



ANNUAL  
REPORT

2012

Antibiotice  
Science and soul





ANNUAL  
REPORT

2012

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# 01

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## CEO's Message

Another year has passed: Antibiotice's 57<sup>th</sup> year of existence. Our company rejoices to tell shareholders, investors and partners that in 2012 our business activity unfolded as smoothly as possible and materialized in an 8.6% turnover increase and a 34% boost of net profit, over the results reported in 2011.

The overall market conditions have not exactly been favorable, 2012 continuing to be marked by a contraction of world outlets, a lack of liquidities and banks tightening their lending terms and conditions. Nevertheless, the opportunity to reinvest profits during the crisis has given our company the chance to complete a number of paramount investments in the last four years, such as building a tablet manufacture facility and developing our modern center for Research and Development. Such investments have made it possible to put on the market new medicinal products, year by year, with a positive influence on the turnover. Thus, despite the economic-financial crisis manifested in years 2008-2012, we managed to boost turnover by 40% and gross profit increased 2.3 times, covering the gap recorded when the crisis began. These economic results have been registered without significant staff reductions, while maintaining the degree of indebtedness under control and optimizing costs.

In retrospect, our company had 1,523 employees back in 2008 and counted on 1,465 employees in late 2012. The indebtedness degree decreased from 31% in 2008 to 30% in 2009 and 28% in 2010, rising to 32% in 2011 and 2012. This evolution shows that Antibiotice is a company which makes careful but clever steps in the direction of business development. In addition, Antibiotice is performance-oriented and provides enough guarantees for our reliable partners.

The goal we embraced in recent years, 2012 included, was aimed at cutting down operating costs and other types of expenses. On the other hand, reducing the budget allotted to marketing and promotion in times of economic turmoil is known to be a business mistake. This is why we continued to invest in promoting our products and bettering our logistics, in order to consolidate the company's position in the anti-infective market where Antibiotice is unquestionably an important player. Moreover, together with the Marketing and Promotion teams we have thought of the most profitable ways to enhance the marketing presence of our therapeutically valuable medicines from the cardiovascular, CNS and oncology classes.

It is true that over the past three years we had to tackle the effects of the clawback tax coupled with a stringent reduction of liquidity, taking into account that in the pharma industry, both the allotment of resources and payments report significant delays. In 2012, the clawback tax paid by Antibiotice amounted to several million RON, which was certainly felt in terms of the working capital, but we managed to cover it by a balanced management of the working capital, without affecting the company's results; moreover, Antibiotice's 2012 gross profit augmented to 32 million RON, compared to only 26 million RON reported in 2011.

Several policies were implemented in order to counteract the clawback tax; one of them aims at including non-prescription medicinal products in our portfolio, whose sale is exempted from the clawback tax. In fact, our in-house R&D center has several projects in the pipeline; soon, we plan to release on the market cardiovascular drugs, CNS-intended drugs and antibacterial products (as required by national health policies) as well as food supplements, cosmetics and veterinary products.

Another leading direction in 2012 was the internationalization of our business, approached both as a means of reducing dependence to the domestic market and a way to guarantee liquidity, for a smooth-running of the marketing activities. Accordingly, the 2012 share of exports in turnover reached 24% thanks to an upward trend in sales of Nystatin API and finished products



from different therapeutic classes. Actually, the constant growth in Nystatin sales has shifted our company's position from second to leading manufacturer worldwide. The fact that we are currently in a complex process for the authorization of Nystatin on the US market – where we aim to become an exclusive supplier for the largest part of US consumers – provides us with sound growth opportunities in the coming years. Nystatin API is used in antimycotics manufacture and in the cosmetics industry.

Antibiotice is a major exporter, with more than 70 products registered in over 60 countries around the world. In addition, the possibilities we foresee on strategic markets across North America, Russia, CIS states, the European Union and the Middle East make our sales revenue targets in foreign markets on 2013 realistic and feasible.

In addition, the FDA inspection conducted in 2013 has reconfirmed that Antibiotice meets the requirements imposed by the North American pharmaceutical industry; as a result, our company is authorized to put on the US market high-quality sterile products for injection and at the same time can extend its business activities in other therapeutic areas.

For over 57 years, we put science and soul in the manufacture of affordable, therapeutically valuable drugs. Thus, Antibiotice has become a leading provider of anti-infective drugs for Romanian hospitals and holds a significant market share in topical products. Moreover, in recent times, through sustained promotional activity, we have increased the share of cardiovascular and CNS drugs sales in turnover.

In the foreseeable future we are confident that Antibiotice will grow sustainably. In my opinion, our company has the advantage of a homogeneous team of specialists in the fields of research, quality, product development and manufacture and marketing, consolidated over the last 10-15 years. Thanks to this, Antibiotice has developed and put on the market high-quality, safe and effective medicines whose manufacture is supervised by a state-of-the-art QA system and recognized by EU regulatory bodies and the FDA, the American agency for food and drug administration.

Although 2013 promises to be a rather hectic year – for instance, the terms for concluding credit contracts will become more stringent, business financing solutions will be more difficult to obtain and the working capital will need securing – we have been envisaging a number of measures in order to keep the company on track.

In the future we'll continue our efforts to go global, to adapt human resources to the strategic orientation of our company, to decrease operating costs and take steps to protect the working capital. I am convinced that such a strategy could turn 2013 into a significant stage in the development of our company, when Antibiotice will reconfirm its well-deserved position in the hierarchy of the most reputed brands in the Romanian pharmaceutical industry and a reliable company for its numerous partners from all over the world.

Ec. Ioan Nani,  
CEO and Vice President  
of the Management Board

# 02

## Company Profile

### Antibiotice today:

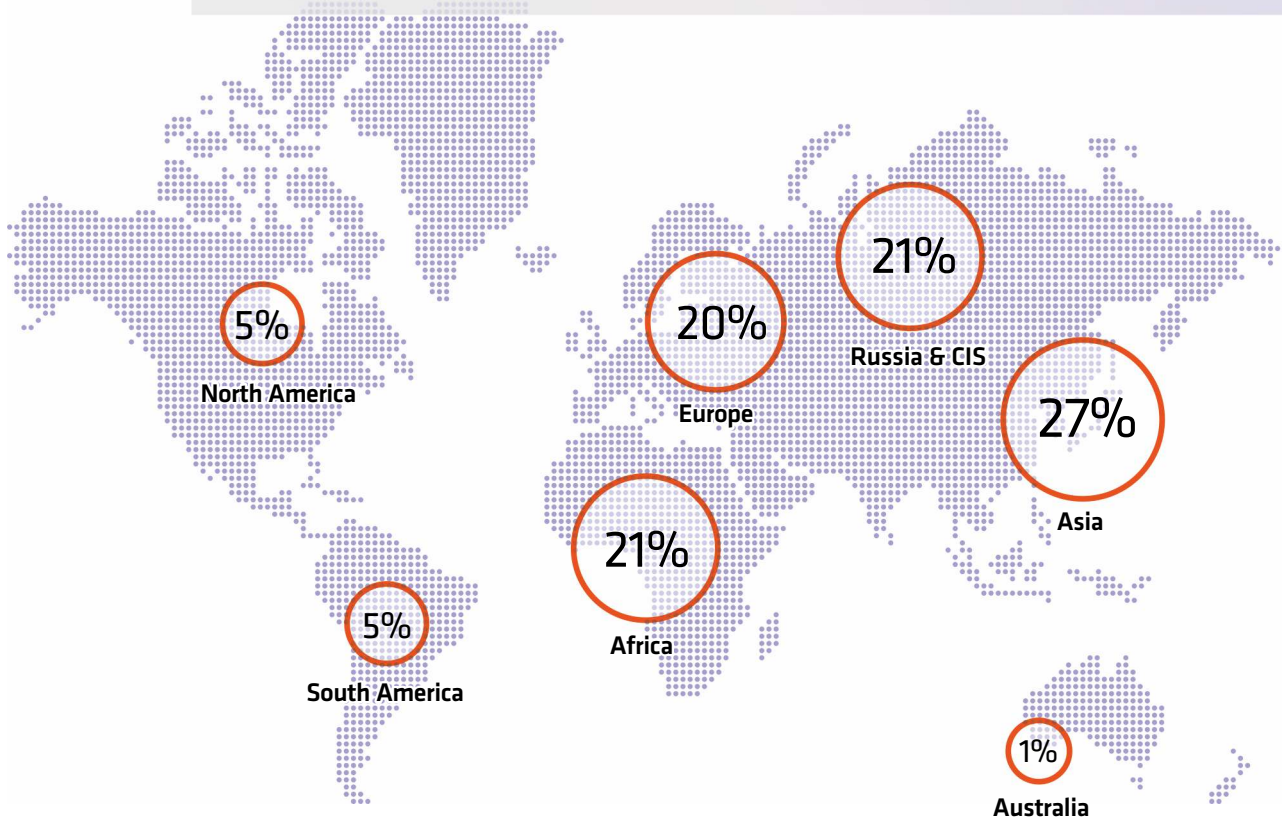
- The principal producer of generic anti-infectives in Romania;
- A portfolio that includes over 140 products of 13 therapeutic classes;
- An important manufacturer of anti-inflammatory drugs, dermatologicals, gastrointestinal, cardiovascular, oncology, and nervous system drugs;
- 8 production lines for: sterile powders for injection, penicillin capsules, non-penicillin capsules, cephalosporin capsules, tablets, ointments, creams and gels, suppositories, active pharmaceutical ingredients produced by biosynthesis;
- Revenue income amounting to RON 304 million (+8.1% compared to 2011);
- Internationally acknowledged approvals and certificates: US FDA approval for Nystatin and products for injection, Certificate of Suitability to the European Pharmacopoeia (CoS) for Nystatin, Good Manufacturing Practice (GMP) certificate for all the manufacturing lines, Integrated Management System;
- Modern in-house R&D Center;
- The first WHO pre-qualified European company for the range of essential anti-tuberculosis drugs;
- Important countrywide employer: 1465 employees.

## Achievements in the domestic market:

- Market leader in terms of quantities sold for the following pharmaceutical forms: suppositories (45% market share), ointments (30% market share), and sterile powders for injection (73% market share);
- Leader in the market of generic prescription drugs intended for hospitals;
- The company ranks fourth among the 254 generic and OTC drug manufacturers (6.6% market share) in Romania;
- The Romanian producer of the full range of essential anti-tuberculosis drugs.

## Active presence in the international market:

- Top producer of Nystatin;
- Export accounts for 24% of the turnover;
- 70 products exported;
- 120 partners in 60 countries all over the world;
- 6 finished products for injection exported to the US following FDA approval.



# History



## 1955

Built in Iași between 1953 and 1955, *Fabrica Chimică nr. 2* (Engl. The Chemical Factory no. 2) is the first manufacturing plant in southeast Europe that produced the active ingredient penicillin. The first batch of Romanian penicillin was produced on December 11, 1955.



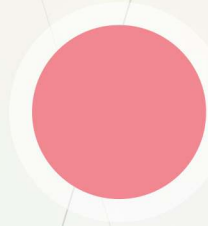
## 1977

The US Food and Drug Administration (FDA) approves the production line for the active pharmaceutical ingredient streptomycin.



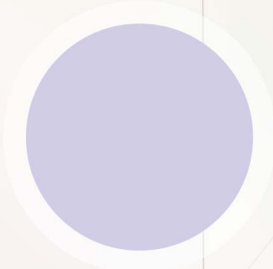
## 1959

The production of API streptomycin starts and the first finished drug products (ointments, creams, and suppositories) are manufactured. *Fabrica Chimică nr. 2* changes its name into *Fabrica de Antibiotice* (Engl. Antibiotics Manufacturing Plant).



## 1993

Ampicillin 250 mg and Oxacillin 250 mg are the first capsules obtained by Antibiotice on the penicillin products line.



## 1990

Antibiotice becomes a joint stock company and takes over the assets of the former *Întreprinderea de Antibiotice Iași* (Engl. Antibiotice Enterprise Iași), in conformity with GD no. 1200 of November 12, 1990.



## 1992

Antibiotice produces the first drug products, formulated as tablets.



## 1997

Starting April 14, the Antibiotice shares (BSE: ATB) are traded in the tier 1 of the Bucharest Stock Exchange; Antibiotice becomes a joint stock company named Antibiotice SA. The company implements an efficient quality assurance system involving a strict control of the manufacturing processes.

## 1999

Antibiotice SA becomes the first Romanian producer to be granted the Good Manufacturing Practice (GMP) certificate for its production line dedicated to powders for injection.



## 2002

FDA approves the production line for nystatin, which opens the way to the export of the active ingredient to the United States. Antibiotic secures its position as a top international manufacturer of nystatin and nystatin becomes the most important product sold abroad.

## 2005

Upon celebrating 50 years of existence, on December 2005, Antibiotic introduces its new brand identity: the logo "Antibiotic a+" and slogan "Science and Soul".



## 2010

Antibiotic makes its first deliveries of finished products to the US, a market on which the company has been present since 2010, but only with active pharmaceutical ingredients.



## 2006

Antibiotic sets up its own Center for Drug Evaluation (CDE), which carries out phase I clinical trials and bioequivalence studies. The CDE is GLP (Good Laboratory Practice) certified and authorized by the Ministry of Health.

The quality management system implemented in Antibiotic is certified in conformity with the ISO 9001:2000 standard by Lloyd's Register Quality Assurance (LRQA).

## 2011

The manufacturing line for penicillins as sterile powders for injection is granted FDA approval, which allows expansion of the export of such products to the US market.

Antibiotic launches its first products intended for the central nervous system therapy.



## 2007

Antibiotic SA gains recognition for implementing the Integrated Management System with respect to quality, environment, occupational health and safety in conformity with the EN ISO 9001:2008, EN ISO 14001:2004, and OHSAS 18001:2007 standards.

By adding four new products, Antibiotic supplements its cardio portfolio with medicinal products intended for the therapy of the main cardiovascular diseases.

## 2012

Antibiotic enters the market of oncology drugs.

# 03

## Strategic Orientation

### Portfolio update and consolidation

The research program dedicated to new products carried out at present is one of the main factors of dynamism and progress of the company. Performing research in an integrated system (i.e. pharmaceutical development, clinical testing, implementation in production), the Research & Development Center ensures sustainable growth by creating safe and effective generic medicines, optimizing and improving the manufacturing processes in conformity with the technological progress, and permanent revision of the product portfolio by adding medicines of interest for the Romanian health care system.

The medicines to be developed mainly by in-house research programs will supplement the company's traditional portfolio designed for antibiotherapy with last generation generics intended for the treatment of diseases with increasing incidence (i.e. cardiovascular, CNS, digestive tract, dermatological), as well as with products designed to enhance the quality of life.

### Adaptation of the portfolio to the new requirements of the market

Diversifying the range of medicines manufactured by subjecting to research and transferring to production new products from therapeutic classes with growing demand will provide the company with a sustainable and marketable portfolio. With this aim in view, in 2012, a number of 20 research projects for new generics, intended mostly for cardiovascular and CNS diseases, but also OTC drugs, dietary supplements and cosmeceuticals were initiated at the in-house R&D Center. Moreover, in 2012, the research and testing of 17 new products (pending marketing authorization) ended; the products are available in the pharmaceutical forms in demand by the market, such as immediate release tablets, modified release tablets, pessaries, creams, etc.

### Consolidation of the leadership position in the anti-infectives segment of the market

In addition, Antibiotice aims at consolidating its leadership position in the systemic use anti-infectives and ointments and suppositories segments. Thus, in 2012, the company was granted the marketing authorization for, launched the first anti-infective product (in two strengths) from the carbapenems group and completed the research for three new topical products.

### Outlook for the research in Antibiotice

The company's long-term research program has in view projects focused on the development of generic drugs in modern pharmaceutical forms, such as tablets with prolonged release, oro-dispersible tablets, capsules filled with pellets, or fixed-dose combination tablets (polypills). The last-generation technical equipment of the R&D Center as well as the interdisciplinary team of specialists with certificates in research and doctor's degree in all the fields required by drug research (i.e. medicine, pharmacy, chemistry, biology) will allow the company to expand and develop the contract research activities (pharmaceutical formulation and clinical trials).

### Modernization and streamlining of the manufacturing lines

Antibiotice will keep modernizing and streamlining the manufacturing lines that will provide the basis for future external partnerships.

In line with the overall objectives of the company, in 2012, investments with a major impact on the company development were made. The most significant ones were:

- investments made to enhance labor productivity, reduce energy losses, and increase operational reliability;
- investments in an automated computer-based data monitoring system for Nystatin biosynthesis;
- investments in state-of-the-art equipment for product quality testing;
- investments for GMP and FDA requirements compliance.

## Turning the portfolio to good account

### Strategies for an active presence in the domestic market

In 2012, Antibiotice continued to organize and develop the marketing operations for the national market aiming at expanding and selling a varied portfolio of products from therapeutic groups currently in demand.

The strategy of the company consisted in the orientation of both the selling structure and the promotion policy towards therapeutically valuable medicines to increase presence of Antibiotice's products in pharmacies.

The company's portfolio was supplemented in 2012 with seven new products belonging to the therapeutic groups which Antibiotice intends to strategically develop over the following years. The future portfolio will address particularly the people in Romania, a population characterized by an increased rate of aging (according to the statistics, there are 5,500,000 retired people, i.e. approximately 29% of the population), multiple disorders (with high incidence, mostly chronic, such as cardiovascular diseases, central nervous system disorders, cancer, diabetes) and last but not least, with low and middle income.

### The 4<sup>th</sup> in the ranking of generics and OTCs manufacturers in Romania

In 2012, Antibiotice was ranked fourth among the 254 producers of generics and OTCs in Romania, with a market share of 6.6%.

### Dynamic growth in the international markets

One of the piers of the company's medium and long-term development strategy is business internationalization. The actions taken in 2012 were directed towards achieving the objectives corresponding to such pier, namely the enhancement the company's presence in the external markets by accessing new markets and registration of new products in the existing markets, positioning the company as a world leader in the market of the API Nystatin, and identification of strategic partnerships in the main markets of interest.

Year 2012 brought an increase in the international sales of active ingredients. The quantitative analysis of Nystatin sales correlated with the available data on the world market for this product place Antibiotice first among the world Nystatin manufacturers. This achievement is equally a recognition of the quality of the active ingredient produced by Antibiotice and the fruition of all the unceasing efforts made to promote the company in the international market.

In parallel, in 2012, the exports of finished pharmaceutical products increased significantly as a result of the consolidation of the existent commercial relationships, focus on strategic markets and the receiving of marketing authorizations for new products.

## Consolidation of trust in effective partnerships

As the worldwide competition has enhanced and the speed of change in the pharmaceutical industry increased, valuable partnerships have become a priority in the company's strategy.

Antibiotice is consistently looking for developing long-term business relationships with companies that are able to provide products of certified quality, modern services and opportunities for developing new products, which generate surplus value to the end users.

The partners interested in working with Antibiotice are supplied with expertise and necessary means for:

- contract manufacturing of pharmaceutical products in 5 pharmaceutical forms on GMP certified production lines;
- procurement of raw materials and materials from authorized suppliers with standard-conforming documentation;
- procurement of therapeutically valuable finished products (antiinfectives, CNS drugs, cardiovascular drugs, oncology drugs) to supplement the strategic portfolio of the company;
- development of new pharmaceutical products using the company's own manufacturing lines;
- representation of the company in the international markets in order to promote and distribute Nystatin and finished products.

## Investing in knowledge and competence

Enhancement of the level of qualification and development of the professional skills of the employees to meet the requirements of the extremely competitive pharmaceutical market are strategic objectives for the company.

Thus, in 2012, the process of ongoing training of the specialists by attending different courses and seminars continued, in tight correlation with the company's medium-term development strategy and the changes to the Community legislation. Moreover, in the same year, the 3rd edition of "Summer School a+" took place. The courses are designed for both personal and professional development of the employees, and to attract valuable candidates for the job openings in research, quality control, marketing, etc.

In 2012, to the purpose of stimulating innovation and creativity, Antibiotice started the project "Ideas are cost-free". Such project includes a complex and precise system for collecting, selection and quantification of new ideas generated and implemented in all the activities of the company, the results of which will be seen starting with 2013.

