

# MANAGEMENT REPORT

**January-December 2019**

**Annual Report according to IFRS**

**For the fiscal year: 2019**

**Report Date: 09.04.2020**

**Name of the trading company: ANTIBIOTICE S.A.**

**Head Office: Iasi, 1 Valea Lupului St.**

**Phone number: 0232/209000, Fax 0232/209633**

**Fiscal registration code: RO 1973096**

**Order number in the Trade Register: J22/285/1991**

**Regulated market on which the issued securities are traded: Bucharest Stock Exchange**

**Subscribed and paid up capital: 67,133,804 LEI**

**Main characteristics of the securities issued by the company: Nominative shares, nominal value: 0.10 LEI**

## **CONTENTS**

### **I Our company's presentation**

### **II Shareholding**

### **III Current activity**

- International business development
- Ensuring a sustainable and marketable portfolio by increasing the degree of renewal
  - Evolution of the pharmaceutical market in Romania
  - Evolution of the pharmaceutical market relevant to Antibiotice SA
  - Research-Development for adapting and durable strengthening our portfolio
  - Complex manufacturing structure adapted to the GMP and FDA requirements
  - Investments for developing our company in the medium and long term
  - Acquisitions - an important link in the value chain
- Optimizing the operating costs and increasing the operating efficiency
- Motivating the human resources and ensuring them with the proper training for developing their skills needed to achieve the company's strategic directions
  - Identifying and attracting qualified staff for ensuring a proper professional structure
  - Carrying out professional training programs
  - Strategies and measures to increase our employees' motivation
  - Providing a favorable working environment and organizational culture oriented to innovation and performance
- Quality management for meeting the legal national and international requirements of the pharmaceutical industry
  - Certified quality
  - Environmental responsibility
  - Labour health and safety
  - Antibiotice, a responsible company involved in the sustainable development

### **IV Corporate governance**

- Governance Code
- Code of Ethics
- General Meeting of Shareholders
- Management Board
- Advisory Committees
- Executive Management
- Internal Audit, Financial Inventory Control, Risk Management

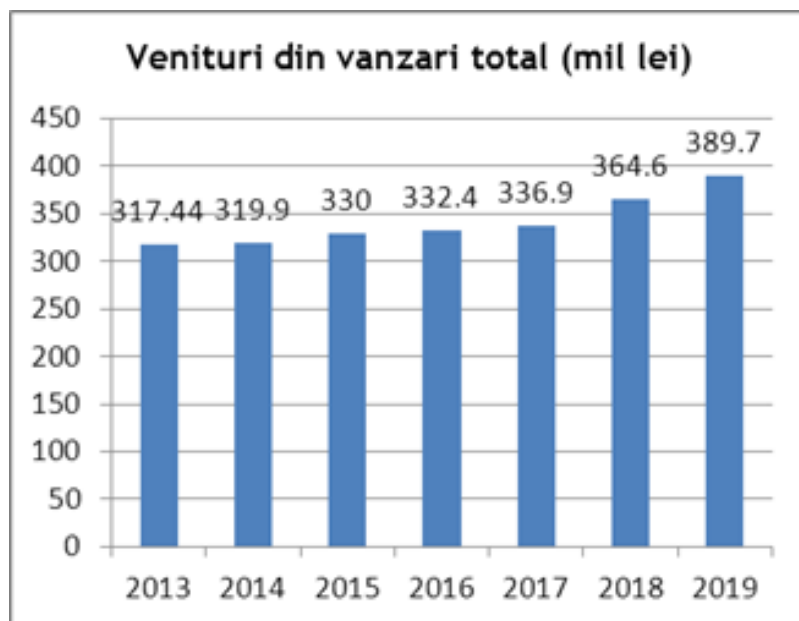
## V Conclusions

### I Antibiotice's presentation

Antibiotice SA is the most important Romanian manufacturer of generic medicines, a nationally and internationally reference brand which has been continuing its mission of producing quality, safe and efficient medicines to give people the hope of a healthy life.

Antibiotice SA :

- the main manufacturer of anti-infectives in Romania, a leader in the production of injectable beta-lactam antibiotics ;
- leader in the production of topicals (ointments, creams, gels) in the Romanian market;
- its exports account for 40% of the turnover;
- ranks first globally in the production of the active substance Nystatin, our product being the USP Reference Standard - an international quality standard;
- has a portfolio comprising 150 products from 12 therapeutic classes:



cardiovasculars, dermatologicals for topical use, inflammatory, digestive tract and genitourinary medicines, food supplements;

- has 8 manufacturing flows for the following pharmaceutical dosage forms: penicillin powders for injection, penicillin capsules, non-beta-lactam capsules, cephalosporin capsules, tablets, ointments, creams, gels; suppositories, pessaries, active

substances obtained through biosynthesis;

- holds internationally recognized certifications and authorizations:

- authorization for Nystatin and injectable penicillin products granted by the Food and Drug Administration (FDA) , the US drug regulatory body;
- Certificate of Suitability (COS) with the European Pharmacopoeia for Nystatin;
- Good Manufacturing Practice (GMP) certificate for all the manufacturing flows, Integrated Management System (quality, environment , occupational health and safety);
- has a modern Research-Development Center and a Clinical Studies Center;
- is the first European company prequalified by the World Health Organization (WHO) for the range of essential first-line antituberculosis medicines.

