth RON 7.2 million were accessed and RON 9.5 million worth dividends were paid.

At the end of the period, cash and cash equivalents amounted to -RON 112.3 million, which represents the value of credits for the current activity (RON 114.1 million) of which RON 1.8 million remained available in banks in the same credit lines.

The company has paid its entirety to the state and local budget amounting to RON 41 million.

### **II. The motivation of the human resource and the provision of the necessary skills to achieve strategic directions**

The human resources policy promotes the diversity and equal opportunity in recruiting, selecting and integrating employees. We provide employees with all the rights deriving from the law, offering fair and equitable working and professional development conditions.

**On 30.06.2018 the average number of the staff was 1420.**

By the nature of the specific activities carried out within Antibiotice, the structure of the staff on levels of education and professional training is as follows:

Higher education - 599 employees out of which:	42.19%
- 32 PhD employees (5%)	
Secondary education - 821 employees	57.81%
Total 1420	100%

In order to achieve the strategic objectives of the Business Plan for the period 2018-2020, the activity of Human Resources Management Unit during the first half of 2018 aimed to fulfil the specific objectives, structured within the strategies and action measures.

**The strategy “The staffing, the training of the skills needed to reach the objectives and the increase of the degree of involvement”**

The concrete actions taken in implementing this strategy aimed at:

#### **1. Identify the staffing needs of each structure to achieve the objectives**

In order to put into practice an integrated vision of all the company's directions regarding the staffing corresponding to the needs of the proposed strategic objectives, Antibiotice operates the *Human Resources Commission*, which has the role of establishing the necessary staffing to ensure an optimal structure functioning, but also to maintain the balance of indicators assumed and approved through the Income and Expenditure Budget.



## ***The Administrator's Report for the first semester of 2018***

During the commission meetings in the year 2018, the results of the staffing needs analysis on the organizational structures of the company were presented taking into account the following:

- the need to fill vacancies
- developing teams in priority areas:
  - o quality assurance
  - o production
  - o promotion and commercial
  - o automation and investments

### ***2. The staffing with specialized personnel and the training of the necessary skills***

#### **Ensuring the staffing needs**

According to the approved human resources drawing plan, 39 people were employed between January and June 2018, namely:

- 15 higher education employees of which 4 for the development of the teams within the Quality Assurance, Promotion and Commercial, Production and 11 employees for completing vacancies;
- 24 secondary education employees of which 4 for the development of production and engineering teams and 20 for filling vacancies.

The recruitment of personnel was carried out by carrying out the specific recruitment and selection stages, as well as by the specific projects of attraction and selection.

#### **The “Performa a+” project, 3<sup>rd</sup> edition**

The project aims at developing practical skills among pharmacists (residents and senior students) for specific activities within the Medical Unit and at the same time creating a platform for long-term communication and collaboration with the “Gr.T.Popa” University of Medicine and Pharmacy, in training and attracting specialized personnel.

The **Perform a+** project has carried out this year's third edition within the Medical Unit, in collaboration with the Faculty of Pharmacy of Iasi, for the selection of graduates for the Pharmaceutical Research and Development activity. The program of theoretical and practical activities was supported by mentors appointed amongst the company's specialists.

#### **Summer School a+, 9<sup>th</sup> edition**

The external component of this project aims at identifying and training specialists in the fields of pharmacy, biology, chemistry, chemical engineering for selection in order to fill vacancies in Research - Pharmaceutical Development, Quality Assurance, Quality Control, Production, by familiarizing the candidates with the working environment, concepts and regulations in the pharmaceutical industry.

Through this project well-known in the Iasi academic environment and among the students of the Iasi senior students, a total of 30 participants have been selected to benefit from training from the specialists in our company. The themes approached during the Summer School a+ classes will present information in the fields of Quality Assurance in a pharmaceutical company, Pharmacovigilance, Regulatory Affairs, specific laboratory

## ***The Administrator's Report for the first semester of 2018***

techniques in Quality Control, research and pharmaceutical formulation, and will take place between July - August 2018.