## 04

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## Company's 2012 achievements

### Strategic evolution

- **Consolidation of its leadership position in the segment of hospital anti-infectives (i.e. powders for injection)** – Increase of the market share by value from 57.7% in 2011 to 59.9% in 2012
- **Maintaining the leadership position in the suppositories market** both in terms of volume (market share: 45.1%) and value (market share: 27.5%)
- **Maintaining the leadership position in the ointments market** in terms of volume (market share: 30.6%)
- **Consolidation of the leadership position in the powders for injection market** both in terms of consumption (market share: 72.8%) and value gained (market share: 18.9%)
- **Consolidation of its position in the top 3 most valuable pharmaceutical corporations, the hospital segment** (market share: 6.95%)
- **Introduction of two new therapeutic classes in the company's product portfolio**, namely the Genito-urinary system and Antineoplastic and immunomodulating agents, which are in ongoing growth in the pharmaceutical market; the y-o-y increases reported for such classes were 12.8% and 3.9% respectively
- **Refreshing of the product portfolio** in 2012 by assimilating **seven new products** from the therapeutic classes Antibiotice took on to strategically develop in the following years, namely the *Antiinfectives*, *Cardiovascular system*, *Nervous system*, and *Antineoplastic agents*.
  - **Anastrozol Atb®** 1 mg, tablets, Antineoplastic and immunomodulating agents
  - **Bicalutamida Atb®** 50 mg, tablets, Antineoplastic and immunomodulating agents

- **Eficef<sup>®</sup>** 100 mg, capsules, Antiinfectives for systemic use
- **Lactic Atb<sup>®</sup>**, pessaries, Genito-urinary system and sex hormones
- **Letrozol Atb<sup>®</sup>** 2.5 mg, tablets, Antineoplastic and immunomodulating agents
- **Paroxetina Atb<sup>®</sup>** 20 mg, tablets, Nervous system
- **Trimetazidina Atb<sup>®</sup>** 35 mg, tablets, Cardiovascular system

● **Strengthening company's presence in the international market:**

- export turnover amounting to over USD 20 million
- export increase by 10% y-o-y
- ranking first in nystatin (active ingredient) production in the world
- expansion of the international presence by exporting the company's products to over 60 markets
- 35 new marketing authorizations granted for the external markets
- increase of the number of international partners to 120 from 100 in 2011

● **Assimilation of new products into the company's portfolio**

- **In 2012, Antibiotice was granted Marketing Authorisations for 3 new drug products, as a result of the company's long-term partnerships:**
  - **Irinotecan Atb<sup>®</sup>** 20 mg/ml, concentrate for solution for infusion – antineoplastic agents
  - **Meropenem Atb<sup>®</sup>** 500 mg, powder for solution for injection/infusion – antiinfectives for systemic use, subgroup of carbapenems
  - **Meropenem Atb<sup>®</sup>** 1000 mg, powder for solution for injection/infusion – antiinfectives for systemic use, subgroup of carbapenems
- **The application dossiers for 17 new drug products in various pharmaceutical forms were completed:**
  - tablets with immediate release (10 products),
  - tablets with prolonged release 1 product),
  - pessaries (3 products),
  - topicals (3 products).

## Top 20 most renowned Antibiotic trademarks

Trademark	International Nonproprietary Name	Therapeutic class + Pharmaceutical form	Main competitors	Sales in 2012* (RON)
<b>Cefort®</b>	ceftriaxonum	Anti-infectives for systemic use; other beta-lactam antibiotics, antibacterials; injectables	Oframax (Ranbaxy) Seftrion (E.I.P.I.CO.) Medaxone (Medochemie)	48,509,916 <b>1<sup>st</sup> place**</b>
<b>Eficef®</b>	cefiximum	Anti-infectives for systemic use; other beta-lactam antibiotics, antibacterials; capsules	Sole producer	9,160,605
<b>AmoxiPlus®</b>	amoxicillinum + acidum clavulanicum	Anti-infectives for systemic use; beta-lactam antibacterials, penicillins injectables; tablets	Augumentin (GlaxoSmithKline) Amoksiklav (Novartis)	8,795,708
<b>Colistină Antibiotice®</b>	colistini sulfas	Anti-infectives for systemic use; other antibacterials; injectables	Sole producer	8,318,937
<b>Ceftamil®</b>	ceftazidimum	Anti-infectives for systemic use; other beta-lactam antibacterials; injectables	Fortum (GlaxoSmithKline)	7,449,510 <b>1<sup>st</sup> place**</b>
<b>Nidoflor®</b>	nystatinum + neomycini sulfas + triamcinoloni acetonidum	Dermatologicals; corticosteroids in combination with antibiotics; ointments	Pimafucort (Astellas Pharma)	6,946,872 <b>1<sup>st</sup> place**</b>
<b>AmpiPlus®</b>	ampicillinum + beta-lactamase inhibitor	Anti-infectives for systemic use; beta-lactamic antibacterials, penicillins injectables	Sole producer	6,517,039
<b>Clafen®</b>	diclofenacum	Musculo-skeletal system; nonsteroidal anti-inflammatory/ antirheumatic drugs; tablets, ointments, suppositories	Diclac/Voltaren (Novartis) Diclofenac/Dicloard (Ranbaxy) Diclorem (Schiapparelli)	5,767,273 <b>4<sup>th</sup> place**</b>
<b>Piafen®</b>	metamizolum natricum + pitofenone Hcl + fenpipramide bromomethylate	Alimentary tract and metabolism; antispastic – analgesic combination; tablets	Quarelin (Sanofi) Algifen (Sanofi)	5,340,720 <b>1<sup>st</sup> place**</b>
<b>Novocalmin®</b>	metamizolum natricum	Central nervous system; analgesics and antipyretics tablets; suppositories	Algocalmin (Sanofi) Algozone (Labormed) Alindor (Laropharm)	5,286,578 <b>2<sup>nd</sup> place**</b>
<b>Hemorzon®</b>	tetracyclinum + hydrocortisonum + benzocainum	Cardiovascular system; topical anti-hemorrhoids; ointments; suppositories	Procto Glyvenol (Novartis) Proctolog (Pfizer) Ultraproct (Bayer Healthcare AG)	5,110,267 <b>1<sup>st</sup> place**</b>
<b>Lisinopril Antibiotice®</b>	lisinoprilum	Cardiovascular system; ACE inhibitors; tablets	Ranolip (Ranbaxy) Tonolysin (Gedeon Richter) Lisinopril Sandoz (Novartis)	4,229,206 <b>2<sup>nd</sup> place**</b>
<b>CiproQuin®</b>	ciprofloxacinum	Anti-infectives for systemic use; antibacterial quinolones; tablets	Ciprinol (KRKA D.D.) Cuminol (Gedeon Richter) Cifran (Ranbaxy)	3,685,476 <b>3<sup>rd</sup> place**</b>
<b>Bisotens®</b>	bisoprololum	Cardiovascular system; beta blocking drugs tablets	Concor (MERCCK KGaA) Bisoblock (Actavis) Bisogamma (Worwag Pharma)	2,819,766 <b>2<sup>nd</sup> place**</b>
<b>Novogast®</b>	omeprazololum	Alimentary tract and metabolism; drugs for peptic ulcer and gastro-esophageal reflux disease; capsules	Omez (DR. REDDY'S LAB.) Omeran (GlaxoSmithKline) Omeprazol (Ranbaxy)	2,336,320 <b>6<sup>th</sup> place**</b>
<b>Cicloserină Antibiotice®</b>	cycloserinum	Anti-infectives for systemic use; antituberculosis preparations; capsules	Sole producer	1,968,455
<b>Lorine®</b>	acidum risedronicum	Musculo-skeletal system; drugs influencing bone structure and mineralization; tablets	Actonel Săptămânal (Sanofi) Risendros (Sanofi) Risedronat TEVA (Teva)	1,779,727 <b>2<sup>nd</sup> place**</b>
<b>Neopreol®</b>	prednisolonum + neomycini sulfas	Dermatologicals; corticosteroids in combination with antibiotics; ointments	Oximed (Mebra) Fucidin h (Leo pharma) Fenistil (Novartis)	1,724,005 <b>2<sup>nd</sup> place**</b>
<b>Almacor®</b>	lamlodipinum	Cardiovascular system; vascular selective calcium channel blockers; tablets	Norvasc (Pfizer) Tenox (KRKA D.D.) Amlohexal (Novartis)	1,721,193 <b>5<sup>th</sup> place**</b>
<b>Nolet®</b>	neivololum	Cardiovascular system; beta blockers; tablets	Nebilet (MENARINI) Nebivolol Actavis (Actavis) Nebivolol Teva (Teva)	1,645,980 <b>5<sup>th</sup> place**</b>

\* calculated based on the pharmacy purchase price; source: Cegedim Romania

\*\* the position held by Antibiotice on the reference market

## Top drugs for which Antibiotice is sole producer

Brand	International Nonproprietary Name (INN)	Therapeutical class + Pharmaceutical form	Sales in 2012* (RON)
<b>Eficef®</b> 200 mg, 100 mg	cefiximum	Anti-infectives for systemic use; capsules	9,160,605
<b>Colistină Antibiotice®</b> 1,000,000 U.I.	colistinum	Anti-infectives for systemic use; injectables	8,318,937
<b>Potassium Penicillin</b> 1,000,000 U.I. and <b>Natrium Penicillin</b> 400,000 U.I. and 1,000,000 U.I.	benzylpenicillinum	Anti-infectives for systemic use; injectables	7,261,779
<b>Nidoflor®</b> 15 g	nystatinum + neomycini sulfas + triamcinoloni acetonidum	Dermatologicals; cream	6,946,872
<b>AmpiPlus®</b> 1.5 g	ampicillinum + sulbactamum	Anti-infectives for systemic use; injectables	6,517,039
<b>Oxacillin</b> 500 mg, 1000 mg	oxacillinum	Anti-infectives for systemic use; injectables	3,902,644
<b>Nystatin</b> 500,000 U.I.	nystatinum	Anti-infectives for systemic use; tablets	2,710,175
<b>Tetracyclin HCL</b> 12 g	tetracyclinum	Dermatologicals; ointments	2,658,637
<b>Kanamycin S</b> 6 g	kanamycinum	Sensitive organs; ophthalmic ointments	2,325,147
<b>Cicloserină Antibiotice®</b> 250 mg	cycloserinum	Anti-infectives for systemic use; capsules	1,968,455
<b>Moldamin</b> 1,200,000 U.I.	benzathini benzylpenicillinum	Anti-infectives for systemic use; injectables	1,908,585
<b>Neopreol®</b> 40 g	prednisolonum + neomycini sulfas	Dermatologicals; ointments	1,724,005
<b>Pyrazinamid</b> 500 mg	pyrazinamidum	Anti-infectives for systemic use; tablets	1,426,158
<b>Ampicillin</b> 250 mg	ampicillinum	Anti-infectives for systemic use; injectables	1,391,374
<b>Cutaden®</b> 40 g	ichtiolum + zinci oxydum + hamamelis virgiana extractum	Dermatologicals; creams	1,344,474
<b>Strevital®</b> 1 g	streptomycinum	Anti-infectives for systemic use; injectables	1,048,043
<b>Sinerdol® ISO</b>	rifampicinum + isoniazidum	Anti-infectives for systemic use capsules	900,522
<b>Ceftamil®</b> 2 g	ceftazidimum	Anti-infectives for systemic use powder for injection, tablets	652,147
<b>Sinerdol®</b> 300 mg	rifampicinum	Anti-infectives for systemic use capsules	465,945
<b>Lisinopril Antibiotice®</b> 40 mg	lisinoprilum	Cardiovascular system tablets	454,186
<b>Izoniazidă Atb®</b> 100 and 300 mg	isoniazidum	Anti-infectives for systemic use; injectables	441,658
<b>Aceclofen®</b>	diclofenacum + paracetamolium	Musculo-skeletal system; suppositories	414,172
<b>Ethambutol</b> 250 mg	ethambutolum	Anti-infectives for systemic use; tablets	3,179

\* calculated based on the pharmacy purchase price; source: Cegedim Romania

## Financial evolution

In 2012, revenues from sales went up by 8.6%, from RON 280.02 million in 2011 to RON 304.09 million in 2012, as a result of actions carried out in all the company's activities with a view to strengthening business.

Operating profit reported an increase of 36.23%, by touching the value of RON 41.8 million as the consequence of the permanent sprint entire ruling team and all employees to reduce costs at all times by optimizing processes so as to improve cost structure.

The net profit recorded the value of RON 27.11 million, 34% higher than in the previous year.

The main diagnostic indicators of the company highlight the financial equilibrium and the ongoing concern for business efficiency:

### Evolution of the main economic and financial indicators

RON	Dec 31, 2012	Dec 31, 2011	2012/2011
<b>Sales revenue</b>	<b>304,086,833</b>	<b>280,020,922</b>	<b>8.59%</b>
<b>Gross profit</b>	<b>32,459,037</b>	<b>26,314,410</b>	<b>23.35%</b>
<b>Net profit</b>	<b>27,110,836</b>	<b>20,196,416</b>	<b>34.24%</b>
<b>Non-current/ fixed assets</b>	<b>203,351,125</b>	<b>212,858,929</b>	<b>-4.47%</b>
<b>Current assets, of which:</b>	<b>310,966,804</b>	<b>274,128,692</b>	<b>13.44%</b>
– receivables	256,986,254	226,845,657	13.29%
– inventory	47,973,857	41,943,038	14.38%
<b>Total debts, of which:</b>	<b>167,769,395</b>	<b>160,299,615</b>	<b>4.66%</b>
– trade debts	58,963,493	57,479,626	2.58%
– bank loans	92,290,294	82,416,576	11.98%
<b>Total assets</b>	<b>514,317,929</b>	<b>486,987,621</b>	<b>5.61%</b>
<b>TOTAL EQUITY</b>	<b>346,548,531</b>	<b>326,688,006</b>	<b>6.08%</b>
Average number of employees	1,465	1,450	1.03%
<b>Labor productivity</b>	<b>207,568</b>	<b>193,118</b>	<b>7.48%</b>
<b>Liquidity indicators</b>			
Overall liquidity	1.85	1.71	8.39%
Current liquidity	1.57	1.45	8.23%

### Evolution of the main economic and financial indicators

		Dec 31, 2012	Dec 31, 2011	2012/2011
<b>EBITDA (RON)</b>	= earnings before interest, taxes, depreciation and amortization	<b>62,267,316</b>	<b>49,118,539</b>	<b>26.77%</b>
<b>EBIT (RON)</b>	= earnings before interest and taxes	<b>34,823,617</b>	<b>28,864,134</b>	<b>20.65%</b>
<b>ROE (return on equity)</b>	= net income / shareholder's equity	<b>10.0%</b>	<b>8.8%</b>	<b>13.73%</b>
<b>ROA (return on assets)</b>	= net profit / total assets	<b>5.3%</b>	<b>4.1%</b>	<b>27.10%</b>
<b>EPS (RON/share)</b>	= net profit / share	<b>0.05</b>	<b>0.04</b>	<b>34.24%</b>
<b>Debt ratio</b>	= total liabilities / total assets	<b>32.6%</b>	<b>32.9%</b>	<b>-0.99%</b>
<b>NET PROFIT RATIO</b>	= profit / net returns	<b>8.9%</b>	<b>7.2%</b>	<b>23.61%</b>
<b>Number of shares (million)</b>		<b>568</b>	<b>568</b>	<b>0.00%</b>





## Stock evolution

In 2012, the company's subscribed and paid-up capital amounted to RON 56,800,710 represented by 568,007,100 shares with a nominal value of RON 0.1000.

Antibiotice S.A. has a strong ownership, the major shareholder being the Ministry of Health.

The company's ownership structure as of July 20, 2012 (according to the latest database held by Antibiotice) is, as follows:

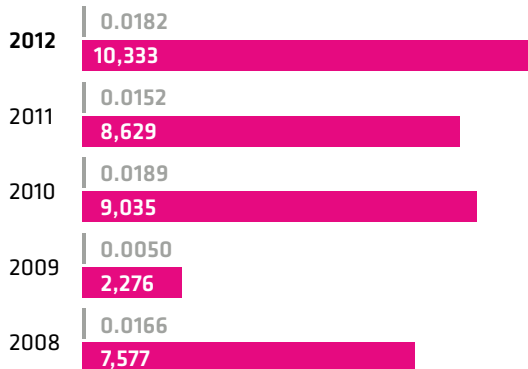
### I. Investors:

- Ministry of Health\*\* - **53.0173%**,
- S.I.F. Oltenia\*\* - **10.0954%**
- Broadhurst Investments Limited - **4.1977%**
- S.I.F. Transilvania - **4.0356%**
- ING Privately Managed Pension Fund/ ING Pensions S.A.F.P.P. - **2.1104%**
- Romanian Oportunities Fund - **1.9189%**
- S.I.F. Banat-Crisana S.A. - **1.3148%**
- A-Invest - **0.6179%**
- Aripi Privately Managed Pension Fund/ Generali S.A.F.P.P. - **0.6514%**
- Polunin Discovery Funds - Frontier Markets Fund - **0.6514%**
- Other natural persons and legal entities - **21.3893%**.

### II. Shareholders by category:

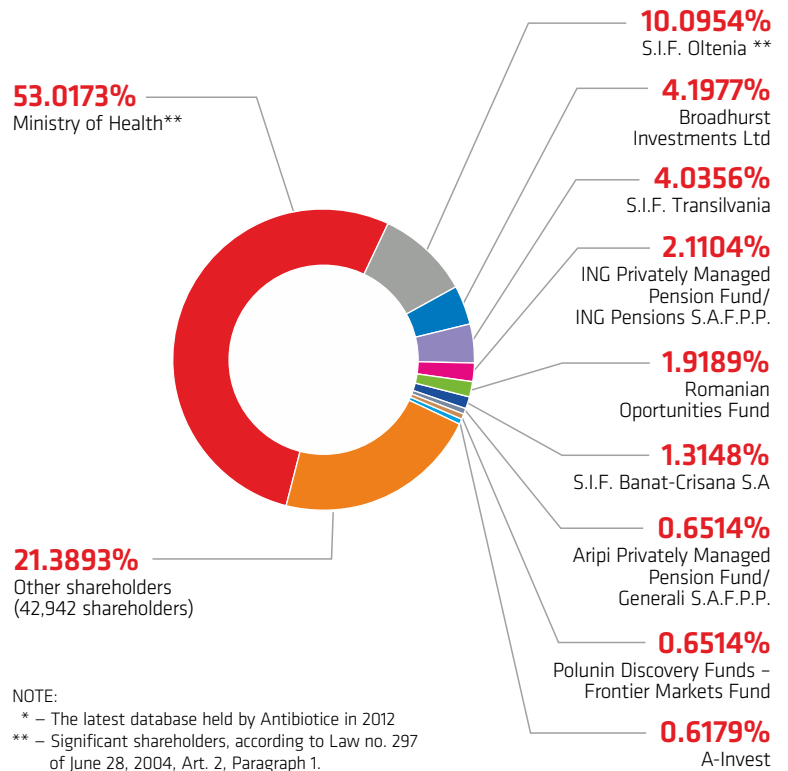
- Legal entities - **85.7023%**
- Natural persons - **14.2977%**

## Amount of gross dividends and gross dividend per share



- Gross dividend (RON/share)
- Amount of gross dividends (thousand RON)

## Shareholders breakdown by investors on July 20, 2012 \*

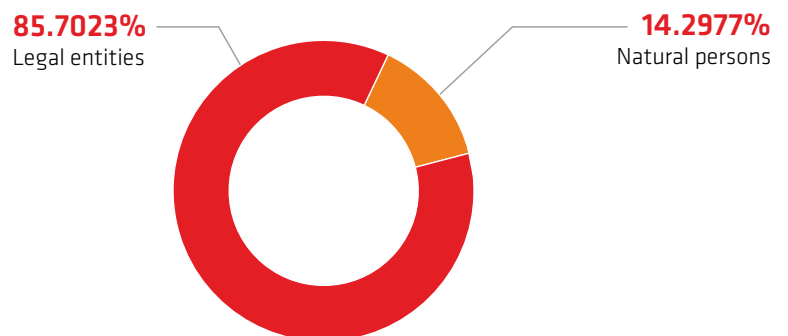


NOTE:

\* - The latest database held by Antibiotice in 2012

\*\* - Significant shareholders, according to Law no. 297 of June 28, 2004, Art. 2, Paragraph 1.

## Ownership breakdown by category of shareholders on July 20, 2012 \*



The decrease of the gross dividend/share value for 2009, as compared to 2008, is a result of financial and economic crisis effects propagated also at the company level.

## Dividend history (2007–2011)

Period	Net dividends						End of dividend payment	
	Due	Paid dividends				Outstanding Dec 31, 2012		
		by Dec 31 2011, RON	Jan 1 ÷ Dec 31 2012, RON	Total, RON	Total, %	RON		%
2007	13,106,611	11,887,890	1,911	11,889,801	91	1,216,810	9	Jan 31, 2012
2008	7,222,070	6,532,772	4,387	6,537,159	91	684,911	9	June 24, 2012
2011	8,204,647	–	7,362,821	7,362,821	90	841,826	10	Payment in progress

During 2012, the total amount of paid dividends for the fiscal years 2007, 2008 and 2011 was RON 7,369,119

For the above years, the dividends were distributed directly from the company's headquarters, by bank transfer/wire and by postal order.