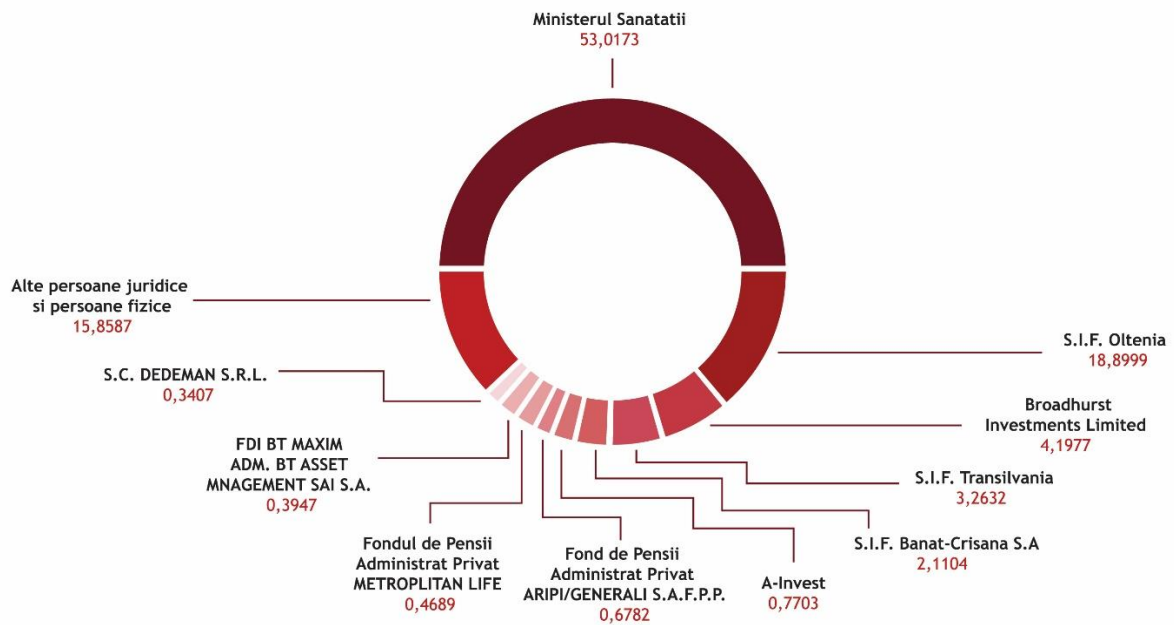
## II. Shareholding

Antibiotice SA is a trading company in which the majority shareholder is the Ministry of Health with 53.0173% of the subscribed and paid-up capital. Bucharest Stock Exchange (BVB) is the regulated market in which the securities issued by Antibiotice SA are traded in the PREMIUM category.

The main Antibiotice shareholders on 31.12.2019 (*extracted from the Shareholders' Registry*):

- Ministry of Health (\*) - 53.0173%,
- S.I.F. Oltenia(\*) - 18.8999%
- Broadhurst Investments Limited - 4.1977%
- S.I.F. Transilvania - 3.2632%
- S.I.F. Banat-Crisana S.A - 2.1104%
- A-Invest - 0.7703%
- Private Pension Fund ARIPI/GENERALI S.A.F.P.P. - 0.6782%
- Private Pension Fund Privat METROPLITAN LIFE - 0.4649%
- FDI BT MAXIM ADM. BT ASSET MNAGEMENT SAI S.A. - 0.3947%
- S.C. DEDEMAN S.R.L. - 0.3407%
- Other legal and natural persons - 15.3452%.

NOTE: (\*) - Significant shareholders, according to Law no. 297 of 28.06.2004, Art. 2, Para. 1



### Ownership breakdown:

- Legal persons - 86.9922%
- Natural persons - 13.0078%

### Antibiotice in the capital market

Since 1997, the shares issued by Antibiotice have been listed in the PREMIUM category of the Bucharest Stock Exchange, under the ATB symbol.

The first transaction was recorded on April 16, 1997, at a reference price of 0.3500 LEI/share. The historical maximum was reached on July 10, 2007, at the price of 2.1700 LEI/share and the historical minimum of 0.0650 LEI/share was recorded on June 8, 2000.

Both the company's business plans and financial results represent a solid guarantee that Antibiotice has consolidated its position in the national pharmaceutical market.

The Antibiotice (ATB ) shares traded on the Bucharest Stock Exchange are included in the BET-Plus index which comprises the Romanian companies listed on the BVB market that meet the minimum selection criteria, except for financial investment companies.

In 2019, the minimum price of the ATB share had the value of 0.4500 LEI. The share price increased to maximum value of 0.5260 LEI/share.

Stock market capitalization of Antibiotice on December 31, 2019 (the last trading day of the year) was 341,040 thousand LEI.

#### Antibiotice shares - ATB / Regular market

	2015	2016	2017	2018	2019
Number of shares	671,338,040	671,338,040	671,338,040	671,338,040	671,338,040
Stock market capitalization (thousand LEI)*	357,152	349,096	361,180	326,942	341,040
Stock market capitalization (thousand EUR)*	78,868	76,875	77,511	70,100	71,370
Stock market capitalization (thousand \$)*	86,167	81,123	92,813	80,259	79,873
Total traded value (million LEI)	11	6	12	9	15
No. of traded shares	18,844,935	12,555,866	21,113,565	17,109,263	30,364,292
Opening price (LEI/share)	0.5850	0.5320	0.5200	0.5780	0.4800
Maximum price (LEI/share)	0.6170	0.5420	0.5920	0.5780	0.5260
Minimum price (LEI/share)	0.5240	0.4200	0.5200	0.4550	0.4500
Price at the end of the period (LEI/share)	0.5320	0.5270	0.5380	0.4870	0.5080
Average price (LEI/share)	0.5836	0.5032	0.5585	0.5028	0.4851
Earnings/share (LEI/share)***	0.0405	0.0452	0.0500	0.0511	0.0459
Gros dividend/share (LEI/share)**	0.0197	0.0384	0.026552598	0.009991506	0.029879738
Dividend yield****	3.69%	4.05%	4.59%	2.05%	6.2
Dividend distribution rate*****	49%	52%	53%	20%	65

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

\*\* Proposed dividend

\*\*\* Calculation of the earnings per share is based on the net profit of each year

\*\*\*\* Dividend per share/price of the share in the first trading day of each year

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

In 2019, a number of 30,364,292 shares were traded, amounting to 14.73 million LEI (3.2 million EUR, 3.6 million USD), with an average price of 0.4851 LEI/share.

In 2019, our company paid dividends for the financial years 2015, 2016 2017 and 2018 amounting to 6,166,189 LEI, as follows:

***Dividend history (2015 - 2016 - 2017 - 2018)'***

Period	Net dividends							Date on which the payment of dividends ceases
	Due	Paid				Unclaimed dividends on 31.12.2019		
		LEI			% (total amount paid)	lei	%	
		Until 31.12.2018	01.01÷31.12.2019	Total				
0	1	2	3	4	5	6	7	8
2015	13.753.343	12,653,207.76	11,948.01	12,665,155.77	92.09	1,088,187.23	7.91	15.09.2019
2016	25.401.595	23,325,012.26	53,762.17	23,378,774.43	92.04	2,022,820.57	7.96	Payment in progress
2017	17.588.679,97	16,093,548.70	44,614.60	16,138,163.30	91.75	1,450,516.67	8.25	Payment in progress
2018	6.612.624,05	-	6,055,864.22	6,055,864.22	91.58	556,759.83	8.42	Payment in progress

Payment of the dividends for the fiscal years 2015, 2016, 2017 and 2018 has been made through the Central Depository Bucharest and, implicitly, through the CEC Bank - the Paying Agent.

**The rights of the holders of financial instruments**

The corporate governance framework adopted and applied:

- protects the shareholders' rights;
- ensures the fair treatment of all shareholders;
- recognizes the role of third parties with interests in the company;
- guarantees the provision of information and its transparency;
- assures the responsibility of the Management Board towards the company and the shareholders.