***Up to now, 38 participants have been hired during the eight previous Summer School a+ editions.***

### **Partnerships with pre-university education institutions**

Within the partnerships established with the “Petru Poni” Technological Highschool in Iasi and the Technological High School of Mechatronics and Automatizations for the 2017-2018 school year, 70 senior high-school students have been practicing in the company, a specialization as laboratory chemist/chemist operator in the medicine and cosmetics industry and for the students from the mechatronist/electromechanical technician specialization Antibiotice was a partner in the development of projects and events organized to encourage them to practice the chosen profession.

The program aims at building practical skills and enhancing students' knowledge in order to attract staff to replace employees facing retirement opportunities.

Under the “A different School” program, Antibiotice welcomed more than 350 students from the pre-university education institutions in Iasi to present them with one of the most famous landmarks in the Iasi industry, with its history and prospects for future development.

### ***3. Carrying out professional skills training programs***

In order to achieve the professional goals and performances necessary to increase the competitiveness and quality of the business, we annually develop human resource development projects with training programs in each direction according to the needs identified for each organizational structure and in close correlation with the community applicable legislative changes and the domestic legislation.

The training programs with internal lecturers, established for each structure according to the specifics of the activity, are complemented by a continuous professional training through access to vocational training programs with external lecturers, according to the Annual Training Plan approved and budgeted for the current year.

During the first semester, 226 employees underwent the scheduled training sessions, by specialization fields, resulting in an average of 19 hours of training/employee.

The internal component of the “Summer School a+” intended for the employees will also offer this year, at the 9<sup>th</sup> edition, the possibility for employees to receive training by pursuing both the development of specialized competencies in quality assurance, regulatory affairs, serialization, new requirements in validating manufacturing processes and equipment requalification as well as the organizational development through employers' brand themes, employee retention, legislative provisions on health and safety at work.

### ***4. Increasing the awareness and information degree of the employees and their involvement at all the levels of the organizational structure***

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### ***Establishing the 2018 objectives for the MBO staff***

Upon the basis of the approved indicators in the Income and Expenditure Budget for 2018 and starting from the Company's Business Plan for the period 2018 - 2020, the annual general objectives were established and the specific objectives for each activity for the employees included in the Management by Objectives system.

These objectives are set in accordance with the company's overall mission and objectives and involve the employees' motivation to achieve them through a focused and well-coordinated effort.

Once established and assumed, the objectives were transposed into additional acts to the individual labor contracts for a total of 340 employees involved in this system.

#### **5. Strategies and measures to increase the employee motivation**

During the first semester a salary study was initiated that would form the foundation of the salary system for the positions in the organizational structure of the company based upon the analyzes of the current salary system compared to the levels of similar positions on the labor market and the hierarchy of positiond on the basis of their complexity.

The analysis aims at restoring salary scales for the higher education and secondary education job positions, establishing career plans and assessing the possibility of aligning salary levels to this grid.

The increase in staff motivation is aimed at developing performance indicators and evaluation systems specific to key organizational components of the company, analyzing the possibility of introducing modern rewarding tools.

#### **6. Strategies and measures to increase the attractiveness of the employer brand**

In 2018, the company aims to develop a program to increase the attractiveness of the company in attracting and retaining the staff for which the instruments and the planning of its achievement were established during the first half of the year, namely:

- The carrying out the impact study on the perception and attractiveness of the employer brand among the target audiences for recruitment
- Establish a plan to increase the brand awareness of the employer and the compliance of the HR practices based on the results of the impact analysis.

#### ***ASPECTS OF DIVERSITY***

**Ensure a favorable work environment and an organizational culture geared towards innovation and performance**

## *The Administrator's Report for the first semester of 2018*

The employees' representatives together with the management of the company identify the best solutions in order to maintain a beneficial climate for the professional activities.

In its activity, Antibiotice applies ethical standards based on principles of honesty, integrity, fairness and transparency and focuses equally on all stakeholders, employees, business partners, authorities, society and the community in general.

Antibiotice increased the number of women employed each year, providing equal opportunities for personal development, so that 54.78% of the total number of employees and 58.19% of the staff with management positions are women.