For years 2007 and 2008, the company distributed dividends exceeding the term prescribed by law. The payment of dividends relative to these years stopped, and the deadline for dividend payment has been established according to the legislation in force, art. 67 Law 31/1990, section 5, republished.

## Antibiotic on the securities market

Throughout 2012, stock sales took place in all fields of activity, including the pharmaceutical one, and neither the fundamental analysis nor the profits obtained were taken into account. In Eastern and Central Europe, prices of the pharma shares were maintained low, reaching levels very attractive to investors.

Many of the shares listed on the Bucharest Stock Exchange, including Antibiotic shares are undervalued so that, from this perspective, they present a high growth potential. The undervalued price was mainly influenced by the negative news on the developments of the international financial markets.

16 years after the first transaction, about 43,000 shareholders watch closely the evolution of ATB shares on the Bucharest Stock Exchange. Although undervalued due to the world economic crisis, the ATB shares enjoy the attention of investors who are aware of and have confidence in the market potential of Antibiotic company.

In recent years, ATB shares have followed a trend imposed by the movements arising on the capital markets.

In 2012, the minimal price of ATB shares has reached the lowest value on July 2 (0.3300 RON/share), in decrease by 8.66% as compared to last year's figure. The share price reached a maximum of 0.4400 RON/share (February 17), down by 31% as compared to 2011.

In comparison with 2011, the BET-C Index (BET Composite) which includes the shares of all companies listed on the BSE, except for the

Financial Investment Funds (SIFs), increased by 6% in 2012, so that the ATB shares reached, in December, a maximum quota of 0.76% of this index.

The Index BET XT (blue-chip index which mirrors the price evolution of the most liquid 25 companies traded on the regulated market, including SIFs), an active support for derivative financial instruments and structured products, also recorded a 20% increase compared to 2011, the ATB shares attaining, at the beginning of the year, a maximum quota of 1.02% of this index.

Since July, the Bucharest Stock Exchange (BSE) has launched a new index – the BK BET index (Bucharest Exchange Trading Benchmark Index). This is a benchmark-type index calculated as a weighted price index of free-float capitalization of the most active companies traded on the BSE regulated market. The ATB shares reached in September a maximum quota of 4.78% of this index.

At the end of 2012, the stock capitalization of Antibiotic Iasi amounted to RON 213,798 thousand.

Paid dividends



## Antibiotic shares – ATB / Total Market

	2011	2012
Number of shares	568,007,100	568,007,100
Market capitalization (thousand RON)*	221,523	213,798
Market capitalization (thousand EUR)*	51,282	48,276
Market capitalization (thousand USD)*	66,338	63,678
Total amount traded (million RON)	17	10
Number of shares traded	33,430,079	24,002,033
Opening price (RON/share)	0.6200	0.3974
Highest price (RON/share)	0.6420	0.4400
Lowest price (RON/share)	0.3613	0.3300
Price at the end of the year (RON/share)	0.3900	0.3764
Average price (RON/share)	0.5209	0.3985
Earning/share (RON/share)**	0.0357	0.0477
Gross dividend /share (RON/share)	0.0152	0.0182
Dividend yield***	3.90%	4.83%
Rate of dividend distribution ****	43%	38%

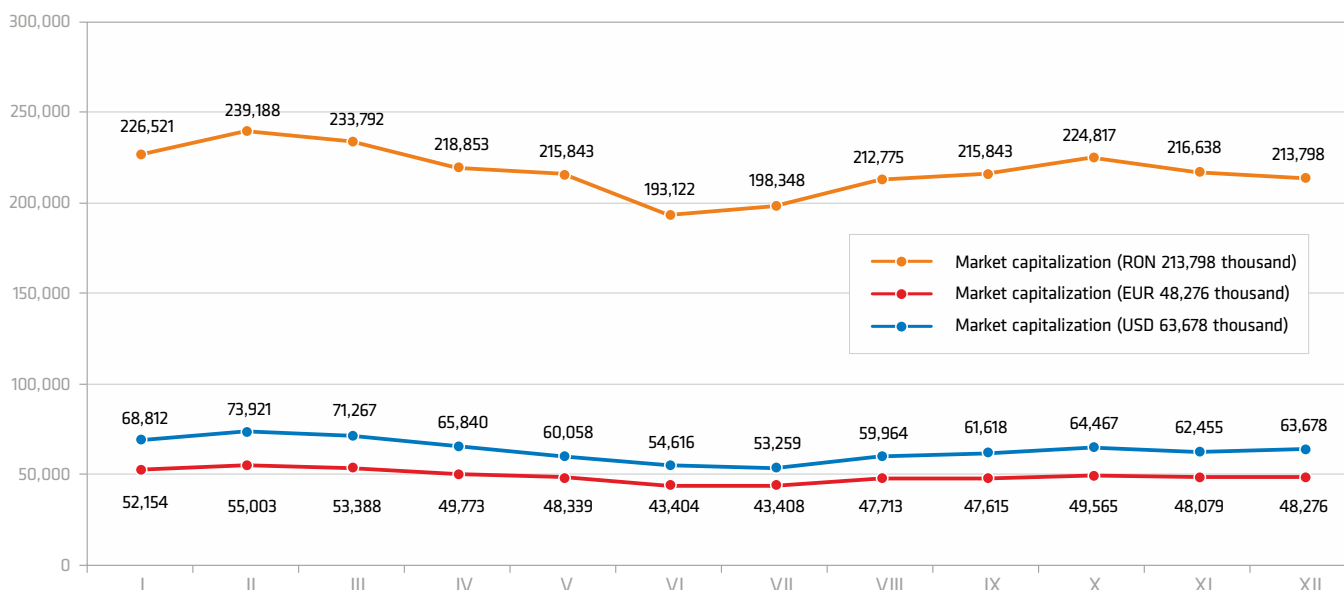
\* Calculation based on the share price on the last trading day of that year

\*\* The calculation of the earning per share is based on the net profit of each year

\*\*\* Dividend per share / share price on the last trading day of each year

\*\*\*\* The dividend distribution rate = (total number of shares x gross dividend per share) / total net profit.

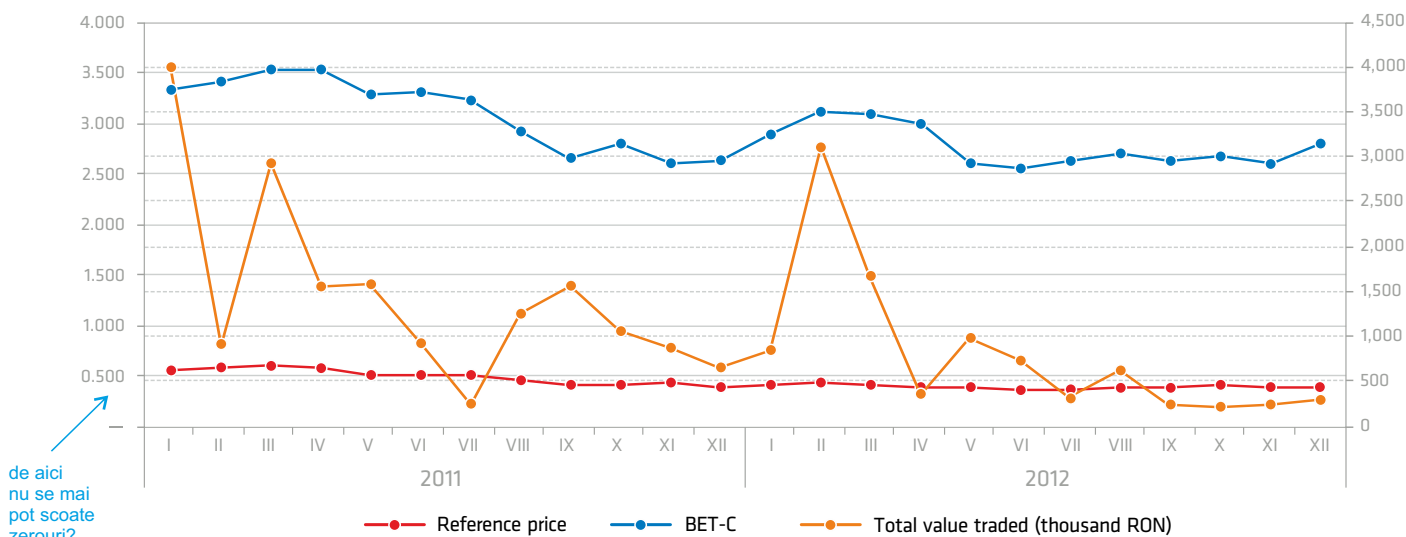
### Evolution of market capitalization in 2012



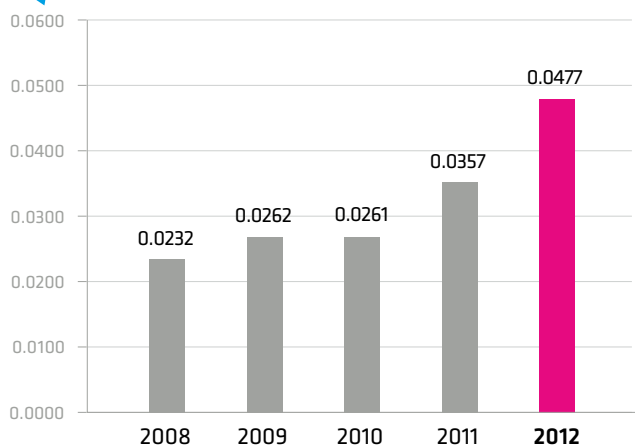
thousand RON

### Evolution of ATB shares and BET-C index

RON



### Earning per share (RON/share)



Antibiotic is present, on average, among the first 11 companies included in the BET-C index, among the first 14 companies of the BET-XT index and the first 15 companies belonging to the BET-BK structure.

The investors who in 2012 took advantage of the opportunity provided by the peak of ATB shares price (0.4400 RON/share), achieved a return on investment of 22% as compared to the investment made by minimum price in the previous year.

Throughout 2012, a number of 24,002,033 shares were traded, amounting to RON 9.6 million (EUR 2.9 million; USD 3.8 million), with an average price of 0.3985 RON/share.

# 05

## Actions and results in 2012

### Antibiotice defines its research-based future

Strategic investments in research made by Antibiotice in the recent years have resulted in the establishment of a modern Research & Development Center, that gives the company the opportunity to develop and complete annually over 15 new research projects.

The R&D Center is a state-of-the-art facility with an interdisciplinary team consisting of over 70 specialists (11 of them with a PhD in chemistry, pharmacy, medicine and biotechnologies) highly experienced in pharmaceutical formulation, physico-chemical analyses, clinical evaluation and international regulations in the field of medicines.

Carrying out the medicines research in an integrated manner, the R&D Center enhances the portfolio diversification for all the manufacturing lines, depending on the market trends. It also provides the constant quality improvement of traditional medicines in order to meet the latest legislative requirements in the field and adapt them to the quality standards required for their registration on various foreign markets.

#### Cardiovascular drugs hold the largest share in the range of products newly introduced in research

In 2012, the new R&D Center started 20 projects on developing new pharmaceuticals from various therapeutic classes, as follows:

- cardiovascular medicines (7 pharmaceuticals in 13 strengths),
- medicines intended to treat diseases of the central nervous system (a product in two strengths),
- antibacterial medicines (a product in two strengths),
- gynecologic medicines (3 products),

- dermatologicals (4 products),
- dietary supplements (4 products).

Having analytical research laboratories equipped with the latest generation equipment, as well as a new research pilot plant for solid pharmaceutical forms, in 2012 the research team completed the market authorization documentation for 17 new medicines in various pharmaceutical forms:

- immediate-release tablets (10 products),
- extended-release tablets (one product),
- pessaries (3 products),
- topical medicines (3 products).

Antibiotice has also improved the formulas and manufacturing technologies for 4 medicines in order to meet the latest requirements of the international pharmacopoeias and/or to register the products on foreign markets.

The generic medicines made by the research team specialized in formulation are tested from the viewpoint of effectiveness and safety in administration by clinical bioequivalence trials performed by the company's Drug Evaluation Center (an integral part of the R&D Center) which was GLP reauthorized by the National Agency for Medicines and Medical Devices in 2012.

10 *in vivo* studies (bioequivalence clinical studies) and more than 50 *in vitro* studies (dissolution profiles and biowaiver studies) were conducted within the clinical research, in compliance with the latest European regulations in the field.

The Regulatory Affairs Department has continued its specific activities for the registration of new products in portfolio, reauthorization of existing products and registration of Antibiotice medicines on the external markets.

20  
new research  
projects launched  
in 2012

**3 new MAs**  
obtained for the  
Romanian market

**35 new MAs**  
obtained for the  
international markets

In this context, in 2012, the company obtained 3 marketing authorizations in Romania for medicines belonging to oncology, antiinfectives for systemic use and carbapenem classes.

#### Marketing authorizations obtained in 2012:

- **Irinotecan Atb®** 20 mg/ml, concentrate for solution for infusion (Oncology)
- **Meropenem Atb®** 500 mg, powder for solution for injection/infusion (antiinfectives for systemic use, carbapenem class)
- **Meropenem Atb®** 1000 mg, powder for solution for injection/infusion (antiinfectives for systemic use, carbapenem class)

In addition, Antibiotice obtained 35 marketing authorizations in 12 countries in Europe, Asia and Africa.

#### Antibiotice's perspectives on research

The Research & Development Center conducts projects on developing both generic medicines in modern pharmaceutical forms, such as: modified-release tablets, capsules, capsules with pellets, polypil type fixed dose tablets, etc. and biotechnological research, whose results will be materialized in the years to come.

Performing the research in an integrated system (pharmaceutical development, clinical testing), the R&D Center ensures the renewal of the company's portfolio with efficient and safe generic drugs according to the latest legislative requirements in the field.

The investments in research carried out by Antibiotice in the recent years, regarding both facilities and human resources, in conjunction with the latest research results, constitute a guarantee of the portfolio's and implicitly of the company's development as a whole in the coming years.

#### Pharmacovigilance

Through the work of the Pharmacovigilance Department, a rigorously regulated domain internationally, Antibiotice continuously monitors the safety of drugs in its portfolio. The aim of assessing the risk/benefit ratio is achieved through collecting, investigating and reporting to the national and international regulatory bodies any information concerning the possible adverse reactions of the company's medicines.

Antibiotice sustains both doctors and patients with professionalism and dedication. The physicians from the Pharmacovigilance Department are well-informed and trained at international standards both as a result of

the exchange of experience with specialists from other countries, and as a result of the continuous self-study. Antibiotice continuously provides updated information related to the safe use of the products in its portfolio through communication and information channels, available 24 hours a day, every day of the week.

By maintaining the connection to the Eudra-vigilance, the European pharmacovigilance network, our company guarantees the transparency and accurate information on the safety of Antibiotice medicines.

The month of July 2012 brought new regulations in this field, requiring transparent policy as regards pharmacovigilance. In this context Antibiotice sent its portfolio to be added to the international database XEVMPD (Extended Medicinal Product Dictionary). This is a list containing all the identifiable medicines authorized and registered in the EU. Based on this dictionary, the regulatory authorities can coordinate and monitor the safety of medicinal products in the European Union.

According to the legislation in force, Antibiotice's pharmacovigilance department ensures the identification and collection of any suspected adverse event occurred anywhere in the world, as a result of administering any drug from its portfolio. It also analyzes the global data, assesses the side effects risks according to the literature data, alerts and intervenes in case of adverse reactions or if a change of the drug profile is observed. Specific documents must be drafted: periodical reports on safety, risk management plans, continuous update of the system. This activity involves drafting specific documents: periodic safety reports, risk management plans, continuous update of the pharmacovigilance system (PSMF), product quality reviews, continuous update of documents on product information, post-certification clinical studies protocols, permanent updating of the database with safety information.

This way, pharmacovigilance ethically offers protection for patients, for our company, for health in general.

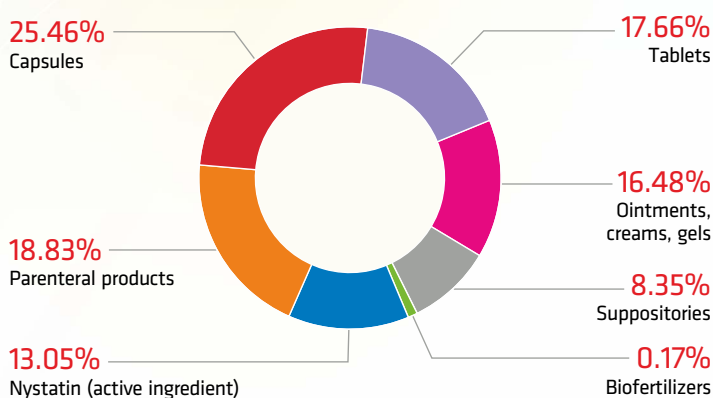


**21.2%** - of the total 2012 production (Nystatin and finished dosage forms) are accounted for by the production for export abroad (in terms of value)

**In 2012, Antibiotic produced:**

- **508 M.U.** formulated as tablets, capsules, parenteral products, ointments, creams, gels, suppositories;
- **68 tons** of bulk active ingredient (Nystatin);
- **105 tons** of biofertilizers

**2012 Production (in terms of value)**



**Manufacture**

**Revamping and streamlining the manufacturing lines**

Antibiotic manufactures **143 medicinal products** in five pharmaceutical forms, for local and foreign partners.

The quality of our products is backed up by processes compliant to the Good Manufacturing Practice norms, all eight manufacturing lines of the company being GMP certified.

The implementation of all regulatory requirements and an evaluation of the quality management system by regulatory authorities and clients ensures the high-quality, efficacy and safety of the medicines produced by Antibiotic.

**Goals achieved in 2012 by the units in charge of production and quality:**

1. Parenteral products manufacture for foreign companies, based on control and manufacturing contracts. The exported production of parenteral products accounted for 31.5% of the total value of products intended for foreign markets.
2. At the tablet manufacturing plant the process of adapting the tableting and primary packaging technologies to the equipment purchased in 2011 continued. At the end of the year, a contract for the acquisition of a secondary packaging equipment (blisters packaged in cardboard folders) was signed. Such upgrades will allow in the future the assimilation of a larger number of products developed by in-house research as well as the increase of the production designed for external regulated markets requiring FDA or EC approval.
3. Cutting down costs for raw-materials by optimizing the manufacturing formulas and identifying new sources for the excipients used in the tablet, ointment and suppository manufacture technology.
4. Cutting down the utilities consumption, by a careful management, in all manufacturing plants.
5. Increasing Nystatin production per batch by 2% against the forecast production.

6. Launching on the market new products from the following therapeutic classes:

- anti-infectives for systemic use: Eficef® (Cefixime) 100 mg, capsules;
- cosmetics: Lactic Atb® (lactic acid), pessaries and Cicatrol® (silver sulfadiazine), regenerating cream.

7. The GMP audit on the parenteral product line was conducted by the National Agency for Medicines and Medical Devices (NAMMD) together with the Pharmaceutical Inspection Convention Scheme (PIC/S) during June 5-7, 2012. The inspection result was favourable, accordingly the GMP certification for the audited line and activities was maintained, as well as the operational/import authorization.

8. On October 29, 2012 the NAMMD conducted the following: the inspection for the reauthorization of the secondary packaging line for injectable cephalosporins, the GLP recertification for the bioanalytical laboratory within the Center for Drug Evaluation (CDE), as well as the audit of the CDE clinical unit. No critical or major non-conformities were reported.

9. The inspection of the National Sanitary Veterinary and Food Safety Authority was conducted in view of the GMP reauthorization of the veterinary products manufacturing lines. The ANSVSA also audited, between November 6 and 9, 2012, the following facilities: the manufacturing lines for Nystatin feed grade, the aseptically prepared products (parenteral products, ointments) and non-sterile products (ointments, tablets, veterinary premixes). Following the inspection, the GMP certificate for veterinary products was issued (November 29, 2012).

10. The audit monitoring the compliance of the manufactured products within the Micro-production Department (aluminum tubes, polyethylene lids and aluminum caps) was performed by SRAC CERTSERV, on April 9-10, 2012. The auditors recommended maintenance of certification.

11. Thanks to the audit conducted by Pharma Quality Consulting for Fougere USA on May 28, 2012 Antibiotice was considered qualified as a supplier of Nystatin API. The inspection reported the company's compliance with the GMP requirements, the employees' expertise in manufacturing and the quality of submitted documents.