On the company's website at [www.antibiotice.ro/investors/informationforshareholders](http://www.antibiotice.ro/investors/informationforshareholders), there is a section dedicated to our shareholders, where they can access and download documents related to the General Meetings of Shareholders: procedures regarding the access and participation in the meetings, the notice to attend, additions to the agenda, informative materials, special representation proxies, correspondence voting forms, decision drafts, decisions, voting results, etc..

Antibiotice makes available to all interested the periodical and annual financial statements prepared according to the legislation in force. The company also complies with all disclosure requirements under the laws of commercial companies and capital market.

Our company has a department specialized in the relations with the existing and potential investors, called Investor Relations, which has as main roles to implement and monitor the corporate governance standards within our company, to inform the shareholders and investors in accordance with the legal provisions, to proactively communicate with our investors focused on their information needs.

The persons appointed to keep in touch with the investors deal with the shareholders' requests with maximum efficiency and facilitate the dialogue with our company's management. Our company creates and develops an appropriate policy to promote an effective communication with our investors and shareholders.

Being permanently focused on developing its transparency towards shareholders, in completing its strategy of improving the relations with investors and from the desire to create value for shareholders, on July 31, 2019 Antibiotice joined the Romanian Investor Relations Association (A.R.I.R.), a lively new community in the Romanian capital market.



**The Romanian Investor Relations Association (A.R.I.R.)** is a non-governmental and non-profit organization that was set-up to provide current and potential issuers a platform for the development of Investor Relations (IR) and contribute to the implementation of best practices in investor communication and corporate governance.

For its Investor Relations activity and for the degree of transparency, accuracy and completeness of the information and accessibility of its website, Antibiotice got the 10 score granted by the Romanian Investor Relations Association that evaluated 78 issuers in the Romanian capital market.

Antibiotice has achieved this performance by approaching new and efficient communication tools. This way, the investors, analysts, brokers, journalists have the opportunity to learn about the Antibiotice business.

### III Current activity

Our company's coherent development strategy is reflected by the evolution of performance indicators, as follows:

No.	Indicators	Currency	2018	2019	2019/ 2018
1	Sales income	million LEI	364,576	389,710	1.07
2	Gross profit	million LEI	35,089	35,180	1.00
3	Arrears	million LEI	0	0	1.00
4	Total expenses related to 1000 lei total income	million LEI	907	914	1.01

These indicators were achieved by applying the actions of the five strategic development directions set out in the Administration Plan for the period 2017-2021:

1. **Developing our business internationally;**
2. **Ensuring a sustainable and marketable portfolio by increasing the degree of renewal;**
3. **Optimizing the operating costs and increasing the operating efficiency;**

4. **Motivating the human resources and providing them with the necessary training to acquire the skills needed for implementing the strategies;**
5. **Quality management for meeting the legal national and international pharmaceutical requirements.**

## **1. Developing our business internationally**

Antibiotice runs its business in all the continents of the world, with a portfolio comprising 95 finished products from various therapeutic classes and Nystatin, the active substance which ranks us as the world market leader.

**In 2019 Antibiotice recorded the highest growth rate of export sales in the last 5 years**

In 2019, the exports accounted for 40 % of our company's turnover, reaching 152,1 million LEI, by about 25% higher than the value recorded in 2018. This growth has been the fastest rate in the last five years.

2019 was the first year in which the sales of finished products in the international markets significantly outpaced the sales of the active substance Nystatin. So, the main growth engine was the export of finished products in the territories where Antibiotice opened its own representative offices, the value of these exports recording an increase past 65% compared to 2018, reaching a value of 44.4 million LEI.



To reach this sales level our company followed the main development directions in international markets, assumed through the management program for 2019:

- **Consolidating and maintaining the world leading position of the active substance Nystatin;**
- **Developing our presence in the North American finished product market;**
- **Increasing the sales in the territories where Antibiotice opened its representative offices;**
- **Initiation of new projects of territorial expansion, as the main pillar of growth in the medium and long term.**

### **Consolidating and maintaining the world leading position of the active substance Nystatin**

Strengthening the leading position of the active substance Nystatin in the international market, a direct result of the indisputable quality of this product, recognized by the USFDA as a USP reference standard is proved by the upward sales trend in the last 5 years. As a result, the number of new partners from Europe, South America, North America increased.

The 2019 selling target for Nystatin was fully achieved through a continuous management of costs, quantities manufactured and strategic partnerships with the main customers.

So, in 2019, our strategy for the product Nystatin sold in the international markets aimed at:

- consolidating our partnerships in the North and South America, leading to a 16% increase in the sales of Nystatin compared to the planned level;
- managing the markets in the Asia-Pacific area and Middle East;
- starting new projects in Europe, a long-term growth source.

These strategies aimed at adapting Nystatin for using this active substance in the formulation of high-added value finished products (powders for oral suspensions, creams, ointments, powders for topical use and pessaries).

Our company aimed also at maintaining a prudent price strategy and efficient policies regarding the partnerships with zonal agents / distributors.

- **Developing our presence in the North American finished product market**

Antibiotice recorded good sales of FDA certified finished products in the US market. So, at the end of 2019, Antibiotice recorded a 50 % increase in the export sales of sterile injectable powders and laid the groundwork for launching a new product in 2020, thus creating the premises for a solid and long-term development of our business in this market.

### **Increased sales in the territories where Antibiotice opened its own representative offices**

In the territories where Antibiotice opened its own representative offices in the last 3 years: Vietnam, Republic of Moldova, Ukraine and Serbia, the sales of finished products increased by about 65% compared to 2018.

Starting from the principle that our company must apply in these territories similar strategies with those applied in the Romanian market in terms of product portfolios, business models, promotion actions, our specialists developed a multiannual strategy (2020 - 2025) based on four strategic development pillars:

- to register a portfolio of anti-infectives intended for the consumption in hospitals, a segment in which our company is the leader in the Romanian market;
  - a market oriented pricing policy;
  - solid partnerships with the local distributors;
  - to increase the corporate brand and product awareness.
- 
- In **Vietnam**, Antibiotice is the main Romanian exporter of pharmaceutical products, with a traded value of about 10 million USD in 2019. In this market Antibiotice registered 17 products, mainly anti-infectives, 4 of which were launched in 2019.

Because 80% of the medicines are sold in hospitals, this destination is compatible with the Antibiotice business which has a traditional portfolio of sterile injectables. Moreover, over 90% of the requests from Vietnam are for products that participate in auctions in hospitals, where the purchases are made according to the manufacturer's price and quality certifications. Antibiotice is among the top pharmaceutical manufacturers selling in the Vietnamese market because of its EU GMP certifications.

- In 2019, our company registered and traded 55 products from all the developed therapeutic classes in the **Republic of Moldova**. Of these, 5 antiinfectives for hospitals were launched in 2019.