In our company there is a balanced distribution of employees according to gender and age:

Age range	20 years	20-30 years	30-40 years	40-50 years	50-55 years	peste 55 years	Total (%)
Women (%)	0.07	4.04	13.18	20.34	9.71	7.44	<b>54.78</b>
Men (%)	0	3.05	9.21	18.14	6.59	8.22	<b>45.22</b>
<b>Total (%)</b>	<b>0.07</b>	<b>7.09</b>	<b>22.40</b>	<b>38.48</b>	<b>16.30</b>	<b>15.66</b>	<b>100</b>

From the confessional point of view, 96% of our employees are Orthodox Christian and 4% are Roman Catholic, a proportion that respects the confessional structure at national level. This feature, as well as those related to gender, age, nationality or the presence of disabilities, are not limiting hiring criteria.

11 of our employees are people with disabilities and benefit from the legal provisions but also from equitable and non-discriminatory treatment at the workplace.

The dialogue with the co-interested groups is important for everything that our social responsibility policy entails. Therefore, we are always looking for opportunities for dialogue with our employees, shareholders, our business partners, local communities and pharmaceutical industry organizations to see how we can work together and how we can improve our performance.

Through collective negotiation within the company, the clauses of the Collective Labor Contract are established at the company level, thus guaranteeing employees the labor protection, social protection, and also providing additional facilities for professional formation and development.

### **III. Quality management for compliance with legal, national and international requirements, specific to the pharmaceutical industry.**

## ***The Administrator's Report for the first semester of 2018***

Increasing the confidence in the quality, efficiency and safety of the company's products is achieved daily by keeping under control and improving the Quality Management System, attested by the results obtained after the following inspections/audits during the first semester of 2018.

### **1. Inspections performed by the authorities**

During the period 13-14.02.2018 the **NAMMD inspection** was carried out for the conformity assessment of the GMP (Good Manufacturing Practice) of the Quality Management System of Antibiotice SA and the manufacturing lines of the ointments and ophthalmic ointments. Following the receipt of the Deficiency List, the CAPA Plan was submitted and a series of subsequent additions. At this time, we expect the receipt of the GMP certificate for the mentioned manufacturing lines.

### **2. Audits from customers**

Partners have performed 2 audits, one at the Parenteral Products Plant and one at the Ointments and Suppositories Plant to qualify the company as a finished product supplier. Audits have been finalized without critical non-compliances.

### **3. Audits to suppliers of raw materials/primary packaging materials/finished products**

In accordance with the Annual External Audit Plan 2018, a total of 5 external audits were carried out at manufacturers of active substances and primary packaging materials. No critical non-conformities were identified. The results were appropriate, the mentioned manufacturers may be maintained/included in the *List of approved suppliers* of Antibiotice SA.

## **Environment protection**

### **Promoting the environmental protection**

Through the Environmental Management System, the environmental protection activity of Antibiotice manages the prevention of pollution and the continuous improvement of the environmental performance, acting in order to comply with the requirements of the environmental legislation.

By obtaining in January 2011 the Integrated Environmental Authorization, valid for 10 years, Antibiotice proves to be a company that observes the environmental requirements; thus, the emissions of pollutants into the air, water and soil are below the limits stipulated by the applicable rules in the field.

Under the Corporate Responsibility Program "Be pro nature. Put soul in it!" during the first semester of 2018 the **Earth Hour 2018** event unfolded. Antibiotice participated for the tenth consecutive year at what became the largest environmental campaign of all time. The „Earth Hour” event was marked by the fact that on March 24, 2018 between 20:30 and 21:30 the external lighting system was interrupted on the territory of the company in the

## ***The Administrator's Report for the first semester of 2018***

areas where it was possible to do so as a symbolic gesture that urges for a responsible resource management.

Also, through the same program „Be pro nature. Put soul in it!”, the “The school orchard project” started in 2017 and continued in 2018, during which, in the first stage, two orchards with fruit trees were planted in the neighboring areas of the company - in two villages in the Lețcani area, through which the respect for the environment is taught to the younger generation, as well as the maintaining of a healthy lifestyle.

### **The responsibility towards the environment**

The activity of the company in the field of the environmental protection is regulated by the Integrated Environmental Authorization no. 1/10.01.2011 issued by the Regional Environmental Protection Agency from Bacău (valid until 10.01.2021) and by the Water Management Permit no. 303/20.12.2010 issued by the National Administration of Romanian Waters, the Prut-Barlad Water Basin Administration (valid until 31.12.2020).