12. The audit conducted by Teva Pharmaceuticals on October 11, 2012 in view of qualifying Antibiotice as a provider of Nystatin API reported Antibiotice's compliance to the GMP requirements and underlined the employees' expertise in manufacturing requirements and the quality of submitted documents.

13. On December 6 and 7, 2012, the audit conducted by Sagent, a distributor on the US market, inspected the cGMP compliance of the manufacturing and control operations of Ampicillin solution for injection, USP. The favorable audit result ascertained the compliance to cGMP requirements and, as a result, Antibiotice obtained the approval to be a contract manufacturer of Ampicillin for Sagent company.

14. Between December 11-12, 2012, the audit conducted by Worldgen, distributor on the US market, confirmed the company's compliance to cGMP norms in terms of sterile products manufacture. The audit had a favorable result, reporting cGMP compliance and Antibiotice was a confirmed contract manufacturer for Worldgen.

15. For ensuring compliance to the GMP requirements for suppliers of raw materials, in accordance with the audit supplier program approved in 2012, 11 Indian companies, 11 Chinese ones and a company in Turkey were audited in view of qualification/requalification.

16. In accordance with Antibiotice's overall objectives, the most important investments implemented in 2012 are presented below:

- **Quality Unit:** purchasing state-of-the art equipment for more accurate methods to verify product quality, in line with international standards.
- **Technical & Production Unit:** investments with a view to increase labour productivity and operational safety, reduce energy loss and comply with regulatory requirements presented during the recertification audits, as follows:
  - **Tablet plant** – the partial restoration of the sewer system/utility distribution routes and the grounding strap, the thermal power station rehabilitation and revamping the transport infrastructure of raw materials and finished products;
  - **Capsule Plant** – Supplementing the supply of technologically compressed air by purchasing a state-of-the-art compressor and implementing upgrades to facilities that would improve the working conditions;
  - **Biosynthesis Plant** – Rehabilitating and upgrading the spray drying facility (production facilities, technical equipment and utility distribution installations) and implementing an automated computer tracking system for Nystatin biosynthesis (parameters and consumption control, automatic addition of nutrients).



## Marketing Development

In 2012 the Romanian pharmaceutical market recorded a 8.3% growth, reaching a value of RON 11.7 billion as compared to RON 10.8 billion in 2011, according to CegeDim, the market research company. (values based on the pharmacy purchase price).

Romanian generic medicine market rose by 13% in 2012 compared with 2011, while the producers of originals recorded a 5.6% increase.

Antibiotice recorded sales on the domestic market amounting to RON 291.2 million in 2012 as compared to RON 273.3 million in 2011, higher by 6.6%. With a 6.6% market share, Antibiotice ranked forth in the top of the companies on the generic and OTC market in Romania.

### Valorization of the traditional anti-infective portfolio

Continuing the company's strategy in recent years focused on strengthening the position as leading manufacturer of anti-infectives, the commercial and promotion policies applied in 2012 were focused toward the superior valorification of the traditional and newly assimilated medicines into the portfolio.

Taking into account that the generic anti-infectives ranks first in terms of contribution to the company's turnover, one of the main goals is to maintain our leading position in this therapeutic class. With a 45.7% market share on this segment in 2012, Antibiotice maintained the growth trend of the previous years: the figure was 38.3% in 2010 and 44.6% in 2011.

As regards the anti-infectives in capsules, our company succeeded by competitive commercial offers and by sustaining the distributor partners, in increasing the consumption by 13.6% (from 119 million capsules in 2011 to 135 million capsules in 2012) while the market share rose by 9% (2011 - 72.5%, 2012 - 81.8%).

### Sustained sale growth of cardiovascular products

Starting from a continuous analysis of the competitors' behaviour, through an intense promotion and competitive offers, our company succeeded in raising the sales of the cardiovascular portfolio by 27.3% (RON 11.8 million) and the traded volume by 31.2% (from 28.7 million therapeutic units in 2011 to 37.6 million therapeutic units in 2012). Maintaining a growth rate higher than the market growth (cardiovascular market increased by 8% in 2012 compared with 2011),

Antibiotice traded 7 cardiovascular molecules in 2012 including Trimetazidina Atb® (*trimetazidinum*) belonging to the coronary therapy subclass, new assimilated in our portfolio.

### Sales evolution - cardiovascular system

Product	Value 2011 (RON)	Value 2012 (RON)	Variation 2012/2011
Lisinopril® range	3,909,869	4,229,206	8.2%
Bisotens® range	2,275,171	2,819,766	23.9%
Almacor® range	911,094	1,721,193	88.9%
Nolet®	1,174,535	1,645,980	40.1%
Gladycor® range	401,010	753,300	87.9%
Trimetazidina ATB®		323,531	

### Leader in the hospital segment. Leader in the ointments & suppository market

In 2012 Antibiotice maintained its leading position on the Hospital segment (powders for injection) recording a 29.1% value market share. Our company has also the leading position in consumption of the whole ointment range (30.6% market share), suppositories (45.1%) and powders for injection (72.8%).

### Launching an oncology medicine portfolio

2012 was also the year of approaching new therapeutic areas by launching on the market three oncological products: Bicalutamida Atb® tablets 50 mg (for the treatment of prostate cancer), Letrozol Atb® tablets 2.5 mg (for the adjuvant treatment of early stage breast cancer with hormone receptors in postmenopausal women) and Anastrozol Atb® tablets 1 mg (for the treatment of advanced-stage breast cancer in postmenopausal women).

### 4 new molecules in portfolio

The product portfolio was also enriched with cardiovascular and psychiatric medicines and anti-infectives: Trimetazidina Atb® tablets 35 mg (used in patients with angina pectoris, in combination with other therapies), Paroxetina Atb® tablets 20 mg (for the treatment of major depression and other obsessive compulsive disorders), the anti-infective product Eficef® capsules 100 mg for pediatric use and Lactic Atb® ovules, for disorders of the genito-urinary apparatus.

1 out of 3  
Romanian patients  
is treated with  
Antibiotice  
anti-infectives

Half  
of the suppository  
market is covered  
by Antibiotice

7  
new products  
launched on the  
market in 2012

**Cefort®**,  
the best selling  
product of the  
company  
(RON 46.17 million)

**Antineoplastic  
and immuno-  
modulating  
agents -  
a new class  
assimilated in 2012**

**Drugs for  
genitourinary  
apparatus -  
a new class  
assimilated in 2012**

**1 out of 3**  
Romanian patients  
with dermatological  
disorders uses the  
Antibiotice  
ointments

The best selling product of the company in 2012 remains the Cefort® with a RON 48.5 million share in turnover (16.7% of total turnover).

#### **Antibiotice attended numerous scientific events**

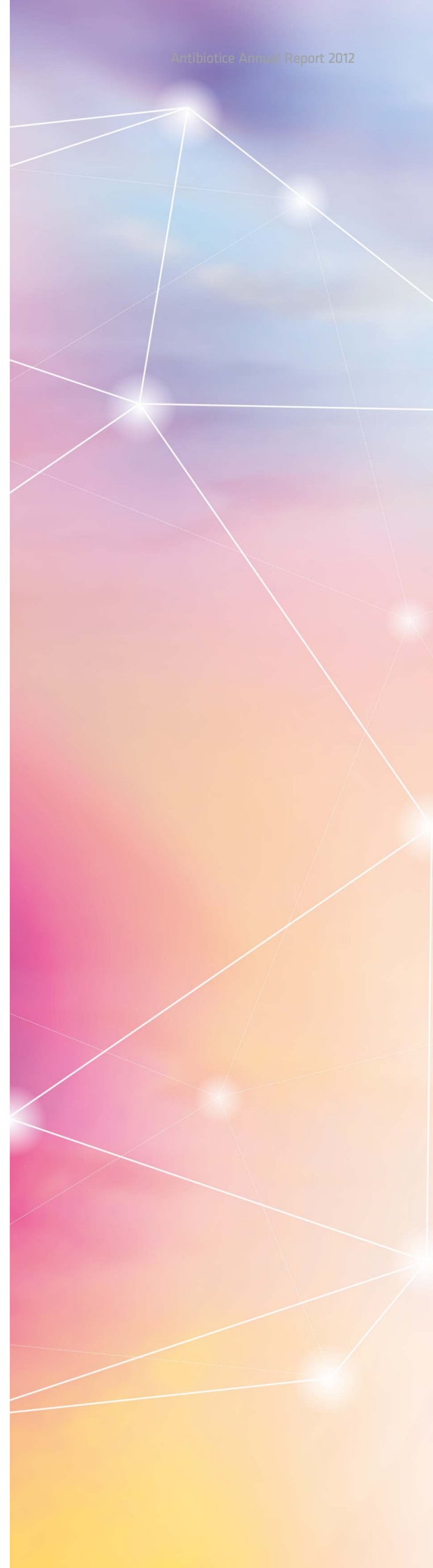
Antibiotice attended numerous areal and national scientific medical events, where, by means of some recognized opinion leaders, the goal was to get more information on the role of generic medicines or on different pathologies.

Of the major national events to which the company participated throughout the year in the main university centers, we mention the followings:

- National Congress of Internal Medicine,
- Romanian Medical Association Congress,
- Congress of the Romanian Society of Anaesthesia and Intensive Care,
- Dermatology Conference "Gh. Nastase Days",
- National Conference of Working Groups of the Romanian Society of Cardiology,
- National Congress of Cardiology,
- National Conference of Psychiatry,
- National Course on Guidelines and Protocols in Anaesthesia,
- Intensive Care and Emergency Medicine,
- National Conference of Oncology and Medical Radiotherapy,
- National Congress of Dermatology,
- Pharma Forum,
- Medical Forum.

Antibiotice also started and supported educational campaigns, both for doctors and patients, namely:

- The symposium "Medicine and spirituality: a multidisciplinary approach of the elderly patient"
- The course on "Diabetic patient's approach in the context of primary health care";
- The symposium "Medicine and faith" - the elderly patient: an approach with science and soul;
- The campaign "A step towards health" to educate the public about the incidence of mycoses;
- The educational campaign "Equilibra - energy each day"
- The educational campaign "Stress management".





## Exports went up three times in the last five years

Exports remained on an upward trend in 2012, reporting a 10% turnover increase in the foreign markets compared to the value recorded in 2011. The year 2012 was equivalent with exceeding the threshold of USD 20 million from sales on international markets, a figure three times higher than five years ago.

In 2012, the largest share of sales in international markets was covered by API sales (Nystatin). The difference was covered by sales of finished products, licenses and services testing pharmaceutical products. In terms of geographical focus, most exports were oriented to Asia, covering 27% of total exports, followed closely by exports to Europe, Russia & CIS and Africa.

### Nystatin exports went up 15%

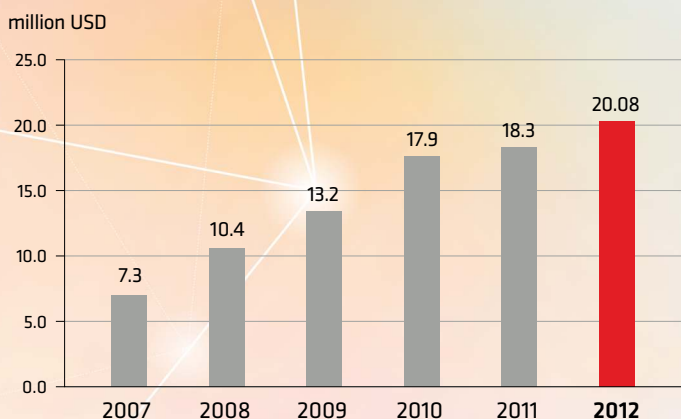
The company's strategy lately was to promote Antibiotice as a leading manufacturer of Nystatin worldwide, by two levers: on the one hand, developing a top product whose quality is certified by prominent authorities in the healthcare industry; on the other, by strengthening partnerships with major manufacturers of Nystatin-based medicines worldwide.

The result of these policies was boosting Nystatin exports by 15% as compared to 2011 - this growth being accounted for by sales of the main types of Nystatin manufactured for export: bulk Nystatin for pharmaceutical use and micronized Nystatin.

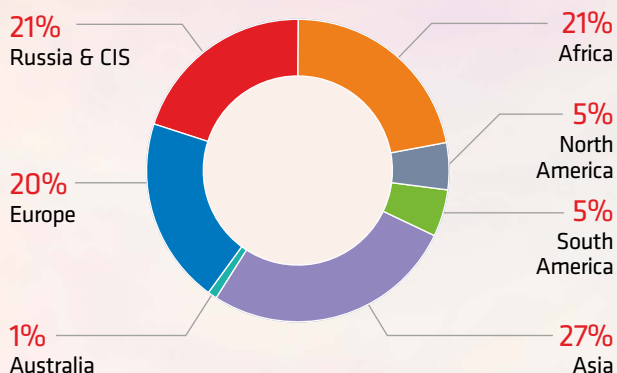
In 2012, Antibiotice exported Nystatin to nearly 100 end-users on 6 continents. The company's key markets were Europe (especially Germany and the Netherlands), the CIS states (Belarus), Asia (the largest share of exports go to China and India), South America (Brazil) and North America (US).

The positive trend of API exports was possible due to analyzing the Nystatin international market so as to outline the trends on each particular outlet and the key user companies. 2012 maintained the tendency practiced in previous years, targeting mainly direct exports of Nystatin API to end-users, for an improved product traceability and in order to encourage our partner's loyalty through direct and constant support.

Exports evolution 2007-2012



Exports breakdown by geographical region in 2012



Exports worth of USD  
**20.1**  
million

**10%**  
annual growth of turnover from exports

**120**  
partners in over 60 countries

**70**  
products registered on foreign markets

**Evolution of finished product exports**

The chief goals pursued by Antibiotice in recent years were promoting the company as a manufacturer of generic drugs and enhancing our presence on key-markets, by registering the company's products with the respective local health authorities. These efforts materialized in 2012 when Antibiotice was granted no less than 35 new MAs on foreign markets.

The value of finished products exports recorded in 2012 was up 4% as compared to 2011, the largest share being reported by sterile injectable products.

Antibiotice reaches the international pharmaceutical market both directly, by recording and promoting products in its own name, as well as indirectly – by sublicensing and contract manufacture for renowned companies in the pharma world. The company's policy in recent years has been to enhance the visibility of Antibiotice brand across the world, so the emphasis was on promoting our products in end-user markets. This resulted in boosted export figures, amounting to 57% in total exports of finished products.

Exports of finished products are oriented towards strategic geographical areas, the most important outlets being North America (U.S. and Canada), Europe (Denmark, Spain, Central and Eastern Europe and non-EU states), North Africa and the Middle East (Algeria, Tunisia, Libya, Saudi Arabia and GCC countries), Russia, the CIS (especially Russia, Azerbaijan, Georgia, Armenia, Ukraine, Kazakhstan), China, and countries in Southeast Asia and Central and South Africa.

**Boosting our presence on the international market**

Against a constant preoccupation for the growth of Antibiotice brand on the international market, the company has continued to actively promote its products on the

international markets bit by taking part in the international fairs and symposia, as well as supporting the marketing actions developed by local partners in the foreign countries.

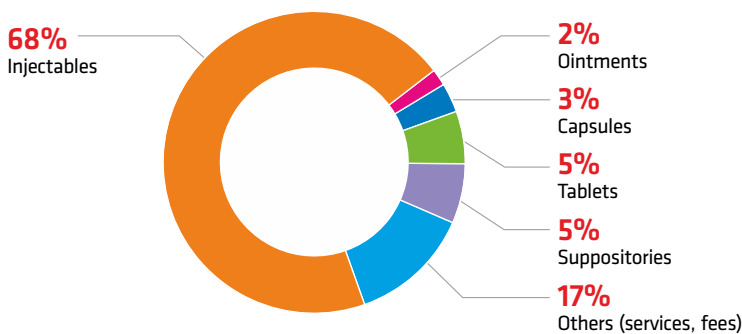
Earlier this year, Antibiotice participated in the Arab Health Fair, an annual event held in Dubai, bringing together experts in the pharmaceutical industry from the Arabic-speaking countries. This event provided an opportunity to organize meetings with significant traditional partners or potential business partners in 12 countries in Northern Africa and the Middle East.

In late 2012 Antibiotice was present at CPhI Worldwide 2012, the leading annual networking event in the pharmaceutical industry. The first edition took place back in 1990, being set up as an international convention in active ingredients that gathered 16 exhibitors and 250 visitors. In 2012 the fair has reached a record number of more than 29,000 visitors and 2200 exhibitors from 133 states.

Antibiotice's participation to CPhI Worldwide has already become traditional, 2012 being the tenth year in a row when our company displays its product portfolio at its own exhibit stand. The constant participation in this event made it possible to identify new growth opportunities on several directions: export of Nystatin and finished products, contract manufacturing for the European and American market, in-licensing and out-licensing files and raw materials import.

In late 2012 Antibiotice began preparing the prequalification procedures with the World Health Organization as an authorized supplier of anti-tuberculosis medicinal products. In Romania, Antibiotice is already recognized as a partner of the Ministry of Health in the fight against tuberculosis, with a portfolio covering all nine first-line treatments for this condition. Once obtained, the WHO Prequalification would allow us to provide products to the major humanitarian organizations in the world, specializing in worldwide anti-tuberculosis programs: UNICEF, Global Fund, UNITAID, Médecins Sans Frontières, Bill Gates Foundation, TB Alliance, etc.

**The breakdown of finished product exports in 2012**



*Contract manufacturing* – production under contract for other companies.  
*in-licensing* – obtaining licenses from other companies for their products.  
*out-licensing* – granting licenses for products to other companies.

## Consolidating trust in valuable partnerships

For the pharmaceutical industry, 2012 was the year in which stability of partnerships played a decisive part. In the current economic climate in which business rules are rewritten and new economically strategic configurations arise, partnerships represent one of the best forms of defense for businesses.

On the other hand, the economic crisis triggered in 2008 determined the companies to reevaluate their activity and partners; at the same time, new regulations were formulated for the pharma industry. Combined, these prompted the continuation of the efforts to consolidate the existing partnerships, with the following elements to consider:

- **management of the relation to each raw material supplier**, developing a common strategy targeting competitive prices, reasonable delivery dates, and payment conditions tailored to the Romanian market;
- **orientation towards various procurement markets** in order to prevent dependance on a particular geographic area or source of supply;
- **focus on satisfying the internal needs of the company** in conformity with its development strategy on the whole.

Thus, the procurement activity has become strategic for the smooth operation of the company. As the worldwide competition has enhanced and the speed of change in the pharmaceutical industry increased, Antibiotice has tried to make its structure as efficient as possible organizing the procurement activities in tight relation to the sales of finished products and the needs of the pharmaceutical market and using a well-defined information loop with external partners.

### The partnerships concluded by Antibiotice may be classified as follows:

#### A. Upstream partnerships

- A.1.** Procurement partnerships for production and new product development;
- A.2.** Finished product procurement partnerships;
- A.3.** Financial partnerships with banking institutions;
- A.4.** Partnerships for product manufacturing;
- A.5.** Partnerships for product research and development.

#### A.1. Procurement partnerships for production and new product development

The challenges in the international pharmaceutical market in the recent years have shown that the most important resource is the *rapidity of response to change*.

Therefore, the importance given to transparent communication between Antibiotice and traditional or recently attracted suppliers has increased. From the first meeting with a partner up to the product launch on the market, the rapidity of response of both partners and the mutual trust are of utmost importance.

#### The supplier portfolio, continuously monitored and supplemented

In 2012, Antibiotice carried on its program aiming at finding and approving alternative sources for each raw material required in manufacturing processes as well as for each finished product contributing to the company turnover.

The company focused on improving the conditions and procurement practices in order to ensure a reliable portfolio of suppliers capable to provide the company with quality products on the delivery dates specified by Antibiotice and in the conditions of the current economic environment. To the purpose of preventing the risks that may derive from cooperating with a single supplier, new partners were assimilated, the criteria for their selection including the quality of the products supplied, the supportive documentation submitted, the prices and the due dates. Thus, the risk of depending on one supplier was avoided; such dependance may result in failure to deliver the ordered goods on time, rigidity in price and delivery terms negotiation as well as in discontinuity of deliveries or production due to special circumstances, with important relational and financial consequences.