- In **Serbia**, Antibiotice sells 13 products (antiinfectives, sterile injectable powders, cardiovasculars and food supplements), one of them being launched in 2019.

The Serbian market is of interest for Antibiotice because it shows similarities in consumption and therapeutic behaviors with the Romanian market.

- Through its representative office from Ukraine, in the fourth quarter of 2019 Antibiotice started the registration procedures for 8 antiinfectives, 12 cardiovascular products and 4 food supplements.

Positioning of the products in these countries is the result of a detailed analysis of the market, national legislation and competition behavior. Antibiotice has been developing ethical and competitive partnerships with the main distributors on the principle of representativeness in the market (covered market share, sales structure - their own chains of pharmacies, promotion teams), safety of the business, ability to multiply the number of sales.

In 2019, we launched in the external markets 10 new products and concluded new local partnerships for extending the finished product portfolio - antiinfectives for the outpatient therapy and topical products (dermatological creams and ointments, anti-inflammatory medicines) and suppositories.

- **Initiation of new projects of territorial expansion, as the main pillar of growth in the medium and long term.**

International expansion of the Antibiotice business has two many directions:

- to develop the product portfolio in the current territories;
- to access new markets in the ASEAN region, EU and Middle East, markets with a recognized potential as regards the consumption of antiinfective, dermatological and cardiovascular medicinal products.

So, in 2019, our company concluded representation contracts in the Scandinavian markets for a 14-product portfolio and started the negotiations for accessing the Saudi Arabia and Philippines markets.

In 2019, Antibiotice SA adapted its external expansion policies to the new legal regulations in the field of health, taking into account both the consumption trends, but also the specific habits of each market.

**2019 key achievements in the international markets:**

- A consolidated position as a world leader in the production of Nystatin;
- The value of export increased by about 25% compared to 2018;
- It is the first year in which the sales of finished products in international markets significantly outpaced the sales of the active substance Nystatin, increasing by 65% compared to the previous year;
- Antibiotice - the main Romanian exporter in the Vietnamese market, with a traded value of about 10 million USD in 2019;
- The sales of sterile injectable penicillins increased by over 50% in the US market;
- New partnerships in Europe (France, Spain, the Scandinavian countries).

## **2. Ensuring a sustainable and marketable portfolio through increasing the degree of renewal**

### **➤ Evolution of the pharmaceutical market in Romania<sup>L11</sup>**

In the Romanian pharmaceutical market, the value of medicinal products released to the patients was 17.82 billion LEI (distribution price), up 10.9% compared to 2018. Quantitative consumption rose by 2.1%, a number of 625.5 million boxes being released by pharmacies.

Cost-volume contracts represent 12% of the total pharmaceutical market in Romania and recorded an increase of 22.7% in 2019, from 1.7 billion LEI to 2.1 billion LEI.

Pharmaceutical market is dominated by the prescription medicines (RX). These represent 77.3% of the total value sales and 64.9% of the total consumption of medicines (no. of boxes) in Romania. The prescription medicines recorded in the analyzed period an increase in terms of value of 10% from 12.5 billion LEI in 2018 to 13.76 billion LEI in 2019; the non-prescription medicines (non-RX: OTCs, food, supplements, medical devices) had also a 14% increase in terms of value, from 3,55 billion LEI in 2018 to 4.05 billion LEI at the end of 2019.

**Evolution of the pharmaceutical market relevant for Antibiotice SA<sup>[2]</sup>** - The market relevant for our company recorded in 2019 a value of 2.15 billion LEI, up 6.7% compared to 2018.

The quantitative consumption rose by 2.5%, a number of 141.5 million boxes being released by pharmacies. This segment also was dominated by the prescription medicines (RX) which represented 57.6% from the total value sales and 66.3% from the total consumption of medicines (reported as number of boxes). The prescription medicinal products recorded in the analyzed period an increase of 2% in terms of value, from 1.21 billion LEI at the end of 2018 to 1.24 billion LEI in 2019. The non-prescription medicinal products (OTCs) recorded an increase of 13.9% in terms of value, from 799 milioane LEI in 2018 la 909.8 million LEI in 2019.

### **Antibiotice in the Romanian pharmaceutical market**

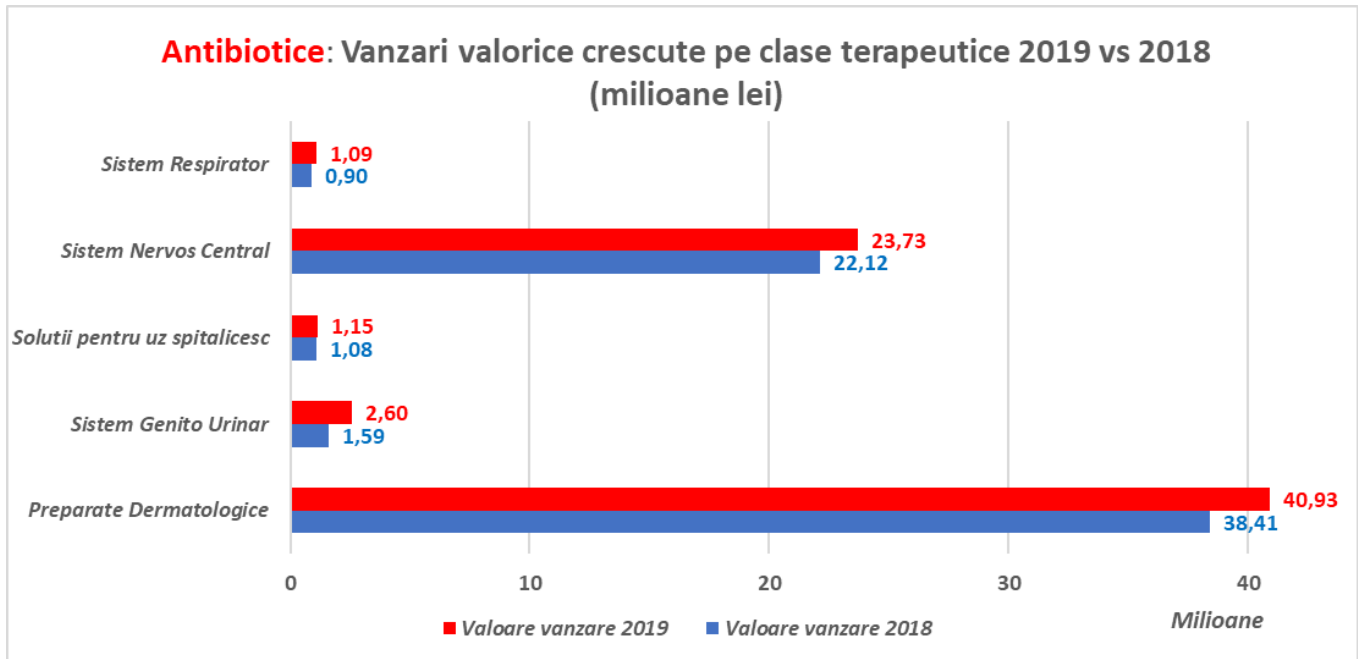
In the domestic market, Antibiotice recorded sales comparable to the sales recorded in 2018, both in pharmacies and hospitals, amounting to 335.9 million LEI.