In March 2018, the revised Integrated Environmental Authorization was issued for the activities carried out by Antibiotice.

In order to comply with the legislation in the field of environmental protection, Antibiotice provided the necessary endowments and qualified staff. The entire activity is regulated by specific procedures of the environmental management system, as well as by operating procedures and working instructions.

The monitoring of the environmental factors has been carried out according to the requirements of the Integrated Environmental Authorization, both through its own laboratories and through third-party laboratories, authorized by the Romanian Accreditation Association (RENAR).

### **Specific consumption and energy use**

The activity within the Biosynthesis Plant where Nystatin active substance is produced falls within the scope of the European Integrated Pollution Prevention and Control Directive (IPPC). During the first semester of 2018, the Biosynthesis Plant has framed the planned specific consumption regarding the quantities of solvents used.

### **Air quality**

During the first semester of 2018, the air quality monitoring was carried out in the laboratory through air pollutant emissions/immissions analyzes for the indicators: nitrogen oxides, ammonia, suspended particulates and sedimentable powders. There have been no exceedances of the maximum admissible concentrations provided in the Integrated Environmental Authorization.

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### **Water quality**

The water quality monitoring required analyzes of the quality of the water entering the company's own sewage treatment plant and discharged into the municipal sewage system, of conventionally clean water discharged into the natural emissary, as well as underground water.

No exceedances of the maximum admissible concentrations established by the Integrated Environmental Authorization, Water Management Permit, and by NTPA 001 and NTPA 002 - 2005 have been recorded.

### **Soil protection and the groundwater**

Of the total area of the land owned by Antibiotice, about 40% is free, with green spaces.

The quality of groundwater was monitored by monthly sampling and analysis of samples obtained from perimeter observation drills and drilling downstream of the landfill site. There was no accidental pollution or environmental incident that would lead to the degradation of the soil quality in the area of influence of the company's activity.

### **Waste management**

Antibiotice has implemented a selective waste collection system, as each production and auxiliary plant is equipped with appropriate collection containers.

The recyclable waste was capitalized on the basis of contracts with authorized economic operators.

The waste that was not capitalized was incinerated in the company's own facility or disposed of by landfilling at the municipal landfill.

The company observes the packaging waste management requirements (corresponding to the quantity of products that Antibiotice has introduced on the Romanian market). The overall objective, as well as the minimum recycling value targets, by type of material, set for 2018 (in accordance with Law No. 249 of 2015, with subsequently amended and supplemented), have been achieved.

### **Environmental plans and programs**

For the first semester of 2018, the environmental objectives established at the company level aimed at:

- Increasing the number of vehicles with EURO 6 equipment by purchasing new vehicles with the Euro 6 pollution standard (26 units) - objective achieved.

### **Prevention and management of emergency situations**

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At Antibiotice, the prevention of emergency situations and the provision of the intervention capacity in the event of accidents are ensured through the activity of the following departments: Emergency Situations, Environmental Protection, Prevention and Protection.

For this purpose, the accident prevention and control plan, the accident prevention policy for the use of hazardous substances (solvents), the fire protection plan (fire prevention and extinguishing), the fire safety scenario, the emergency response procedures, the emergency preparedness and response capability procedures, authorizations/documents required for all the equipment subject to the regulations of the State Inspection for the Control of Boilers, Pressure Vessels and Hoisting Equipment (ISCIR).

During the first semester of 2018, an internal alarm exercise was conducted, in which the response capabilities of the emergency response teams were tested and assessed.

Within the legal deadline imposed by the Order of the Minister of Public Finance 1938/2016, Antibiotice SA undertakes to publish a Non-Financial Report which will be made available to the public on the company's website.

### **Conclusions:**

- Sales revenue higher by 7% compared to the same period of 2017;
- Higher net profit by 5% compared to the first semester 2017;
- 22 new Antibiotice Marketing Authorizations in 3 countries in Asia and Europe;
- Investment program supported by contracts concluded at least 83% of the budgeted value;
- Starting the program to increase the attractiveness of the employer brand.

**Vice-Chairman of the Management Board,  
Ec. Ioan Nani**

**Economic Manager,  
Ec. Paula - Luminita Coman**