#### The antiinfective APIs, the largest share of total acquisitions

Antibiotice purchases particularly active pharmaceutical ingredients used in the production

45

traditional suppliers account for 55% of the value of imports

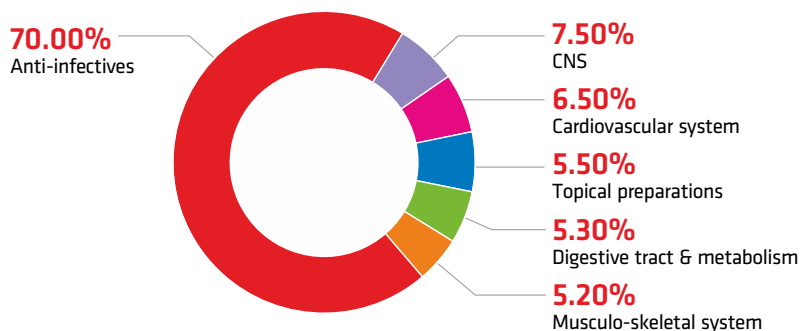
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suppliers of raw materials for antiinfective drugs

15

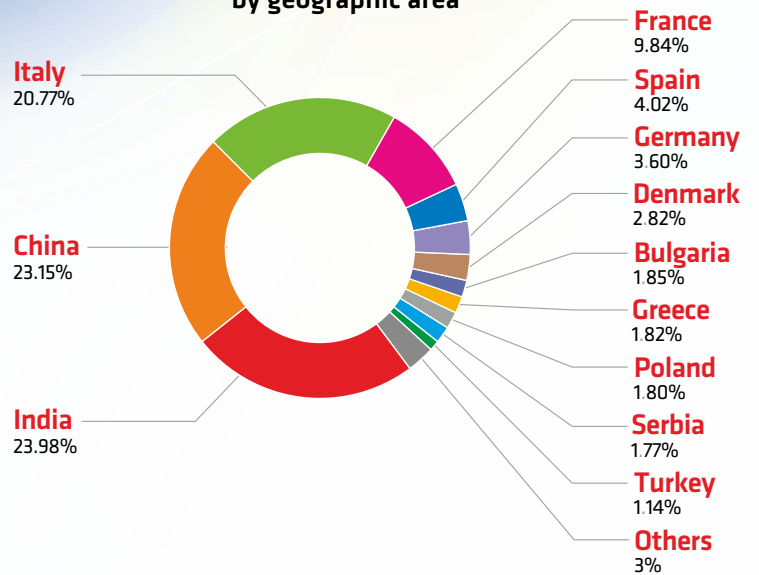
new suppliers of raw materials attracted in the last 5 years

API procurement by therapeutic class





**Breakdown of procurement spending by geographic area**



of anti-infectives drugs. The active ingredients of this therapeutic class are characterized by a cyclical behaviour of prices while the number of the companies producing them continues to diminish. Nevertheless, Antibiotice has been cooperating with the most prominent manufacturers in the field for more than 10-15 years and has developed solid partnerships in the market segment.

The partners of the company are GMP certified and the quality of their products is internationally recognized. Moreover, they are periodically evaluated by the company's Quality Assurance Dept.

### Strategies to minimize financial risks

International procurement is directly and indirectly liable to various risks. Such risks pertain to the assets of the company, the business partners, the socio-economic and political environment in which all operate. Therefore, the implementation of a risk management system becomes an important objective for the procurement operations and not only.

In order to reduce the impact of exposing the company to the price risk, particular measures were taken when concluding procurement agreements: the prices were negotiated on medium term, both in national and foreign currency, with at least two-three suppliers of raw materials.

On the other hand, another action taken by the procurement department was the correlation of the balance of external payments with the balance of external receipts. Taking into account that in the last years the exports have accounted for an increasing share of the turnover and likely to be commensurate with the foreign acquisitions of raw materials and finished products, the company intends to make the payments to the foreign suppliers mainly using the receipts from the foreign partners.

Moreover, to minimize the impact of international changes, Antibiotice aims at a balanced geographic distribution of its partnerships. The cooperation with the largest pharmaceutical manufacturers from various countries in the world provides the advantage of being able to continuously update the documentation according to the requirements of the European or US regulations if needed.

### Keeping the inventory under control

The procurement process also includes the development of an efficient strategy for merchandise storage to the purpose of attaining an optimal balance among storage costs, orders, and exhausted stocks. At the same time, the company intends to maintain some safety stocks, which would allow the fulfillment of additional orders placed by the

company's partners. All these are the result of the permanent cooperation among the production, domestic sales and international sales departments.

### A.2. Finished product procurement partnerships

For the continuous update of the product portfolio by supplementing it with modern drugs and taking into consideration the competition in the market and that time management is an essential factor, Antibiotice cooperates with leading pharmaceutical companies for finished product procurements (in-licensing). To the purpose of ensuring the financial stability of the company, in 2012, new assessment criteria were introduced aiming at streamlining the contractual relationships with the business partners. Antibiotice developed such partnerships with world-renowned producers both from Europe and other parts of the world.

In 2012, the finished product acquisitions were made from manufacturers from Europe and India to an equal extent. In this way, the company managed to reduce financial loss generated by the fluctuations of the rate of exchange (EUR vs USD).

In addition, despite the economic uncertainty in the pharmaceutical market in 2012, Antibiotice succeeded both in maintaining its market share for the portfolio of finished products, and in acquiring products intended for different therapies. Thus, the company managed to launch onto the market a number of oncology products and penetrated a new market segment that provides additional benefits for health in general and represents a new resource for maintaining the upward trend of the turnover. Moreover, in 2012, the company started discussing with its partners to enter the market, in time, with new products to supplement the range of drugs designed for the treatment of central nervous system disorders as well as with products from other therapeutic classes in concert with the company's development strategy.

### A.3. Financial partnerships with banking institutions

The financial straits of some European countries determined Antibiotice to adopt a cautious policy with the banks and, at the same time, make efforts to optimize the relations with such business partners.

In order to minimize the economic negative influences, the company intends to conclude partnerships with banks and use specific payment instruments to optimize and secure the relationships with these partners.



GMP-certified  
production lines

### 2012 certifications and available capacities corresponding to all eight manufacturing lines

Manufacturing line	Certification/ approval	Production capacity available
<b>Nystatin</b> • active pharmaceutical ingredient	<ul style="list-style-type: none"> <li>• GMP certificate issued by NAMMD in August 2001</li> <li>• Latest GMP certificate renewal in June 2010</li> <li>• FDA approval in 2002</li> <li>• Latest FDA approval in April 2007</li> </ul>	
<b>Sterile products</b> • powders for solutions and suspensions for injection • $\beta$ -lactam antibiotics, penicillins	<ul style="list-style-type: none"> <li>• GMP certificate since December 1999</li> <li>• Latest GMP certificate renewal in May 2010</li> <li>• FDA approval in 2011</li> </ul>	20 million vials/year
<b>Non-sterile products</b> • capsules containing $\beta$ -lactam antibiotics, penicillins	<ul style="list-style-type: none"> <li>• GMP certificate since December 1999</li> <li>• Latest GMP certificate renewal in October 2011</li> </ul>	
<b>Non-sterile products</b> • capsules containing $\beta$ -lactam antibiotics, cephalosporins	<ul style="list-style-type: none"> <li>• GMP certificate since December 1999</li> <li>• Latest GMP certificate renewal in October 2011</li> </ul>	30 million capsules/year
<b>Non-sterile products</b> • capsules containing other antibiotics	<ul style="list-style-type: none"> <li>• GMP certificate since December 1999</li> <li>• Latest GMP certificate renewal in October 2011</li> </ul>	20 million capsules/year
<b>Non-sterile products</b> • tablets • film-coated tablets	<ul style="list-style-type: none"> <li>• GMP certificate since December 2000</li> <li>• Latest GMP certificate renewal in October 2011</li> </ul>	100 million tablets/year
<b>Non-sterile semisolid products</b> • ointments, creams, gels <b>Sterile semisolid products</b> • ophthalmic ointments	<ul style="list-style-type: none"> <li>• GMP certificate since April 2002</li> <li>• Latest GMP certificate renewal in October 2011</li> </ul>	8 million tubes/year
<b>Non-sterile products</b> • suppositories	<ul style="list-style-type: none"> <li>• GMP certificate since April 2002</li> <li>• Latest GMP certificate renewal in Oct. 2011</li> </ul>	30 million suppositories/year
<b>Product for veterinary use</b> • Nystatin feed-grade, parenterals, ointments, tablets	<ul style="list-style-type: none"> <li>• GMP certificate since February 2005</li> <li>• Latest GMP certificate renewal in November 2012</li> </ul>	

#### FDA approval for:

- Nystatin manufacturing line
- penicillin products for injection manufacturing line

#### A.4. Partnerships for product manufacturing

Antibiotice manufactures drug products in 5 pharmaceutical forms on all its 8 GMP-certified production lines, which enables the delivery of quality products to all the domestic and foreign partners.

In December 2012, two important US distributors (i.e. Sagent and Worldgen) audited the company to assess the conformity of the manufacturing operations and controls related to the production line for penicillins for injection with the cGMP regulations. The good results of the audit as well as the existent FDA approval for the sterile penicillins for injection production line allow the delivery of the products Ampicillin (4 strengths) and Nafcillin (2 strengths) to the US market.

The value of the products made by Antibiotice is acknowledged also by the Certificate of Suitability to the European Pharmacopoeia (for Nystatin, API) issued by the European Directo-

rate for the Quality of Medicines (EDQM) and the FDA approval of the Nystatin manufacturing line and penicillins for injection line.

#### A.5. Partnerships for product research and development

At its in-house Research and Development Center, Antibiotice is prepared to offer today to the international pharmaceutical manufacturers full services, which include *generic product research and development, confirmation of their efficacy* by bioequivalence studies, and *preparation of the application dossiers for marketing authorization*.

The Research and Development Center (R&DC) is a modern research unit with a multidisciplinary team consisting of over 70 specialists (11 of which with a doctoral degree) with expertise in pharmaceutical formulation, clinical evaluation, and international regulations in the field. The Center for Drug Evaluation from the R&D Center has Good Laboratory Practice certification and has been evaluated relative



to the conformity with the Good Clinical Practice regulations by the National Agency for Medicines and Medical Devices.

## B. Downstream partnerships

### B1. Internal partnerships

The key to distribution, both in the domestic and the international market, is to conclude mutually profitable partnerships, which are flexible to the continual changes in the market and have commonly agreed objectives.

The extremely varied product portfolio of Antibiotice, which equally address the **hospital** segment (i.e. hospitals, public health directorates) and the **retail** one (national pharmacy chains, mini-chains, independent pharmacies) require a distribution nationwide:

- **The hospital segment:** For this segment, Antibiotice has 8 partners representing the company in the tenders or offer selections organized by health care facilities with beds.
- **The retail segment:** For this segment, Antibiotice cooperates with 9 distributors with national distribution networks, specialized sales and tele-sales teams. The main objective pursued by such distributors is to ensure, by means of commercial and competitive practices, an active and continuous presence of the products made by Antibiotice both in independent pharmacies (community pharmacies) and pharmaceutical groups (national chains and mini-chains).

The partnerships between Antibiotice and distributors aim at achieving the common objective of being present in the domestic pharmaceutical market; the parties' mutual interest is to identify the best means to support the promotion and sale process as well as the most beneficial combination between delivery and payment terms.

### B2. External partnerships

The success of the export of Antibiotice products depends, irrespective of the fact they are API or finished products exports, on the capability of the company to develop and maintain long-term partnerships founded on shared objectives, mutual trust and transparency.

The relation with the international partners goes beyond the level of simple commercial relationships.

Taking into account the specificity of the international pharmaceutical market and the regulations related to product registration, which require investments for preparing the specific documents and studies as well as a

prolonged period of time for project implementation, it is crucial for the company to identify longlasting partnerships that can provide stability and security.

#### Partnerships for the export of APIs

For the export of the APIs, Antibiotice aims equally at building long-term relationships with the end-users from different countries by receiving approval as a supplier registered with the local regulatory authorities, and providing support to the partners representing Antibiotice in the external markets, by supplying them with the required appropriate documents. Fixing firm delivery dates, guaranteeing the quality conditions, and ensuring continued conformity of the international certifications with the latest standards are significant elements in the contractual relationships for the export of active ingredients as well.

Moreover, the company maintains its partnerships with important agents that facilitate access to fragmented or high-risk markets.

#### Partnerships for the export of finished products

In what concerns the export of finished pharmaceutical products, Antibiotice sets up its strategy according to the particularities of each target market. In most external markets, the company focuses on the identification of local distributors that can act as Antibiotice's designated representatives in the relation with the authorities, distributors, hospitals, pharmacies and patients.

The representatives in the target countries take up the responsibilities of the company related to the provision and delivery of affordable and quality products for different therapies, they supervise the conformity of product quality with the requirements throughout the entire shelf-life and monitor the impact of the products in the market. Therefore, it is essential for Antibiotice to build the relationships with the local partners on mutual trust and loyalty.

In the difficult markets or in the markets the local regulations hinder the distribution of import products, the company turns to partnerships with local pharmaceutical companies that can market under their own brands the products manufactured by Antibiotice. For such projects, the company cooperates with established companies widely recognized in the local and international markets.

## Investment in knowledge and competence, a priority in 2012

One of the main goals of the company is to continually train and adapt the human resources, in line with its strategic directions. For this purpose, in 2012, the human resources policy was predominantly geared towards staff recruitment, selection, training and continuous motivation, in order to improve the employees' performance and attract valuable employees, from the pharmaceutical field. Together, these strands resulted in getting a labour productivity of RON 207,568/person in 2012, higher by 7.48% compared to 2011, when the same indicator was RON 193,118/person.

### 35% of employees attended training courses

Improving the performance and motivating the employees require continuous investments in the human capital. Therefore, in 2012, the company allocated funds for the participation of more than 500 employees to seminars and vocational training & continuous improvement courses with external lecturers, in accordance with the needs identified for each organizational structure and in close correlation with the community legislative changes, applicable to the domestic legislation. This number of employees account for about 35% of total staff.

### Employee Performance Appraisal in 2012

The activity of each employee was evaluated in 2012, according to a system implemented by our company in 2003 and steadily improved, year after year.

This evaluation process takes into account both the quantitative performance and the employees' behaviour generating a productive working environment.

Along with the legislative changes to the Labour Code establishing as mandatory the annual evaluation of performances, the assessment process has been integrated into the Internal Regulation and the assessment criteria have become addenda to individual labour contracts.

### 47 new employees in the company

In order to develop new areas of activity and filling vacancies, 47 higher-education people joined the Antibiotice team in 2012, this figure representing a 1% increase in the share of the higher-education employees. The new employees were hired in medical promotion,

marketing, quality control, quality assurance, manufacturing, Regulatory Affairs, pharmacovigilance, pharmaceutical development, bioequivalence studies, risk management.

60% of all newly hired staff was attracted in marketing, promotion and product management, in order to reinforce the medical team who apply the company's sales policy.

### Summer school a+, an opportunity for a career in the pharmaceutical industry

Continuing the tradition, in 2012, Antibiotice developed the third edition of the project "Summer School a+", aimed at both the professional development of its employees, as well as attracting young specialists in research, development, production, quality control, and so on.

#### 1. Staff training

About 500 employees from top management, middle management to execution staff (with secondary and higher education), attended courses for developing the professional competencies and skills.

Topics covered areas such as creativity, innovation, improvement of processes, organizational behavior, management skills development, specific legislation.

The training sessions were conducted by renowned professors from Alexandru Ioan Cuza University of Iasi, within a traditional business-academia collaboration.

#### 2. Development of potential human resources

The Summer school a+ courses were attended also by 35 students and graduates of the Faculty of Medicine and Pharmacy, Faculty of Chemistry and Chemical Engineering faculty who wanted to complete their professional education with a series of concepts and rules specific to the pharmaceutical industry.

Thus, the Antibiotice professionals in various fields provided the future specialists with a theoretical and practical training on the peculiarities of the generic drug industry.

Out of the participants to the Summer School a+ (the first, second and third edition) about 20 young people in pharmaceutical development, Regulatory Affairs and bioequivalence studies were employed.

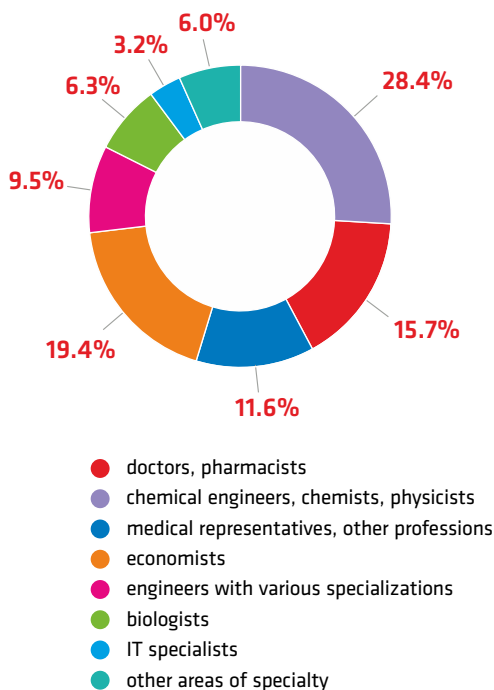
Performed actions	Results
<ul style="list-style-type: none"> <li>Attracting 47 higher-education people</li> </ul>	<ul style="list-style-type: none"> <li>1% increase in the number of employees with a higher education degree (36.3% of total staff) – a strategic direction in the human resources policy</li> </ul>
<ul style="list-style-type: none"> <li>Attracting 27 people (60% of total newly employed staff) in the Medical – Promotion – Marketing – Sales areas</li> </ul>	<ul style="list-style-type: none"> <li>Expanding and strengthening the promotion &amp; sales team in order to achieve the estimated targets, turnover and market share</li> </ul>
<ul style="list-style-type: none"> <li>Training programmes with internal and external lecturers, in important areas such as Assurance and Quality control, Regulatory Affairs, Marketing and Promotion, Product Development, Pharmaceutical Assessment, Management</li> <li>More than 500 higher and secondary education employees, representing 35% of staff, were included in the training programs with external lecturers</li> <li>525 employees attended the Summer school a+, an increasing number compared with the previous years</li> </ul>	<ul style="list-style-type: none"> <li>Increasing the level of competence and adaptation to the job changes and requirements, according to the developments in the pharmaceutical industry</li> </ul>
<ul style="list-style-type: none"> <li>The Management by Objectives System (MBO) will continue to be applied for 171 employees with managing and execution positions</li> </ul>	<ul style="list-style-type: none"> <li>Increasing the satisfaction and motivation level among employees</li> <li>Increasing the employees' stability and loyalty</li> <li>Staff fluctuation rate in 2012 was 5.34% compared to previous years when the percentage was 7.58%</li> </ul>

### Ideas are free of charge – a new project intended to foster the innovative spirit

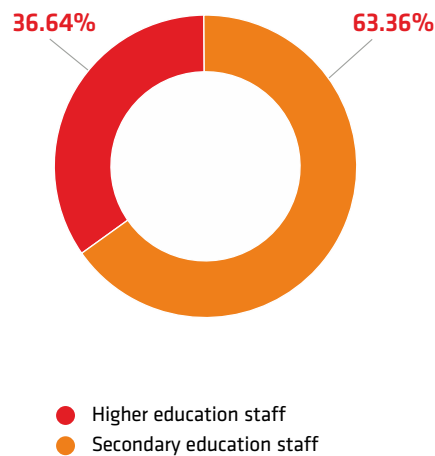
The company's vision in terms of human resources is to motivate employees to think and act in the spirit of the innovation and collective performance.

In this direction, the project **Ideas are free of charge** was initiated in 2012, a managerial tool stimulating innovation and creativity in the processes conducted within the company. The project started in the last quarter of 2012 contains a complex and precise system for collecting, sorting and quantifying the results implemented in all the company's areas of activity.

Higher education staff breakdown



Staff breakdown by professional training



# 06

## Risk management

The main goal of risk management is to assist a company in understanding and identifying the risks to which it is exposed so that they can be anticipated and managed in such a way as not to affect the efficient achievement of the company's objectives.

Antibiotice strategy on the management of significant risks provides the framework for identifying, assessing, monitoring and controlling these risks, in order to maintain them at acceptable levels according to the risk appetite of the company and its ability to cover (absorb) these risks.

### **The strategy's objectives on managing the significant risks are:**

- determination of significant risks that may arise in the normal course of the company's business and formalization of a robust framework for the risk management and control, according to the general business strategy goals of the company. This is achieved through the adoption of best practices, tailored to the company's size, profile and risk strategy;
- development of risk maps to facilitate their identification, to structure and prioritize them depending on the possible impact on the current activities;
- promoting a culture of awareness and risk management to all levels of the company.

The Risk Management Department seeks to achieve these objectives.

In the process of managing the risk, the company aims to develop policies, standards and procedures through which the significant risks can be identified, evaluated, monitored and reduced. This framework shall be periodically reviewed, according to the risk profile and tolerance, as well as to the legislative amendments and internal or external changes. For this purpose, identifying and evaluating the risks that may arise in carrying out the significant activities, is a permanent activity.