The main therapeutic classes that recorded in 2019 significant increases in terms of value compared to 2018 were : dermatological preparations, medicinal products for the central nervous system, genitourinary system and respiratory system.

---

[1] As per CEGEDIM Romania 2019

[2] The relevant market is the market to which the Antibiotice portfolio relates as regards the therapeutic indication of the product (molecule, form, concentration).



Antibiotice in the Romanian market:

- is the leader in the segment of generics and OTCs sold in hospitals, with a 15.6% market share;
- is the leader in terms of quantity for the following pharmaceutical dosage forms: ointments (23.9%), suppositories (42.5%) and injectable powders (72.9%). Because Antibiotice has been building the largest plant for solid and semisolid topicals from Europe, our strategy focuses on maintaining the leader status in the segment of topical products (creams, ointments, gels) intended especially for dermatological, inflammatory musculoskeletal and peripheral vascular disorders;
- ranks sixth in the segment of generics and OTCs (4.53% market share) and the 20<sup>th</sup> in the total pharmaceutical market (a 1.89% market share).
- ranks 16<sup>th</sup> (among 230 companies) as a manufacturer of non-prescription medicines (OTCs) and dietary supplements;
- ranks first in the relevant market of prescription and non-prescription medicines (OTCs, food supplements, medical devices) with a 15.7% market share.



In 2019, the Antibiotice portfolio was promoted to scientific events organized in partnership with the main medical professional bodies. Promotional actions were also carried out for health professionals, doctors and pharmacists, which aimed to increase the good reputation of our company brand as well as the product brands from the following classes: anti-infectives for systemic use, dermatological preparations, medicines for genito-urinary system, musculoskeletal system and the Nutriensa® range of dietary supplements.

These events promoted our products belonging to the following portfolios: Hospital & Partners, Dermatologicals as well as the Quality of Life, the latter including the Women's Health and Nutriensa concepts.

**Hospital&Partners** is the portfolio for hospitals, the promotion focusing on the development of good practices in the use of antibiotics, supported by the campaign "Antibiotics of the Third Millennium".

**"Quality of Life"** is the concept defined in medicine as being the physical, mental and social well-being as well as the ability of individuals to perform their usual tasks. Quality of life = prevention + treatment to maintain a normal biological condition.

In this context, our company's portfolio comprise, under the "Quality of Life" concept, therapeutic solutions for different conditions in the following areas: cardiovascular, genito-urinary, musculoskeletal, dermatology, digestive tract as well as remedies designed to maintain the body's homeostasis such as dietary supplements.

**"Women's Health"** - by the Women's Health concept, Antibiotice aims to strengthen the identity of the portfolio intended for the prevention and treatment of diseases in obstetrics - gynecology.

As a communication platform for the "Women's Health" concept, regional scientific events were held at which gynecologists and family doctors were invited.

**Nutriensa®** - Nutriensa® is an umbrella brand for the dietary supplements manufactured by Antibiotice from highest quality ingredients, in unique combinations, to maintain the health of each system of the human organism: central nervous system, digestive tract,

peripheral vascular system, musculoskeletal system: Equilibra®, Fezivit C®, Fluxiv® tablets, Fluxiv® cream, Lejer®, Silithor®, Soriso®, Sprinten®.

All the dietary supplements manufactured by Antibiotice are based on the experience of our researchers being manufactured to quality standards met for the medicinal products.

Our company's business expands successfully in the domestic and international markets by a sustainable portfolio developed through investments in new products created on our own research-development premises, in accordance with the current therapeutic trends.

Our company's strategy regarding the product portfolio is mainly oriented to highly efficient therapies supported by medicines that proved their quality over the last 64 years, but also to products aimed at maintaining the well-being and health of the population.

➤ **Research-Development for adapting and durably consolidating our company portfolio**

The main objective of the Research-Development Unit is to develop new medicines (topicals, tablets, capsules, sterile products and other new pharmaceutical dosage forms) in line with the company's development strategic directions until 2015. The products under research will complete the following classes of the Antibiotice portfolio: antiinfectives (sterile oral and injectable powders), dermatological, cardiovascular, non-steroidal anti-inflammatory products, medicines for the digestive system and medicines for women's health.

The products under research in 2019 included a number of 15 projects that, during the past year, went through different stages of research:

- a project for a sterile injectable powder;
- four projects for topical products;
- ten projects for oral solid products.

**Moldamin - injectable product, the first recommendation in the prevention of acute joint rheumatism and rheumatic carditis.**

2019 meant the completion of the research project, obtaining of the Marketing Authorization and resumption of the manufacture of Moldamin®, a recognized brand lasting for almost 60 years in our company's portfolio. Moldamin® returns in the medical

practice, in a new formula, made according to modern formulation principles, containing the same active substance, benzatin benzyl penicillin, but other excipients. Moldamin® is a prolonged-action penicillin and is the first-line medicine in infections where it is necessary to provide prolonged antibiotic concentrations, such as in respiratory infections (streptococcal angina - red in the neck, otitis, sinusitis), venereal diseases ( syphilis), skin infections (erysipelas). It is also the first recommendation in the prevention of acute joint rheumatism and rheumatic carditis.

The research projects for topicals focus on products for dermatological use, local anti-inflammatory/anti-infective/anesthetic products and medicines for women's health.

Of the ten research projects for oral solid products, four are food supplements that will complement the portfolio of products aimed at improving and maintaining the well-being and health of the population.

### **Increasing our international sales by authorizing new products**

In order to extend its presence in the international market, our company obtained five new Marketing Authorizations (MA) for the Antibiotice medicinal products which are to be traded in the territories from Asia and Europe.

Several products have been also optimized in accordance with the requirements in the territories where our company has representative offices. We refer to 5 products in the form of sterile injectable powder, two topical products and four oral solid medicines which will receive the MA within the next 4 years.

### ***Pharmacovigilance***

Monitoring the effectiveness and safety in the administration of medicines for which Antibiotice holds marketing authorizations (MAs), is part of a continuous process, carried out through our internal Pharmacovigilance Department. Our pharamcovigilance system is connected to EudraVigilance (the European network for processing data on medicine safety) and permanently updated, in accordance with the European Community legislation.