All employees must become aware of the risks that may arise in their work, as well as of their responsibilities on the management of these risks. Thus, the company shall continuously develop and maintain a robust and coherent risk culture at the level of all structures.

### **Currency risk**

In a company's business affairs, one of the high frequency risks is the currency risk, which may consist in financial losses arising from variations in foreign exchange rates and/or from the correlations between them.

Macroeconomic changes has lead to exchange rate fluctuations which are reflected both in the cost of imported raw materials, as well as in the prices of finished goods for export.

On the other hand, the depreciation of the national currency against the major currencies is caused also by the domestic political instability that negatively affected the financial markets, the currency exchange rate and the stock exchange.

Owing to this instability the major currencies reached historical maximum values (4.5484 RON/EUR, 3.6993 RON/USD).

### **Measures for controlling the currency risk**

As a measure to reduce this risk, the company constantly tries to synchronize the export operations with the import ones, by correlating the payment and collection terms, as well as by correlating the share of currencies so that the payments and collection of receivables from export to be made as close as possible, or even simultaneously.

Another measure is to anticipate or delay the payment or collection of receivables by fixing the proper due date and by introducing some protective price margins in conjunction with the evolution forecasts of the currency in which payment are to be made.

## Liquidity risk

This risk arises from the company's failure to honour at any moment the short-term payment obligations.

In 2012 the company was exposed to this risk caused on the one hand, by the forced crediting of the National Health Insurance House, the average collection term for the counter-value of the drugs being 390 days (end of 2012). This generates significant arrears, given the fact that the contract term of the NHIH with the hospitals and pharmacies is 210 days. This risk is all the more so as the company does not translate these delays in collecting the receivables to the suppliers, by extending the terms of payment to the latter.

On the other hand, liquidity risk is caused by increased taxation. When we speak of taxation we refer in the first instance to the predictability and the business environment is exposed to changes from one day to another from fiscal viewpoint (new taxes, fees, contributions). Such a tax with a significant impact on the company's cashflow was the clawback tax. This tax implies that the producers have to pay the difference between the actual consumption and budget allocated by the authorities.

### Control measures on liquidity risk

In order to improve its cashflow, Antibiotic focused on internationalization: export turnover recorded a three-fold increase, from USD 7 million in 2007 to over USD 20 million in 2012.

Our company is permanently focused on:

- adjusting the export portfolio to the world market's requirements through the introduction of new products;
- developing new projects by focusing on the markets with a high potential for absorbing generic medicines and generating a significant turnover (USA, Europe, Russian Federation);
- developing the current partnerships.

This export growth strategy has in view collecting the receivables from the foreign markets in 60-90 days as compared to more than 300 days on the domestic market. At the same time, in order to reduce the risk of domestic non-collection our company has taken the following measures:

- rating in many ways the creditworthiness of the trading partners before concluding any contract;
- monitoring the receivables by a continuous risk control and evaluation;

- developing loyal and constructive relationships with the customers through regular meetings;
- constituting the expense provisions for covering the non-payment risk.

## The risk of interrupting the imported raw material flow

The raw materials of pharmaceutical industry are subject to very strict rules concerning the product quality standards which the raw material suppliers must comply with.

Their failure in receiving the certifications/recertifications as well as the costs and long authorization period may lead to the supply gaps which generate the obstruction of certain production flows.

The environmental measures taken at the global level in recent years have led to reducing the number of manufacturers with a high risk of pollution or their relocation in other areas. Currently, most of the raw materials used by the company are imported from Asia.

In accordance with the Council Directive 2010/62/EU all imported active substances shall be manufactured in accordance with the GMP standards or at least equivalent to the GMP in force in the EU.

As regards the manufacturing of active substances in third countries, we should ensure ourselves that the applicable legislative provisions for the manufacture of active substances intended for export to the European Union, as well as the inspection of installations and implementation of the provisions in force provide a level of protection of the public health equivalent to that offered by EU. The application of this Directive could result in non-certifying certain unique suppliers of active ingredients, which could lead to rupture in stocks.

### Measures to control the risk of interrupting the acquisition flow of imported raw materials

In order to reduce this risk, the company permanently invests in:

- authorizing new sources of raw materials;
- ensuring a safe portfolio of suppliers;
- improving the relationships with the business partners.

## Price reduction risk

Our company is exposed to a risk of reducing the prices of medicines, because of the issues on the health expenditures escalating in Europe,

reduced national budgets as a result of the prolonged economic crisis, aggression of the low prices of the Asian companies.

On the generics market, the influence of the companies from India and China has been becoming more and more significant, these companies meeting the international regulations and adopting aggressive policies to promote their exports by practicing low prices. A large number of developing countries promote centralized medicine procurement policies imposing this way low price levels.

#### **Measures to control the price reduction risk**

To mitigate these risks, the company has a promotion policy by emphasizing its advantages such as the high quality and compliance with the international regulations. On the other hand, it aims at consolidating its position on the regulated markets which have more restrictive conditions for market access and relatively higher price levels.

### **Legislative risk**

The legislative changes concerning the pharmaceutical market lead to a legislative risk, which must be continuously managed.

The pharmaceutical market is a regulated one with clear legislative provisions developed for monitoring the quality and therapeutic effectiveness of drugs on the market and for avoiding counterfeiting.

Internally, the control is performed both by the National Agency of Medicines and Medical Devices (NAMMD) at product level and by the Ministry of Health at the level of the marketing price.

In terms of exports, the company must comply with the legal provisions from the target countries concerning the authorization of medicinal products, quality standards and marketing. Adaptation to these provisions is reflected both in the extra cost for upgrading the documentation in line with the last quality standards as well as in the delays on placing our products on the market.

#### **Measures for controlling the legislative risk**

The company's strategy in managing these risks involves:

- the permanent concern for obtaining international certifications for our manufacturing lines;
- updating the authorization documentation for the products in the portfolio;
- conducting bioequivalence and stability studies;
- keeping continuously track of legislative changes.

### **The risk of losing some markets (contracts)**

Changing the legal conditions on the local market, lowering the price of competing products in the market which lead to a noncompetitive position, partners losing their interest for the Antibiotice products as a result of penetrating new products on the market, lead to the loss of some markets (contracts) or to the reduction of the future access possibilities, influencing the forecasts related to the export of finished products. The same happens because of the protectionist policy on the access of medicinal products on the market (Algeria, Tunisia, Israel, South America) or the emergence of some conflict areas such as Syria, Egypt and Afghanistan.

#### **Measures to control the risk of losing some markets (contracts)**

To manage this risk the company envisages:

- continuous tracking of trends in international trade policy and approaching a diversified export strategy, from the structural and geographical viewpoint with a differentiated approach of the developed and developing markets;
- concluding strategic partnerships with companies holding important positions on the international markets, which are able to efficiently track such risks;
- anticipating the legislative conditions in order to adapt the products' documentation to the new requirements or to approach other markets;
- customer retention;
- identifying new business partners and other ways of cooperation (compensation).

Antibiotice continuously supervises the operational risks in order to take measures to maintain them at acceptable levels that do not threaten the company's financial stability, the interests of creditors, shareholders, employees and partners.

# 07

## Corporate governance

### Management Board

As per law 31/1990, republished with all subsequent amendments, section 1 – The Unitary System, Art. 137, subsections 1 and 2) and the company's Articles of Association, Antibiotice is managed by a unitary system by a Management Board. This Board is responsible for fulfilling all tasks necessary to achieve the company's object of activity, except as lawfully provided by the General Meeting of Shareholders.

In the 8 sessions held through 2012, the Management Board adopted decisions which allowed fulfilling its duties in an effective and efficient manner. Thus, at the quarterly meetings, the Board examined in detail the financial outcomes obtained during the reporting period and cumulatively since the beginning of the year; also, the company's economic performance in relation to the budget and to the same period of the previous year was reviewed.

Depending on the situation, the executive team provided the Management Board with detailed explanations on the plans to enhance the efficiency of production, investment plans, provisions made, liquidity management and operational/overall business profitability.

Following the detailed analysis of the results obtained during the mentioned period, the Board decided to approve them in view of publishing and sending them to the Bucharest Stock Exchange and the National Securities Commission, observing the Financial Communication Calendar.

The members of the Board have guaranteed the efficiency in monitoring, analyzing and assessing the activity of the executive directors, and also the fair treatment of shareholders.

In 2012 the structure of the Management Board was changed by replacing the former

board with a new one, which was constituted in accordance with the GEO no. 109/2011.

GEO no. 109/2011 established the mandatory implementation of the corporate governance in public enterprises (autonomous organizations and trading companies where the state is either the majority or the unique shareholder)

Within Antibiotice, the corporate governance was materialized by introducing the principles developed by the Organization for Economic Cooperation and Development, based on the most advanced legislative standards and good corporate practice.

These measures establish ways of ensuring the objectivity and transparency in the selection of management and administration members; ensure the professionalism and responsibility in taking managerial decisions, introduce additional mechanisms for the protection of the minority shareholders' rights and an increased transparency with reference to the state-owned companies and to the shareholding policy of the state.

The General Meeting of Shareholders of 26 April 2012 confirmed by vote the candidates proposed by the Nominating Committee within the Management Board, these candidates being selected by an independent human resources expert, in accordance with the criteria of selection and advertising imposed by the Government Emergency Ordinance no. 109/2011.

Thus, the mandates of Ms. Ancamaria-Mihaela Negru, Ms. Vasilica-Rodica Dobra and Mr. Florian-Teodor D. Buzatu ceased. A new member of the Board was elected, namely Mr. Nicolae Stoian.

The Management Board of Antibiotice consists of five members, of whom one President and one Vice President.

The company's corporate governance system is based on:

- The Management Board,
- Advisory Committees,
- The Corporate Executive Team,
- The Code of Ethics.

The details on compliance with the principles and recommendations laid down in the Corporate Governance Code of the Bucharest Stock Exchange are presented in the Statement on compliance or noncompliance with the provisions of Corporate Governance Code – the “Apply or Explain Statement”.

## The members of the Management Board of Antibiotice as of December 31, 2012 are:

### **Ec. Valentin Radu, PhD, aged 63**

**President of the Management Board and representative of the Ministry of Health.**  
At the Ordinary General Meeting of Shareholders (OGMS) of 26 April 2012, Mr. Radu was reconfirmed as a member of the Board for a four-year period and elected President of the Board.

Mr. Valentin Radu holds a PhD in economics, is an auditor and an expert in administrative law and director in the Ministry of Health; member of the Antibiotice Board since 2009.  
**Number of ATB shares owned: 0\***

### **Ec. Ioan Nani, aged 53**

**Vice-President of the Management Board and CEO**

At the OGMS of 26 April 2012, Mr. Nani was reconfirmed as a member of the Board for a four-year period and elected Vice-President of the Board.

Mr. Ioan Nani is an economist specialized in management and chartered accountant, member of the Management Board since 2009 and Chief Executive Officer (1998–2008 and since 2009 to date).

**Number of ATB shares owned: 1,280\***

### **Dr. Geza B. Molnar, aged 69**

**Member of the Management Board and representative of the Ministry of Health**  
He is a Doctor of Medicine (MD), epidemiologist, primary care physician and associated professor; he is a member of the Board since 2009, reconfirmed in 2012, and has been working at the Institute of Public Health “Prof. Dr. Iuliu Moldovan” in Cluj-Napoca.  
**Number of ATB shares owned: 0\***

### **Ec. Nicolae Stoian, aged 56**

**Member of the Management Board and representative of SIF Oltenia and other shareholding legal entities**

At the OGMS of 26 April 2012, Mr. Stoian was elected as a member of the Management Board for a four-year period. He is a chartered accountant, tax consultant and financial auditor; he is also the representative of the Internal Control Department of SIF Oltenia.

**Number of ATB shares owned: 0\***

### **Eng. Gabriela Ilie, aged 63**

**Member of the Management Board and representative of SIF Oltenia and other shareholding legal entities**

Ms. Ilie was reconfirmed as a member of the Board in 2005, 2008 and, again, at the OGMS

of 26 April 2012, for another four years. She is a chemical engineer and a former director of SIF Oltenia. Currently, she is retired.  
**Number of ATB shares owned: 12,601\***

## Advisory Committees

The Management Board has set up the following specialized advisory committees:

- Audit Committee;
- Committee for remuneration, selection and establishment of jobs;
- Committee for quality and investment development;
- Committee for marketing and market analysis.

The advisory committees have conducted investigations and analyses, have drawn-up recommendations for the Management Board in their specific areas, elaborating periodical reports on the work developed.

## Executive Team

Antibiotice is represented by the CEO, who signs documents legally binding against third parties and in court (as per Article 17, Chapter V, Articles of Association of the trading company Antibiotice).

The Management Board retains the power of representation of the Company in its relations with the directors appointed by the Board.

In 2012 the structure of the Executive Team changed by setting up a specialized Unit: Business Development, headed by Mr. Mihai Stoian.

The executive management of Antibiotice is ensured by ten directors: a CEO (who also holds the position of Vice President of the Management Board) and nine specialized directors.

## The members of the Executive Team of Antibiotice on December 31, 2012, are:

### **Ec. Ioan Nani, aged 53**

**Vice President of the Management Board and Chief Executive Officer**

Mr. Ioan Nani is a graduate of the Faculty of Economic Sciences of the Alexandru Ioan Cuza University, Iasi. He is an economist specialized in management and a chartered accountant. In 1987, he began his work as an economist at Antibiotice.

Between 1991 and 1993, Mr. Nani was a financial inspector within the General Directorate of Public Finances in Iasi and afterwards worked with the Romanian Court of Accounts.

\* Number of Antibiotice (ATB) shares held on July 20, 2012 (as per the latest database held by Antibiotice Iasi in 2012).



In 1994 he returned to Antibiotice as Financial Executive Director, and in 1998 was appointed Chief Executive Officer.

In February 2009, Mr. Ioan Nani was invested Vice President of the Authority for State Assets Recovery (AVAS), Bucharest.

In June of the same year, he was reappointed Chief Executive Officer of Antibiotice. He has been holding this position since 2009.

**Number of ATB shares owned: 1,280\***

#### **Eng. Cornelia Moraru, aged 47**

##### **Technical & Production Director**

Ms. Cornelia Moraru is a graduate of the Faculty of Chemical Technology of the Gheorghe Asachi Technical University Iași. She worked as a chemical engineer at Fălticeni Chemistry Factory. She has been working for Antibiotice since 1990. Until 1998, she worked in Antibiotice's Penicillin II Plant, then, for one year, at the Biosynthesis Plant. Since July 1999 Ms. Moraru worked as a senior biosynthesis technologist at the Penicillin II Plant. In January 2001, she was appointed Manager of the Tablet Plant; in May 2003 she became Director of the Pharmaceutical Division. Since 2005, she has been holding the position of Technical and Production Director.

**Number of ATB shares owned: 1,280\***

#### **Ec. Paula Luminița Coman, aged 45**

##### **Financial Director**

Ms. Coman graduated from the Faculty of Economics and Business Administration at the Alexandru Ioan Cuza University Iași. She has been a chartered accountant since 2006 and tax consultant since 2007.

After graduation, she worked as an economist at the County Office of Tourism, Iași. She joined Antibiotice in 1991 as an economist in the Price Efficiency Office.

In 1998 she became head of the Economic Analysis Department and, later in 2003, head of the Financial and Accounting Department. She has been holding the position of Financial Director since 2011.

**Number of ATB shares owned: 0\***

#### **Ec. Vasile Chebac, aged 58**

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

Mr. Chebac graduated from the faculty of Economics of the Alexandru Ioan Cuza University Iași. Since 2003 he has been an active member of the Body of Chartered Accountant Experts, Iași, and a financial auditor, member of the Romanian Chamber of Auditors since 2008. He began to work with Antibiotice in 1972. In 1987, he joined the Planning-Development Office, within the Investment Department, as an economist.

Since February 1991 he activated as a financial inspector at the General Directorate of Public Finance Iași and in July 1993 he was nominated as a financial auditor at the Chamber of Accounts Iași. In January 1998, Mr. Chebac was appointed Chief Commissioner at the Financial Guard Iași. In September 2001, he returned to Antibiotice as executive Commercial and General Services Director. Since 2005, he has

been holding the position of Commercial and Logistics Director.

**Number of ATB shares owned: 0\***

#### **Eng. Eugen Florin Osadeț, aged 57**

##### **Engineering & Investment Director**

Mr. Osadeț is a graduate of the Gheorghe Asachi Technical University, Faculty of Mechanical Engineering. In 2000 he obtained the MBA degree granted by the same University. He has been working with Antibiotice since 1980, first as a mechanical engineer in the workshop for industrial cold production, later as a thermal engineer dispatcher. In 1997, Mr. Osadeț became the Head of the Thermal Engineering Service.

Since 2000, he has been holding the position of Engineering and Investment Director.

**Number of ATB shares owned: 1,279\***

#### **Eng. Cristina Lavinia Dimitriu, aged 55**

##### **Quality Director**

Ms. Dimitriu is a graduate of the Faculty of Chemical Technology at the Gheorghe Asachi Technical University, Iași. She holds an MBA degree granted in 2000 by the same university and a Master's degree in Management and Marketing granted in 2007 by the Faculty of Pharmacy of the "Gr. T. Popa" University of Medicine of Iași. Since 2007, Ms. Dimitriu has been a PhD student at the Faculty of Pharmacy, Iași. After graduating, she worked as a chemical engineer at the Făgăraș Chemical Plant. Since 1987 she has been working with Antibiotice company first as a chemical engineer at the Biosynthesis - Lysine Plant. In 1990 she became Production Manager at the Parenteral Products Plant and in 2000 she was appointed Quality Control Manager - Physical-Chemical & Microbiological Analyses. Starting with 2007, Ms. Dimitriu has become a Qualified Person in the manufacturing/import units of medicines for human use and Antibiotice's management representative for the integrated management system. She has been holding the position of Quality Director since 2003.

**Number of ATB shares owned: 0\***

#### **Ec. Gica Rusu, aged 49**

##### **Human Resources Director**

Ms. Rusu graduated from the Faculty of Economic Sciences of the Alexandru Ioan Cuza University, Iași. She holds a MA degree in Business Management granted by the same University in 2003. She has been working with Antibiotice since 1981, first as an economist at the Penicillin Production Plant, and from 1996 within the Financial Department. In 1999, Ms. Rusu became Head of the Human Resources Department.

She has been holding the position of Human Resources Director since 2004.

**Number of ATB shares owned: 1,278\***

#### **Ec. Ovidiu Bățaș, aged 35**

##### **Marketing and Domestic Sales Director**

Mr. Bățaș graduated from the Faculty of Economics and Business Administration (FEEA)

of the Alexandru Ioan Cuza University, Iași. He holds three MA degrees in financial management (2001), pharmaceutical marketing, granted by the Gr. T. Popa University of Medicine and Pharmacy (2003) and project management, granted by the Gheorghe Asachi Technical University in (2007). After graduation Mr. Bățaș was a teaching assistant at the Currency and Credit Department within FEAA. He joined Antibiotice in February 2001 as an economist in the departments of Economic Analysis, Accounting and Marketing. In January 2006, he was appointed head of the Market Analysis and Strategic Planning. Mr. Bățaș has been holding the position of Marketing and Domestic Sales Director since 2010.

**Number of ATB shares owned: 0\***

#### **Dr. Mihaela Moșneguțu, aged 43**

##### **Medical Director**

Ms. Moșneguțu is a graduate of the Faculty of General Medicine within the Grigore T. Popa University of Medicine and Pharmacy, Iași, and is specialized in family medicine.

She started her professional activity as a physician in Iași, then she joined Antibiotice company in 2000 within the Promotion Office, whose head she became in 2001.

In 2005, Ms. Moșneguțu was appointed head of the Pharmacovigilance and Medical Consulting Department. In 2009, she was nominated Manager in charge of the Medical Division and Retail Promotion. She has been holding the position of Medical Director since 2011.

**Number of ATB shares owned: 0\***

#### **Ec. Mihai Stoian, aged 37**

##### **Business Development Director**

Mr. Stoian graduated from the Faculty of Economics and Business Administration, (specialized in international transactions) at the Alexandru Ioan Cuza University, Iași.

In 2000, he was appointed promotion adviser at the Chamber of Commerce Iași, and since 2001, he has been working in foreign trade.

Since 2005, Mr. Stoian has been working with Antibiotice company in the Export Department, first as an Area Sales Manager for active substances, then as Export Manager (2008) and Business Development Manager (2011). He has been holding the position of Business Development Director since 2012.