In 2019, Antibiotice monitored the safety of the medicinal products for which it holds marketing authorizations through the following actions:

- maintained and updated the database with information related to the products authorized in Europe;

- collected and evaluated the reports on the medicinal products suspected by adverse reactions;
- elaborated risk management plans;
- reported periodically the updated data on the medicine safety.

### ***Center for Clinical Studies***

In 2019, our Center for Clinical Studies ( a research unit authorized by the Ministry of Health) conducted bioequivalence studies but also efficiency studies, instrumental tests and several projects for developing and validating analytical methods, necessary to support the research plan.

Clinical bioequivalence studies certify that the generic medicines developed by Antibiotice SA are therapeutically equivalent to the innovative reference medicines, according to the European and national requirements on the Good Clinical Practice and Good Laboratory Practice for medicinal products of human use.

Two bioequivalence studies were completed in 2019. One of them was conducted for an external partner, the other one (carried out in four stages), was conducted for an Antibiotice product.

A first clinical study for an Antibiotice topical product was also initiated in 2019 in partnership with several clinical centers in the country. This product has a valuable potential of development in the Antibiotice territories (where the company opened its own representative offices) and in the assimilated areas.

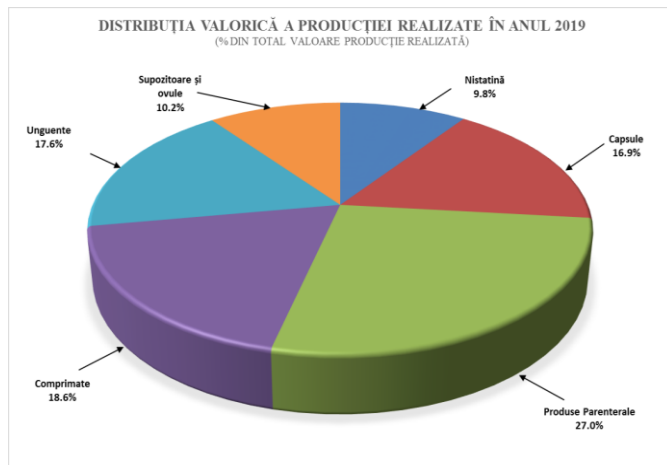
#### **➤ Complex manufacturing structure adapted to international quality standards (GMP and FDA)**

The Antibiotice's product portfolio is manufactured on the most complex manufacturing structure in Romania which comprises 8 distinct manufacturing sites for sterile injectable powders, capsule, tablets, topical products (ointments, creams, gels), suppositories, pessaries and the active substance Nystatin.

Our 2019 production materialized in 546 million pharmaceutical units, 21 million pharmaceutical units more than in 2018 (525 million pharmaceutical units).

The total value of the production made in 2019 was 394.4 million LEI, up 9.5% compared to the previous year.

2019 Production breakdown in terms of value:



Starting with February 2019, the manufacturing processes were harmonized with the serialization process of the prescription medicines, in accordance with the EU Directive 62/2011, a mandatory condition for the marketing of medicinal products.

### New products manufactured in 2019

In 2019, our company launched in manufacturing four new products from the following therapeutic classes:

- Antiinfectives for systemic use: **Moldamin1200000 IU** for injection, **Levofloxacin 500 mg** tablets;
- Cardiovasculars: **Nolet 5 mg** tablets;
- Food supplements (for digestive tract): **Lejer** capsules.

➤ **Medium and long -term development through investments**

The investments made in 2019 amounted to 65,539,962 LEI, as follows:

**I. Investments in new manufacturing sites - our company continued to build a new production capacity for topical products (ointments, creams, gels) and suppositories**

This investment totaling about 20 million EUR started in 2017 and consists of the construction of a fully equipped production capacity according to the EU-GMP (Good Manufacturing Practice) and FDA (Food and Drug Administration) requirements. This investment is performed according to the established schedule, so that in the latter part of 2020 it will enter into the authorization process.

The new manufacturing plant will provide modern conditions for manufacturing medicinal products in compliance with the legislative and pharmacopoeia requirements necessary for their registration and marketing in all the regulated markets. Capacity of the plant will be 540 tons/year, from which 388 tons/year ointment mass (10 million tubes with an average mass of 40 g/tube) and 152 tons/year suppository mass (76 million suppositories with an average mass of 2g/suppository).

## **II. R & D investments**

From the total amounts invested in 2019 by our company, 8.18 % was oriented towards the research-development activity.

The research represents one of the most dynamic activities within our company, experiencing permanent changes and an upward evolution.

The research-development investment program includes equipment and software for supporting and improving the research activities, in order to obtain new quality, safe and efficient products, highly competitive in the market.

**III. Investments for modernizing the existent manufacturing sites** consisted in the purchase of production and laboratory equipment, installations for revamping the manufacturing flows and represented 10.60% of the total amount invested in 2019.

We purchased last generation manufacturing equipment, with a higher productivity, low energy consumption and high degree of safety in operation.

**IV. Investments in the Integrated Management System** (1,99% of the amount invested in 2019) for the product quality control (through the acquisition of state-of-the-art equipment for ensuring the quality control of manufactured products to international standards); environmental protection (in order to comply with the legal requirements regarding the protection of the environment); occupational safety and health (aiming to continuously improve the employees' working conditions and the labour health and safety).

**V. Investments for rehabilitating the industrial site** (24.26% of the total amount invested in 2019): reintegration into the industrial circuit of land released after the demolition of the old plants; rehabilitation of the buildings (both manufacturing plants and auxiliary buildings); modernization of the transport and storage infrastructure (investments in the car fleet, storage areas); modernization of the utilities production, distribution and maintenance infrastructure (so that savings to be achieved by reducing consumption and eliminating losses).

➤ **Procurement - an important link in the value chain**

Procurement represents an important link in the value chain that generates favorable conditions for the long term development of our business, bringing its contribution to the profitability of the company. The activity is organized to meet the needs of the company, developing business relationships both with the suppliers from Romania and from the intra- and extra-community areas. In the context of an increased complexity and competitiveness in the world pharmaceutical market, Antibiotice has demonstrated its ability to build and maintain stable, ethical and trustworthy business partnerships with its suppliers for its own benefit and for the benefit of its employees, partners and not least of the Romanian economy in general.

In the current economical, technological and Regulatory Affairs context, the efficient management of the purchasing chain is a permanent preoccupation of our company.