**Number of ATB shares owned: 0\***

## **The Code of Ethics**


The code of ethics of Antibiotice presents the ethical norms which establish and regulate the corporate values, responsibilities, way of conduct the business obligations of the company and the way in which it operates.

The Code of Ethics is a guide for the employees of the company and provides information on the way they can solve the ethical issues in business.

The Code provides rules in the key areas relating to the employees, human rights, management of the environment, social responsibility and corporate governance. The Code contains the guidelines which help the company to follow its values, presents the set of rules on the basis of which the company has been developing, the ethical rules of conduct in business and how to prevent those illegal actions which might arise during the business activities within the company.

The Code of Ethics is compulsory and applies to all structures and activities of the company. All the company's employees will comply with the letter and the spirit of these regulations.

The Code of Ethics is presented in detail on the company's website:

 [www.antibiotice.ro](http://www.antibiotice.ro) > Investors >


1. Reference documents > Code of Ethics.

### **Rights of the holders of financial instruments**

The corporate governance frame of the company adopted and partially implemented:

- protects the shareholders' rights;
- ensures a fair treatment for all shareholders;
- recognizes the role of third parties with interests in the company;
- guarantees the information and transparency;
- ensures the Management Board's responsibility to the company and shareholders.

On the company's website, at

 [www.antibiotice.ro](http://www.antibiotice.ro) > Investors, there is a section dedicated to shareholders where they can access and download documents relating to the General Meeting of Shareholders (procedures for access to and attending meetings, convening notice, additions to the agenda, informative materials, special powers-of-attorney for representation, vote-by-mail forms, decisions and draft decisions, voting results, etc.).

Antibiotice makes available the periodical and annual financial statements drawn-up in accordance with the legislation in force. The company complies with all the requirements in force under the legislation on trading companies and capital market.

Within Antibiotice there is a specialized structure for the relationship with the existing and potential investors, called "Investor Relations"; its main role is to ensure a good communication with the shareholders. The persons designated to keep in touch with the investors, treat with efficiency the shareholder's requests and facilitate the dialogue with the company's management.

The company creates and develops an appropriate policy to promote an effective communication with the investors and shareholders.

\* Number of Antibiotice (ATB) shares held on July 20, 2012 (as per the latest database held by Antibiotice Iasi in 2012).

## General Meeting of Shareholders (GMS)

The General Meeting of Shareholders is the highest decision-making body of the company, where the shareholders directly participate and take decisions. Among its attributions, the GMS decides on: profit distribution, the election of the Management Board members and their remuneration, and the appointment of the auditors.

During 2012, the Management Board convened two Ordinary General Meetings of Shareholders (OGMS) (on April 26 and August 9) and two Extraordinary General Meetings of Shareholders (EGMS) (on April 26 and August 9). All necessary documents related to the smooth development of the GMSs were duly published on time as required by law.

In the OGMS held on April 26, the company's financial statements for 2011 were approved, these results being drawn-up as per Public Finance Minister's Order no 3055/2009 for the approval of accounting regulations in accordance with the European Directives and with the updated Accounting Law no. 82/1991.

During the same OGMS, the following measures were approved:

- Approval of the net profit allotment for 2011, worth of RON 20,298,909; setting the gross dividend value per share of RON 0.015191574; payment of dividends within 6 months after the GMS, as per general provisions of Art. 238, par.2 of the republished Law 297/2004, in case the next GMS shall not decide the investment of the 2011 dividends by capitalization;
- Approval to discharge the Management Board from the liability related to the activity performed during the financial year 2011 based on the submitted reports;
- Approval of Revenue and Expenditure Budget for 2012;
- Approval of the degree of fulfilling objectives and performance criteria by the Chief Executive Officer;
- Approval of implementation of the GEO 109/2011 at the company level;
- Approval to substitute the current Management Board with a new Management Board established in accordance with the GEO 109/2011;
- Approval of the management plan, of the objectives and the performance criteria for the Management Board;
- Setting the remuneration of the Management Board members;
- Approval of the empowerment of the Ministry of Health representative to sign the mandate contracts with the new administrators.

In the Ordinary General Meeting of Shareholders held on August 9, 2012, the financial statements of the company for the first semester of 2012 were approved; these statements were drawn-up in accordance with the Public Finance Minister's Order no. 3055/2009 for approval of accounting regulations according with the European Directives and the updated Accounting Law no. 82/1991.

At the Extraordinary General Meeting of Shareholders of April 26, the shareholders decided:

- Approval to change the company's Articles of Association as a result of implementing the Government Emergency Ordinance no. 109/2011.

At the Extraordinary General Meeting of Shareholders of August 9, the shareholders decided, as follows:

- "Ratification of the Antibiotice Management Board's decision with respect to the credit agreement conclusion with ING Bank Amsterdam N.N., Bucharest branch, as follows:

A. Non-binding credit line for financing the working capital, available as overdraft and for issuing contingent liabilities with a maturity of up to 1 year.

B. The loan amount: maximum EUR 9,500,000 of which:

- a. sub-limit overdraft: EUR 9,500,000,
- b. sub-limit issue of contingent liabilities: EUR 500,000, having the uncollected receivable as a guarantee.

The loan is secured by real estate, property of the company, registered in the Iasi Town Land Registry nos. 133201 and 133207.;"

- supplementation of the mortgage loan from ING Bank Amsterdam N.N. Bucharest Branch for the building of the Research Center, inventory number 10114, with the remaining book value on May 31, 2012 of RON 7,750,351.93;
- approval of a multi-option loan agreement with Alpha Bank Romania, as follows:
  - A - sub-limit: RON 8,000,000,
  - B - the sub-limit of EURO 100,000 having the uncollected receivable as a guarantee;
- approval of the Antibiotice Articles of Association amendment and the completion of article 18 "Duties of the Management Board".

### General Meeting of Shareholders in 2013

The General Meeting of Shareholders, which shall analyze and approve the financial results of the year 2012, is scheduled for April 25/26, 2013, according to the calendar of financial communication transmitted to the Bucharest Stock Exchange and the National Securities Commission. The General Meeting is held at the headquarters of Antibiotice company in Iași, no. 1 Valea Lupului Street.

08

## Social responsibility

100

employees donated  
blood to save lives

250

people in need  
were helped by  
the Antibiotice  
"Science and Soul"  
Foundation around  
Easter time.

A company's success is measured not only in terms of turnover, but also on how well it serves the community, protects the planet's resources and changes people's lives. Antibiotice assumes the responsibility to be involved as a "good citizen" in the life of the community through charity, donations, sponsorships, carrying out humanitarian, educational or cultural projects, working to develop a better society and also protect and improve the environment.

### "Antibiotice – Science and Soul" Foundation

The "Antibiotice – Science and Soul" Foundation decided to continue the company's tradition in carrying out charitable, humanitarian, educational and cultural projects in order to improve the health of the population and solve certain social issues.

Also, the Foundation supports the scientific activities for both physicians, by organizing training programs and continuous medical education seminars and for the public, by increasing awareness on the role of the generic medicinal product and various pathologies, by educational and preventive events.

Throughout 2012, the "Antibiotice – Science and Soul" Foundation carried out humanitarian campaigns that helped numerous families, children in serious health conditions, institutionalized children, elderly people, sick people in need. The actions promoted by the campaigns "The power of deed", "Donate blood, save a life" "Offer a toy, offer a smile", "Close to people with science and soul", "A gift from the heart! Be Santa Claus" brought joy and hope to those who needed humanitarian aid.

### **Donate blood! Save a life!**

Under the motto "Donate blood! Save a life!" Antibiotice – Science and Soul Foundation organized, on World Health Day, a blood donation campaign for the second consecutive year.

A total of 100 Antibiotice employees made a valuable gesture by donating blood. The donation campaign was held in the clinical unit of the Center for Drug Evaluation within Antibiotice. Following the positive feedback, this mobile blood collection campaign will be carried out in the coming years by the Science and Soul Foundation.

### **It is in our power to do a good deed!**

On the occasion of the World Health Day the company's employees responded promptly to the blood donation campaign; they also donated some of their food vouchers for providing food to poor families around Easter time. The "Antibiotice – Science and Soul" Foundation donated an additional amount of money. Thus, the contributions of the Foundation and of the company's employees materialized in the acquisition of food for 250 people in need from families with many children and low incomes, who needed material help during the Easter holidays.

### **Offer a toy, offer a smile!**

Two years in a row Antibiotice developed the campaign "Offer a book, offer a smile" offering books to children in hospitals, in order to celebrate the International Children's Day.

In 2012, the "Antibiotice – Science and Soul" Foundation offered 300 toys to the children hospitalized in "Sf. Maria" children's Hospital and various gifts to the small children in the "Sf. Nicolae" Day Care Center, in Ciurea.

Several Antibiotice employees responded to the call of the "Antibiotice – Science and Soul" Foundation to offer a toy to sick children and make them happy.

Three hundred soft toys, colourful toy-cars, dolls and puzzles were donated by the employees' children to the little ones who came to the hospital's playground, with the desire to alleviate their suffering, at least for a few moments.

On the occasion of June 1, the Foundation offered gift packs to 25 children in the "Sf. Nicolae" Day Care Center, in Ciurea. These children come from underprivileged families facing dropout risk. Within this center, they are provided with a hot meal and teaching guidance.

### **Antibiotice is close to the employees' children**

On the International Children's Day, Antibiotice offered toys to the employees' children, who agreed to take part in the activities organized on this occasion. A fairy-tale like show with characters such as Mickey Mouse, Spiderman, Tom and Jerry entertained the children by several sports competitions. The "Funny Olympics" gathered 70 children that had a lot of fun and received prizes for their participation in the competitions.

### ***A gift from the heart! Be Santa Claus!***

During the winter holiday season, the Foundation offered sweets and school supplies to children who gathered around the Christmas tree - adorned in the company's festivity hall - and sang carols. Among them there were 25 children from the "Sf. Nicolae" Day Care Center who, this year, met Santa Claus here at Antibiotice. Also, we offered sweets to 50 orphans from the "Sf. Andrei" foster home in Iași.

### **Antibiotice supports the Association of Former Employees**

Antibiotice supports the Association of Former Employees of our company by visiting the suffering, providing medicines and legal assistance in disputes with local or national authorities, thematic trips in the county or across the country. The Association is a bridge linking the company management and the former employees. The Association of Former Employees was founded in 2005 and it aims to monitor and solve various issues that the retirees face.

All these actions prove the concern Antibiotice has for people who have contributed over the years to developing and strengthening our business on the pharmaceutical market.

## **Education**

### **"Science and Soul" scholarships**

For over 12 years Antibiotice has been sustaining the "Pro Ruralis" Association that supports a scholarship program for high IQ students coming from poor families, living in rural areas. In November 2010, the project was taken over by the "Antibiotice - Science and Soul" Foundation. Initiated in 2001, the project

# 300

toys donated by Antibiotice employees to children in hospitals

# 70

of the personnel's children enjoyed lots of surprises on June 1<sup>st</sup>



12

years of granting the "Science and Soul" scholarships

offers an opportunity to intelligent, disadvantaged children from rural areas to complete their education according to their potential in elite high-schools in Iași.

Antibiotice participated to this generous program during the academic year 2012-2013, offering 5 "Science and Soul" scholarships.

The first 5 young people who have recently benefited from the financial support provided by Antibiotice graduated high school in the summer of 2009 and now attend various universities. In addition, on the occasion of various events and official holidays, the company offers schoolchildren gifts consisting in school supplies, clothing and shoes, invitations to various shows.

### Promoting the environmental protection

Regarding the protection of the environment, Antibiotice has committed itself through the Environmental Management System to prevent pollution, to continuously improve environmental performance by observing the environmental legislation. Due to obtaining, in December 2010, the Integrated Environmental Authorization, valid for 10 years, Antibiotice proves to be a company that meets the environmental requirements. Accordingly the emissions of pollutants in the air, water and soil are below the limits set by the European rules in this field.

The environmental program "Be pro nature. Get involved!" debuted at Antibiotice in 2008. Through this program, the company proves its responsibility and involvement in protecting the environment, investing significant resources in protecting the water, air and soil.

Under this program, the 2012 campaign included the following actions:

#### **Let's Do It, Romania! The National Cleaning Day**

On September 29, 2012 Antibiotice participated for the third year in a row along with high school students and employees of various institutions in Iași in the most important social awareness action conducted in Romania so far. Antibiotice volunteers helped collecting piles of household waste scattered around. The company also provided a means of transport that facilitated the transportation of volunteers to areas previously mapped.

Antibiotice also provided the organizers with 300 trash bags and ensured the voluntary participation of the company staff to the collection of waste in and around Iași city.

### **Earth Hour 2012**

Antibiotice participated for the fourth consecutive year in what has become the largest environmental campaign ever.

On March 31, 2012 Earth Hour was celebrated between 20:30 and 21:30 the outer lighting was turned off in areas where it was possible, as a symbolic gesture urging to a responsible management of resources. Raising awareness concerning the environmental issues is part of the company's strategy to manage resources responsibly (from consumption to recycling), as a first step in the effort to protect the environment. The participation in the Earth Hour campaign is included in the Environmental program "Be pro nature! Get involved!".

### Environmental responsibility

The company's activity in the field of environmental protection is regulated by the integrated environmental authorization no. 1/10.01.2011 issued by the Regional Agency for Environmental Protection Bacău (valid until 10.01.2021) and the Water Management Permit no. 303/20.12.2010 issued by the Romanian Waters National Administration, Water Basin Administration, Prut-Bârlad branch (valid until 31.12.2020).

All manufacture plants within the company own GMP and ISO 9001-certified technological flows, and both Nystatin and parenteral products manufacturing lines are FDA approved.

Antibiotice has implemented the integrated management system in the environmental, quality, health and occupational safety fields according to the EN ISO 14001:2004, EN ISO 9001:2008 and ISO 18001:2007 standards, certified in 2007 by Lloyd's Register Quality Assurance (the latest recertification audit took place in 2011).

There were no alterations in production capacity, development or cancellation of activities against the provisions of the Integrated Environmental Authorization.

In order to comply with the environmental legislation, Antibiotice provided the specific facilities and qualified personnel. The entire activity is regulated by the procedures relative to the environmental management system and environmental operating instructions.

The environmental monitoring was performed according to the requirements of the Integrated Environment Authorization, both in our laboratories as well as in a laboratory authorized by the Romanian Accreditation Association (RENAR).

4

years of participation in the Earth Hour Campaign

The measures taken by the environment control authorities have been solved and the requests for the integrated environmental permit have been met. No incidents/environment accidents or complaints have been reported.

### Specific consumptions and energy use

At Antibiotice, the Biosynthesis Manufacture Plant which produces Nystatin active ingredient is regulated by the International Plant Protection Convention (IPPC). The main raw materials used in the manufacture of Nystatin are: soy flour, corn starch, corn extract (45%), dextrose monohydrate, refined soy oil, subtilase, calcium carbonate, ammonium sulfate, ferrous sulfate, solid diammonium phosphate (dibasic), solid monopotassium phosphate, technical ammonia, acetone and methanol. In 2012, the specific consumptions of the Biosynthesis Manufacture Plant fell within the planned value range.

### Total environmental costs in 2012

Activity	Costs 2012 (RON)
Waste water treatment plant – operation, monitoring, third party services, staff expenditure	2,941,681
Incineration of waste – installation operation, collection, transport, staff expenditure	634,443
Environmental management – waste collection and transport, maintenance and landscaping	462,572

### Specific consumption of acetone and methanol – Biosynthesis Plant in 2012

Solvent	BOU	Planned specific consumption	Specific consumption 2011	Specific consumption 2012
Acetone	kg solvent/BOU Nystatin*	1.040	1.02745	1.03917
Methanol	kg solvent/BOU Nystatin*	1.032	0.95156	0.92509

\* BOU = billions of units

### Specific consumption Indicators at company level in 2012 (utilities per 1000 RON)

Year	Electricity (MWh)	Natural gas (thousand m <sup>3</sup> )	Drinking water (thousand m <sup>3</sup> )	Total utilities (thousand RON)	Commodity output value (thousand RON)	Electricity/Commodity output (MWh/thousand RON)	Natural gas/Commodity output (m <sup>3</sup> /thousand RON)	Drinking water/Commodity output (m <sup>3</sup> /thousand RON)
2011	11,262	5,158	140	8,388	272,369.5	0.0413	18.94	0.514
2012	13,601	5,468	169	11,016	285,170.7	0.0477	19.17	0.593

### Air quality

In 2012, air quality monitoring was carried in our in-house laboratory within the waste treatment plant, where 3,432 analyses of pollutant emissions were performed, for the following indicators: nitrogen oxides, ammonia, particulate matter and sedimentable powder.

There were no exceedances of the maximum acceptable concentrations specified in the Integrated Environmental Authorization. The emissions of non-methane volatile organic compounds (nmCOV) of the Nystatin API extraction equipment were determined based on the balance of solvents and samples taken and analyzed by Givaroli Bucharest, a third party laboratory.

The monitoring of emissions from our own incineration facility was performed according to the Integrated Environmental Authorization. The analyses were performed by the Givaroli Bucharest laboratory. The results, written down in the certificates of analysis reveal that the equipment operates within

the designed parameters, in compliance with the environmental standards aligned to the European directives.

The analysis of the exhaust gas produced by our own power plant revealed no exceedances of the emission limit values (ELV).

### Water quality

The water quality monitoring involved the performance of 24,490 water-quality tests monitoring the water entering our own wastewater treatment plant and discharging into the municipal sewer system, the conventionally clean waters discharged in the natural emissary, as well as the underground water.

There were no exceedances of the maximum permissible concentrations provided by the Integrated Environmental Authorization, the Water Management Authorization and GD no. 352/2005 (NTPA 001 and NTPA 002).

The wastewater treatment plant operated with yields ranging between 85% and 98%, which corresponds to a highly-performing operation.

### **Soil and groundwater protection**

Of a total of 41.50 ha of land owned by Antibiotice, approximately 16.50 ha are undeveloped and arranged as green space.

The groundwater quality was monitored through monthly sampling and testing from the nine observation wells and the drilling located downstream from the waste warehouse.

There was no accidental pollution or environmental incident leading to the degradation of soil quality in the area influenced by the company's activity.

### **Waste management**

Antibiotice has implemented a system of selective waste collection, thus each manufacture plant and auxiliary activity is equipped with suitable containers for collection.

The recyclable waste were exploited by concluding contracts with licensed operators.

The unused waste was incinerated in our own facility or disposed of in the municipal waste landfill.

The overall and the minimal objectives of recovery through recycling by types of materials set for 2012 (according to GD no. 621/2005, amended and supplemented) have been met.

Our company complies with the packaging waste management norms (in accordance with the amount of products Antibiotice has put to the Romanian market). In 2012 we maintained the contract with an authorized economic operator who collected and capitalized, on behalf of our company 350,500 kg of glass, 214,000 kg of paper and cardboard, 49,750 kg of plastic and 30,910 kg of metals (aluminium).

The waste electrical and electronic equipment (WEEE) were collected under the internal procedure and the total amount in stock is 4888.50 kg. The WEEE are stored within our company in adequate premises (closed, masonry facilities) and they are handed over to authorized economic operators.

### **Emergency prevention and management**

At Antibiotice, the emergency prevention and interventions in case of accidents are covered by the following services: Emergency, Environmental Protection and Prevention and Protection.

To this end, the following plans were developed: the plan to prevent and control accidental pollution, the accident prevention policy for hazardous substances (solvents), the plan for fire protection (firefighting and fire prevention), fire safety scenario, fire scenario approach, the procedure for emergency preparedness and response, authorizations/documents required for all equipments covered by the regulations of the State Inspection for Control of Boilers, Pressure Vessels and Hoisting (ISCIR).

In 2012, seven internal fire alarm drills were performed on the company premises. On the occasion of the annual inspection of the Inspectorate for Emergency Situations of Iași County (ISUJ Iași), our company together with the ISUJ representatives simulated an accident involving hazardous substances and another one in a high fire risk area. The alarm drills tested and assessed the response of the emergency response teams.



# 09

## Economic and financial results in 2012

In 2012, the activity conducted by Antibiotice was harmonized to the policy for accomplishing the objectives and targets set in the Revenue and Expenditure Budget.

Adopting the International Financial Reporting Standards for the first time required the restatement of accounting records according to the Minister of Public Finance's Order no. 881/2012 and 1286/2012.

### Statement of the global result

#### 8.6% growth in sales revenue over 2011

Sales revenue recorded in 2012 amounted to RON 304.09 million, up 8.6% over 2011, when sales revenue accounted for RON 280.02 million, the result of sustained efforts made by the entire company to consolidate the business.

In 2012, the production sold reported a 9.8% growth, amounting to RON 286.03 million as compared to RON 260.47 million in 2011.