The staff involved in the procurement activity has:

- to comply with the regulations and legislation in force on the procurement procedures;
- to treat impartially the suppliers in the selection process, offering them competitive contracting opportunities;
- to meet the efficiency and efficacy criteria in the supplier selection process;
- to secure the purchasing sources, by making the medium and long-term partnerships transparent and predictable;
- to diminish the risks throughout the acquisition chain, in order to ensure the continuity of the company's operations;

- to generate competitive advantages, by identifying and optimizing the suppliers' capabilities (technology, production facilities, know-how, staff experience and professionalism).

Professionalism, ethics, flexibility, interdisciplinarity and cost optimization are essential attributes of procurement departments for ensuring a sustainable future of their companies.

### 3. Optimizing the operating costs and increasing the operating efficiency

#### Global result statement

Indicator	31.12.2018	31.12.2019	31.12.2019/ 31.12.2018
1	2	3	4=3/2
<b>Sales income</b>	<b>364,576,46</b>	<b>389,710,740</b>	<b>1.07</b>
Other operating revenues	45,405,000	33,008,685	0.73
Income related to the cost of product	-1,259,715	4,564,960	-3.62
Income generated by the entity and capitalized	3,489,144	4,660,869	1.34
Expenditure on raw materials and consumables	138,844,375	146,016,104	1.05
Staff costs	90,864,735	102,852,132	1.13
Amortization and depreciation expenses	20,237,870	21,416,603	1.06
Other operating expenses	122,951,124	121,652,509	0.99
<b>Operating profit</b>	<b>39,312,791</b>	<b>40,007,906</b>	<b>1.02</b>
Net financial income	-4,224,180	-4,828,013	1.14
<b>Pre-tax profit</b>	<b>35,088,611</b>	<b>35,179,893</b>	<b>1.00</b>
Income tax and other taxes	784,823	4,356,615	5.55
<b>Profit</b>	<b>34,303,788</b>	<b>30,823,278</b>	<b>0.90</b>

In 2019, the value of **sales income** was 389.71 million LEI, by 7% higher than the value recorded in 2018. The value of other **operating income** amounted to 33 million LEI, by 27 % lower than the value recorded in 2018.



**Income generated by the entity and capitalized** amounted to 4.66 million LEI, by 33% higher than the value recorded in 2018.

These results made it possible to promote a new payroll system, which sought to correlate the benefits with each employee's performance level. This increased the **staff costs** to 102.85 million LEI, by 13 % higher than the value recorded in 2018 (90. 86 million LEI). This measure highlighted once again how important the human resources are for our business.

**Amortization and depreciation expenses** amounted to 21.42 million LEI, by 6 % higher than the value recorded in 2018. In 2019, our company highly invested in the new Ointment & Suppository Plant, but being an ongoing investment, the impact on depreciation expense will be reflected after the investment is put into service.

In the structure of **other operating expenses**, the value of energy and water expenses increased by 19%, from 9.3 million LEI to 11.1 million LEI, an increase due to the electricity tariffs. Our contribution to the finance of some health expenses (claw-back tax) increased by 12.9% as well.

The value of **net financial income** was negative, due to higher financial expenses represented by the interest paid for the contracted bank credits, in comparison with the financial income.

As a result of the revenues and expenses recorded, **the gross profit** registered in 2019 amounted to 35.18 million LEI, about the same level as the one recorded in 2018.

The amount of 77.39 million LEI, representing the gross profit and the claw-back tax for 2019 was by 8% higher than in 2018 (71.57 million LEI) this proving the process improvement.

The value of the **expenses with the profit tax and other taxes** was higher in 2019 compared to 2018 as a result of the reduction of the fiscal facilities, determined by the diminution of the non-taxable income and profit invested in the acquisition of technological equipment, electronic computers and peripheral equipment, home, control and invoicing appliances, computer programs, as well as for the right to use computer programs.

As a result of the recorded revenues and expenses, **net profit** in 2019 amounted to **30.8 million LEI**.

**Total assets** recorded on 31.12.2019 amounted to 794.02 million LEI, by 12% higher compared to the value recorded on 31.12.2018, as shown by the financial position statement. In their structure, **tangible assets** rose significantly by 17%, as a result of the intense investment process carried out in 2019 for building the new plant for topical products.

The value of stocks recorded on 31.12.2019 was higher by 14% compared to the previous year as a result of the purchase of raw materials necessary for additional production made by the existent Ointment & Suppository Plant to ensure the continuity of sales during the period when the transition from the current flow to the new manufacturing flow will be done.

The value of **commercial and similar receivables** recorded on 31.12.2019 was by 8 % higher compared to the value recorded in 2018.

Consistent with the value of total assets, the value of **equity and debt** increased by 12% compared to the value recorded on 31.12.2018.

In their structure, a significant increase of 114% was recorded to the **long-term bank credit**, necessary to provide the financial resources for building the new manufacturing plant and purchasing the necessary equipment for compliance with the serialization requirements.

### Financial Position Statement

INDICATORS	31.12.2018	31.12.2019	31.12.2018/ 31.12.2019
1	2	3	4=3/2
<b>ASSETS</b>			
<b>FIXED ASSETS</b>			
Tangible assets	310,640,665	363,616,611	1.17
Intangible assets	15,028,716	16,385,709	1.09
<b>TOTAL FIXED ASSETS</b>	<b>325,669,381</b>	<b>380,002,320</b>	<b>1.17</b>
<b>CURRENT ASSETS</b>			
Stocks	64,964,662	72,573,359	1.12
Trade and similar receivables	313,094,458	338,159,774	1.08
Cash and cash equivalents	2,376,682	1,877,409	0.79
<b>TOTAL CURRENT ASSETS</b>	<b>380,435,802</b>	<b>412,610,542</b>	<b>1.08</b>
<b>TOTAL ASSETS</b>	<b>706,105,183</b>	<b>792,612,862</b>	<b>1.12</b>
<b>LIABILITIES</b>			
<b>CURRENT LIABILITIES</b>			

Commercial and similar debts	67,171,084	63,785,810	0.95
Amounts owed to credit institutions	100,729,229	125,875,879	1.25
Debts from current taxes	10,421,393	13,267,396	1.27
Short-term provisions	0	7,149,401	
Subventions for investments	637,008	0	
<b>TOTAL CURRENT LIABILITIES</b>	<b>178,958,714</b>	<b>210,078,486</b>	<b>1.17</b>
<b>LONG -TERM LIABILITIES</b>			
Subventions for investments	2,489,791	3,079,169	1.24
Deferred tax	25,266,930	25,531,938	1.01
Amounts owed to credit institutions	26,662,433	57,080,354	2.14
<b>TOTAL LONG-TERM LIABILITIES</b>	<b>54,419,154</b>	<b>85,691,461</b>	<b>1.57</b>
<b>TOTAL LIABILITIES</b>	<b>233,377,868</b>	<b>295,769,947</b>	<b>1.27</b>
Share capital and reserves			
Share capital	264,835,156	264,835,156	1.00
Revaluation reserves	53,459,597	50,804,319	0.95
Legal reserves	13,426,761	13,426,761	1.00
Other reserves	190,422,002	200,655,367	1.05
Retained earnings	-60,182,699	-56,432,683	0.90
Distribution of profit	-23,537,290	-7,269,283	0.27
Current result	34,303,788	30,823,278	0.89
<b>TOTAL EQUITY</b>	<b>472,727,315</b>	<b>496,842,915</b>	<b>1.05</b>
<b>TOTAL CAPITALS AND LIABILITIES</b>	<b>706,105,183</b>	<b>792,612,862</b>	<b>1.12</b>