The revenues generated by product sales amounting to RON 56.95 million represent, for the main part, the counter value of products manufactured in manufacturing facilities abroad (out-sourcing), specialized manufacture lines pursuant to the requirements imposed by the GMP guidelines applicable.

Expenses on raw materials and consumables grew by 17.39% compared to 2011 due to changes in the production structure, hence in the quantities supplied, and due to higher prices of raw materials.

Commodity production went up 5% totaling RON 272.37 million while utilities increased by 34% due to the policy aligning our prices to EU prices, as follows: electricity increased by 13%, methane gas by 26% and water by 5%.

RON	Dec 31, 2012	Dec 31, 2011	2012/2011
<b>Sales revenue</b>	<b>304,086,833</b>	<b>280,020,922</b>	<b>8.59%</b>
Other operating income	27,279,538	31,162,111	-12.46%
Income relative to cost of product stocks	520,299	870,962	-40.26%
Income from the capitalized activity	2,346,621	567,689	313.36%
Expenses on raw materials and consumables	(102,129,986)	(87,002,398)	17.39%
Personnel expenses	(68,929,460)	(68,426,642)	0.73%
Expenses on amortization and depreciation	(18,124,209)	(15,902,068)	13.97%
Other operating expenses	(103,271,107)	(110,623,830)	-6.65%
<b>Operating profit</b>	<b>41,778,528</b>	<b>30,666,747</b>	<b>36.23%</b>
Net financial income	(9,319,490)	(4,352,336)	114.13%
<b>Profit before tax</b>	<b>32,459,037</b>	<b>26,314,410</b>	<b>23.35%</b>
Expenses on current income tax and deferred tax	(5,348,201)	(6,117,994)	-12.58%
<b>Profit</b>	<b>27,110,836</b>	<b>20,196,416</b>	<b>34.24%</b>

RON	Dec 31, 2012	Dec 31, 2011	2012/2011
Sales of finished products	286,030,387	260,469,015	9.8%
Sales of goods	56,947,765	61,912,253	-8.0%
Trade discounts	(38,891,319)	(42,360,345)	-8.2%
<b>TOTAL</b>	<b>304,086,833</b>	<b>280,020,923</b>	<b>8.6%</b>

**Other operating expenses**

RON	Dec 31, 2012	Dec 31, 2011	2012/2011
Utilities	11,016,102	8,222,129	34%
Repairs	3,042,316	3,803,303	-20%
Rent	163,130	143,115	14%
Insurance	1,152,204	1,443,896	-20%
Banking fees	1,319,161	1,561,999	-16%
Advertising and promotion	2,676,795	3,787,915	-29%
Travel and transport	3,469,717	2,824,992	23%
Telecommunication and postal services	538,393	440,859	22%
Other services provided by third parties	36,624,262	45,996,635	-20%
Other taxes and fees	16,855,939	2,664,730	533%
Environmental protection	–	7,806	
Expenses generated by assignment of assets	31,894	–	
Losses and adjustments to uncertain receivables	6,947,098	20,200,792	-66%
Other provisions	2,900,000	2,293,525	26%
Foreign exchange differences	14,961,996	16,402,883	-9%
Miscellaneous	1,572,099	829,251	90%
<b>TOTAL</b>	<b>103,271,107</b>	<b>110,623,830</b>	<b>-7%</b>

The indicator other operating expenses is influenced by the claw back tax which generated a 533% increase of taxes and charges, from RON 2.66 million in 2011 to RON 16.86 million in 2012.

**8.6%**  
growth in sales  
revenue over 2011

**Cutting down costs by process optimization**

With Antibiotice, a constant concern of the entire management team as well as employees is to constantly reduce costs through process optimization, in order to improve cost structure. The share of payroll expenses reported a decrease of approximately 1%, leading to an increased labor productivity by 8%, evolving from 193,118 RON/employee in 2011 to 207.568 RON/employee in 2012.

Expenditure on tangible and intangible assets amortization and depreciation rose 14%, from RON 15.9 million in 2011 to RON 18.12 million in 2012, as a result of aligning to the IFRS.

**Profit distribution in 2012**

Destination	Amount (RON)
<b>Profit distribution:</b>	<b>27,110,836</b>
legal reserve	18,699
self-financing sources and profit distribution pursuant to the law	16,759,043
dividends, of which:	10,333,094
- dividends due to the majority shareholder	5,478,325
- dividends due to individuals and corporate shareholders	4,854,769

Furthermore, the influence of a rigorous management of all expenses resulted in an operating profit of RON 41.78 million, up 36% as compared to the value reported in 2011, RON 30.67 million.

**Foreign exchange rate evolution**

The USD exchange rates reported fluctuations throughout 2012, from RON 3.339 on December 31, 2011 to 3.358 RON as of December 31, 2012, with a maximum of 3.573 RON in November 2012 and a minimum of 3.238 RON in January 2012.

With respect to the EURO, exchange rates rose from RON 4.3197 on December 31, 2011 to RON 4.429 on December 31, 2012 with a peak of RON 4.648 in August 2012 and a low of RON 4.327 in January 2012.

Net financial income was mainly influenced by the following charges:

- bank interest amounting to RON 2.36 million;
- expenditure on discounts in the amount of RON 7.04 million.

In 2012, profit before tax amounted to RON 32.46 million, 23% higher than the figure recorded in 2011, i.e. RON 26.31 million.

Profit after tax amounted to RON 27.11 million, 34% higher than 2011 when it was only RON 20.2 million.

The distribution of the accounting profit recorded after deducing income tax was conducted according to G.O. 64/2001 approved and amended by Law 769/2001 and G.O. 61/2004.

The amount of RON 16,759,043 standing for self-financing sources in conformity with the applicable law, consists of:

- Amounts generated by the capitalization of fixed assets amounting to RON 44,113.
- Amounts generated by waste valorization amounting to RON 1,434,942.
- Amounts generated by adjustments to the reported result amounting to RON 2,486,809.
- Amounts resulting from dividends reported as income RON 1,920,713.
- Financial facilities for R&D activities pursuant to art. 19 in the Fiscal Code.
- Self-financing sources amounting to RON 10,333,095.

Total dividends amounting to RON 10,333,094, distributed as follows:

- The Ministry of Health (53.0173%) – RON 5,478,325
- Other legal and natural persons (46.9827%) – RON 4,854,769

**Balance sheet for the financial period 2010-2012**

Financial statement (RON)	Dec 31, 2012	Dec 31, 2011	Dec 31, 2010	2012 / 2011	2011 / 2010
<b>ASSETS</b>					
<b>FIXED ASSETS</b>					
Tangible assets	198,463,669	211,206,357	210,983,245	-6%	0,1%
Intangible assets	4,887,455	1,652,572	1,989,253	196%	-17%
<b>Fixed assets</b>	<b>203,351,125</b>	<b>212,858,929</b>	<b>212,972,497</b>	<b>-4%</b>	<b>-0,1%</b>
<b>CURRENT ASSETS</b>					
Stocks	47,973,857	41,943,038	40,289,331	14%	4%
Trade and similar receivables	256,986,254	226,845,657	181,673,656	13%	25%
Financial assets intended for sale	140	140	60,140	0%	-100%
Cash and cash equivalents	6,006,554	5,339,857	3,723,380	12%	43%
<b>Total current assets</b>	<b>310,966,804</b>	<b>274,128,692</b>	<b>225,746,507</b>	<b>13%</b>	<b>21%</b>
<b>TOTAL ASSETS</b>	<b>514,317,929</b>	<b>486,987,621</b>	<b>438,719,004</b>	<b>6%</b>	<b>11%</b>
<b>LIABILITIES</b>					
<b>CURRENT LIABILITIES</b>					
Trade and similar payables	58,963,493	57,479,626	40,103,069	3%	43%
Credits	92,290,294	82,416,576	69,335,186	12%	19%
Debt relative to corporate	1,139,461	1,080,877	1,166,680	5%	-7%
Taxes	2,812,412	1,745,012	47,533	61%	3571%
Provisions	2,900,000	2,090,000	1,400,000	39%	49%
<b>Total current liabilities</b>	<b>158,105,660</b>	<b>144,812,091</b>	<b>112,052,468</b>	<b>9%</b>	<b>29%</b>
<b>LONG-TERM DEBT</b>					
Subventions for investments	4,431,688	4,938,038	5,582,049	-10%	-12%
Deferred tax	918,436	6,027,912	7,354,785	-85%	-18%
Provisions	4,313,611	4,521,574	4,318,049	-5%	5%
<b>Total long-term debt</b>	<b>9,663,735</b>	<b>15,487,524</b>	<b>17,254,883</b>	<b>-38%</b>	<b>-10%</b>
<b>TOTAL DEBT</b>	<b>167,769,395</b>	<b>160,299,615</b>	<b>129,307,351</b>	<b>5%</b>	<b>24%</b>
<b>NET ASSETS</b>	<b>346,548,531</b>	<b>326,688,006</b>	<b>309,411,653</b>	<b>6%</b>	<b>6%</b>
<b>SHARE CAPITAL AND RESERVES</b>					
Share capital	254,502,062	249,129,629	238,748,469	2%	4%
Revaluation reserves	135,933,818	142,267,991	150,477,382	-4%	-5%
Legal reserves	11,341,443	10,021,560	9,097,946	13%	10%
Other reserves	101,607,532	91,900,555	89,341,613	11%	3%
Reported result	(156,836,324)	(166,631,730)	(178,253,757)	-6%	-7%
<b>TOTAL EQUITY</b>	<b>346,548,531</b>	<b>326,688,006</b>	<b>309,411,653</b>	<b>6%</b>	<b>6%</b>
<b>TOTAL EQUITY AND LIABILITIES</b>	<b>514,317,929</b>	<b>486,987,621</b>	<b>438,719,004</b>	<b>6%</b>	<b>11%</b>

**Statement of the financial position**

On December 31, 2012 the buildings and land owned by Antibiotice were revalued, causing a 4% drop of fixed assets compared to the values recorded in early 2012. Depreciation was calculated using the straight line depreciation method, as per IFRS.

## Current assets

In late 2012 stocks reported a 14% increase over the value recorded at the beginning of the year, due to providing the supply of raw materials for the Q1 2013 production, without exceeding the stock estimates approved.

Overall, the value of receivables went up by 13%, from RON 226.85 million in early 2012 to RON 256.99 million, against an 8.6% boost in sales over the previous year.

In 2012, the average period for collecting receivables from the foreign market was 93 days. In contrast to this, the similar interval for the domestic market was 393 days, with an average of 324 days. Cash and cash equivalents increased by 12% since 2011, while the company's assets reported a 6% boost against 2011.

## Liabilities

As of December 31, 2012, the company recorded current liabilities amounting to RON 158.11 million, up 9% from 2011.

At the end of fiscal year 2012, the amounts owed to financial institutions were 12% higher than in the previous year, rising from RON 82.42 million on December 31, 2011 to RON 92.29 million on December 31, 2012.

The provision for wages made at the end of 2012 represents the employees' contribution to profit as well as the variable compensation of Management Board members for achieving the financial indicators. Net assets have recorded a steady dynamic growth of 6%.

Share capital has been restated in accordance with IAS 29 hyperinflationary economies, amounting to 254.5 million.

## Cash flows

The level of cash and cash equivalents at the beginning of the period was RON 5.34 million. Cash receipts from operating activities amounted to RON 264.46 million. Cash payments to suppliers of goods and services were RON 167.24 million, while payments

## Amounts owed to financial institutions as of 31.12.2012

Short-term contract no. 28/18.04.2005 concluded with **Alpha Bank Iași**

Type of loan	Line of credit – current capital
Amount	RON 8,000,000 EUR 100,000
Maturity date	31.05.2013
Balance on December 31, 2012	EUR 6,771,418
Warranty	Claim assignment agreement

Short-term contract no. 5175/17.07.2006 concluded with **RBS Bank Romania**

Type of product	Line of credit – current capital
Amount	EUR 11,000,000
Maturity date	31.07.2013
Balance on December 31, 2012	EUR 10,621,877 (RON 47,041,109)
Warranty	Mortgage on buildings and land

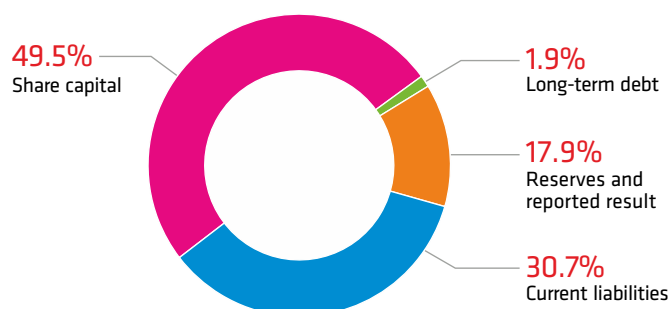
Short-term contract no. 12239/22.05.2012 concluded with **ING BANK N.V. AMSTERDAM, Romania**

Type of product	Line of credit – current capital
Amount	EUR 9,500,000
Maturity date	22.05.2013
Balance on December 31, 2012	EUR 8,688,276 (RON 38,477,767)
Warranty	Claim assignment agreement/ Mortgage on buildings and land

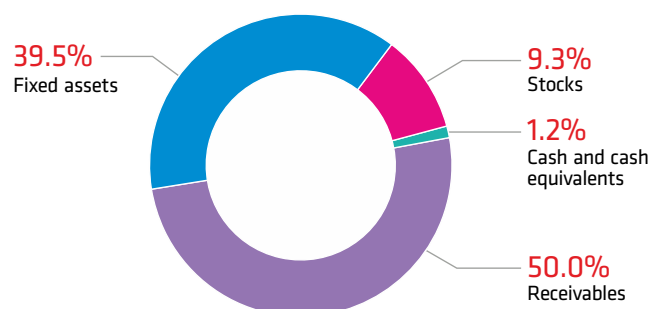
to and on behalf of employees (together with payments relative to personnel) totaled RON 66.86 million.

Payments amounting to RON 9.36 million covered the income tax, VAT, local taxes and bank interest; payments for purchasing fixed assets worth of RON 9.63 million were made. In addition, RON 14.56 million paid consisted of contributions to the Ministry of Health, covering the claw back tax.

## Liabilities



## Assets



## Cash flow statement

RON	Relative to financial year ending	Dec 31, 2012	Dec 31, 2011
<b>I. OPERATING CASH FLOW</b>			
Cash receipts from sales of goods and provision of services		264,462,896	201,054,849
Cash receipts from royalties, fees, commissions and other types of income		–	9,044,885
Cash payments to suppliers of goods and services		(167,244,481)	(124,738,999)
Cash payments to and on behalf of the employees and personnel-related payments		(66,860,018)	(65,947,785)
VAT paid		(987,665)	–
VAT collected		2,903,713	1,401,405
Contributions to the Ministry of Health and the Environment		(14,555,828)	(876,843)
Other taxes, fees and similar charges		(1,057,711)	(59,266)
<b>Operating cash flow</b>		<b>16,541,358</b>	<b>19,878,246</b>
Interest charged		86,131	46,791
Interest paid		(2,287,538)	(2,548,848)
Income tax paid		(5,026,660)	(4,334,627)
<b>Net operating cash flows</b>		<b>9,313,290</b>	<b>13,041,563</b>
<b>II. INVESTMENT CASH FLOW</b>			
Cash payments for purchasing land and fixed assets, intangible assets and other long-term assets		(9,630,027)	(22,247,995)
Interest charged		(1,283)	186
Dividends earned		–	628
<b>Net investment cash flows</b>		<b>(9,631,310)</b>	<b>(22,247,181)</b>
<b>III. FINANCING CASH FLOW</b>			
Proceeds/repayments from long-term loans		–	–
Proceeds/repayments from short-term loans		8,771,395	11,408,158
Payments for financial leasing operations		–	(55,918)
Dividends paid		(7,786,678)	(530,144)
<b>Net financing cash flows</b>		<b>984,717</b>	<b>10,822,096</b>
<b>Net cash increase / (decrease)</b>		<b>666,697</b>	<b>1,616,477</b>
<b>Cash and cash equivalents at the beginning of the period</b>		<b>5,339,857</b>	<b>3,723,380</b>
<b>Cash and cash equivalents at the end of the period</b>		<b>6,006,554</b>	<b>5,339,857</b>

In terms of financing activities cash collections were reported amounting to RON 8.77 million, consisting of short-term loans and payment of dividends worth RON 7.79 million.

At the end of the financial year, the level of cash and cash equivalents was RON 6 million.

# 10

## Independent Auditor's Report to Antibiotice shareholders

(1) We have audited the enclosed financial statements of the trading company Antibiotice S.A. (hereby referred to as the Company) comprising the balance sheet as of December 31, 2012, profit and loss account, statement of changes in equity and cash flow statement for the financial year ended at the above-mentioned date and a summary of the significant accounting policies and other explanatory notes.

### Executive team's responsibility for the financial statements

(2) The Company's executive team is responsible for the preparation and fair presentation of these financial statements in accordance with the International Financial Reporting Standards (IFRS) and for the internal control which the management considers it relevant for elaborating the financial statements without significant misstatements due to fraud or error.

### Auditor's Responsibility

(3) Our responsibility is to express an opinion on these financial statements, based on our audit. We conducted our audit in accordance with the International Standards on Auditing. These standards require us to comply with the ethical requirements, to plan and perform the audit in order to obtain reasonable assurance that the financial statements are free from significant misstatements.

(4) An audit involves performing procedures to obtain audit evidence on the amounts and information contained in the financial statements. The selection of procedures is based on the professional judgment of the auditor, including the evaluation of risks relative to significant misstatements in the financial statements due to error or fraud. In conducting these risk evaluations the auditor takes into account the internal control relevant for the drawing up and faithful presentation of these financial statements in order to set the relevant auditing procedures in the given circumstances, but not with the aim of expressing an opinion on the effectiveness of the internal control system of the company. Auditing the financial statements equally includes evaluating the appropriateness of the accounting

policies used, the reasonableness of the management's accounting estimates, as well as the assessment of the overall financial statement presentation.

(5) We consider that the audit evidence obtained provide a reasonable basis for our qualified opinion.

### Basis for our qualified opinion

(6) The financial statements include the costs of services purchased from distributors, without being able to quantify the level of the trade discounts included in these costs. As a result of the above, we are unable to estimate the real impact on the global result.

### Our qualified opinion

(7) In our opinion, with the exception of the possible adjustments resulting from those set out in paragraph (6), the financial statements give a true and fair view, in all significant aspects, of the financial position of Antibiotice company on December 31, 2012, as well as of the financial performance and cash flows for the financial year ended on the above-mentioned date in accordance with the International Financial Reporting Standards.

### Report on the compliance of the executive team's report with the financial statements

(8) In accordance with the Order of the Minister of Public Finances no. 1286/2012, annex 1, article 16 (1), paragraph (c), we have read the executive team's report attached to the financial statements. The executive team's report is not part of the financial statements. We have not identified in the executive team's report any item of financial information significantly non-compliant with the information presented in the attached financial statements.

In the name of:

**BDO AUDIT SRL**

Registered at the Chamber of Financial Auditors of Romania with the no. 18/02.08.2001

Signatory's name:

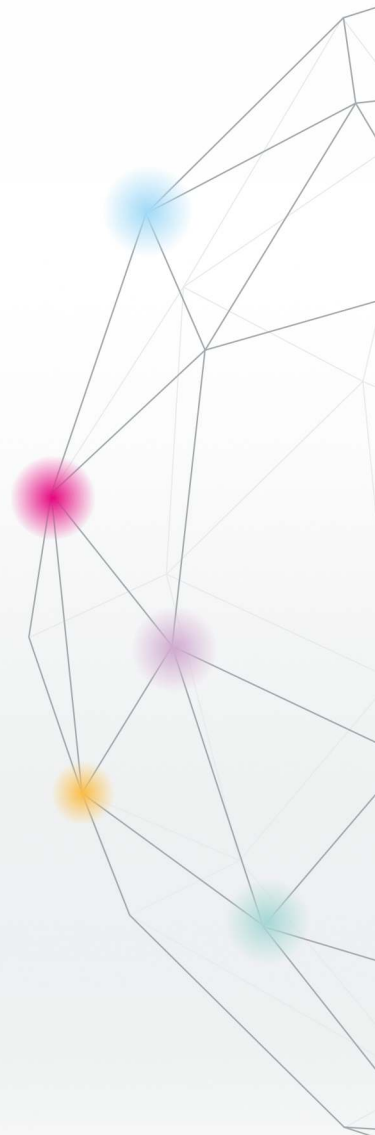
**Mircea Tudor**

Registered at the Chamber of Financial Auditors of Romania with the no. 2566/25.06.2008

April 4, 2013



ANNUAL  
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2012



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