**Subsidies for investments** were included in the long-term debt, representing the amounts collected in 2019 for the project: „Modernization of Energy Consumption in Industrial Consumers”, co-financed from European funds, with the objective of reducing the specific energy consumption. Their value recorded on 31.12.2019 was 3.08 million LEI, by 24% higher than the one recorded in the previous year.

The **amounts owed to credit institutions** on 31.12.2019 amounted to 182,956,233 LEI, of which:

- amounts due in the short term: 125,875,879 LEI;
- amounts due in the long term (interest included) 57,080,354 LEI

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

Objective	Credit line - working capital
Amount	50,000,000 LEI
Maturity	16.08.2020
<b>Balance at December 31, 2019</b>	<b>54,330,807.68 LEI</b>
Guaranties	Mortgage contract for buildings, land / Contract for assignment of receivables

Contract no. IAS3-20-2018/03.05.2018 concluded with Unicredit Bank S.A.

Objective	Capital investment loan
Amount	15,406,300 EUR
Maturity	02.05.2028
<b>Balance at December 31, 2019</b>	<b>11,943,245.63 EUR (57,080,353.84 LEI)</b>
Guaranties	Mortgage contract for buildings, land / Contract for assignment of receivables

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

Objective	Credit line - working capital
Amount	30,000,000 LEI
Maturity	24.06.2020
<b>Balance at December 31, 2019</b>	<b>29,592,915.74 LEI</b>
Guaranties	Mortgage contract for buildings, land / Contract for assignment of receivables

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

Objective	Credit line - working capital
Amount	9,500,000 EUR
Maturity	22.05.2020
<b>Balance at December 31, 2019</b>	<b>24,021,730.10 LEI 3,251,946.88 EUR ( 15,542,029.72 LEI ) 560,551.01 USD ( 2,388,395.74 LEI )</b>
Guaranties	Mortgage contract for buildings, land / Contract for assignment of receivables

### Cash flow

Cash and cash equivalents at the beginning of 2019 were -98.35 million LEI, representing lines of credit worth 100.73 million LEI of which 2.38 million LEI remained available in the bank accounts from the amounts drawn from the credit lines. The cash receipts from the operating activity were 363.06 million LEI. Cash payments to suppliers of goods and services were 203.13 million LEI, and those to and on behalf of employees were 89.95 million LEI.

Our company made payments amounting to 7.88 million LEI representing income tax, local taxes, bank interests and 69.18 million LEI for the acquisition of fixed assets. The amounts paid to the state budget representing the contribution for financing some health expenses (clawback tax) were 41.91 million LEI.

As regards the financing activity, dividends of 6.15 million LEI were paid.

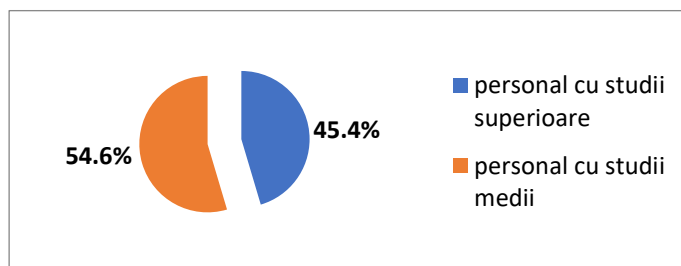
At the end of the period the cash and cash equivalents were 123,99 million LEI, representing credit lines for the current activity (125.87 million LEI) of which 1.88 million LEI remained available in banks from the amounts drawn from the credit lines.

On 31.12.2019 our company did not register overdue obligations to the state and local budgets.

#### **4. Motivating the human resources and providing them with the necessary skills to achieve the strategic directions**

The human resources policy applied in Antibiotice promotes the diversity and equal opportunities in recruiting, selecting and integrating the employees. Our staff benefits from all the rights deriving from the law, our company offering fair and equitable conditions of work and professional development.

At the end of 2019, our 1415 employees were distributed by level of education, as follows:



Higher education staff: 45.4%

Secondary education staff: 54.6%

Distribution of employees by gender and age in the Antibiotice company:

Age range	20 -30	30 - 40	40 -50	50 - 55	>55	Total
Women (%)	4.37	12.46	19.70	12.61	6.09	55.23
Men (%)	3.15	8.88	16.76	8.45	7.53	44.77
<b>Total</b>	7.52	21.34	36.46	21.06	13.62	100.00

Antibiotice SA ensures a fair and non-discriminatory treatment at the workplace. Proper conditions were created for a number of 11 employees with disabilities to carry out their activity, benefiting from facilities in accordance with the applicable legal provisions.

In order to achieve the objectives set in the multiannual strategic plan, the human resources management activities have pursued the fulfillment of the following specific objectives:

**To identify and attract qualified staff for ensuring the optimal professional structure.**

This objective was supported by continuing the projects for promoting the employer brand towards the target audience:

- **Perform a+**, the 4<sup>th</sup> edition, a project for practical training and personnel selection, through partnership with the University of Medicine and Pharmacy Iasi. The edition held in 2019 attracted 10 participants. To date, of the 42 students who followed Perform a+, 12 are employed in the company, in research, production and quality assurance.
- **Summer school a+**, the 10<sup>th</sup> edition, organized in partnership with the university centers of Iasi to identify future specialists to be selected for the recruitment sessions on the vacant positions in research - development, quality assurance, quality control and pharmaceutical production. The program, which has become a tradition, offers participants the opportunity to become familiar with the working environment, concepts and regulations of the pharmaceutical industry. About 400 students and graduates participated in the ten editions, of which 46 are employed on the vacant positions in our company.
- **Partnerships established with pre-university educational institutions**, Petru Poni Technological High School and Technological High School of Mechatronics and Automation

Iasi, for internships in our company. In 2019, within these partnerships, the Iasi County School Inspectorate approved the organization of a dual education project that will ensure the preparation of 15 students for the profession of chemical operator for medicines and cosmetics and 10 students for the profession of electrician in the 2020-2021 school year.

### **Development of professional skill training programs**

The training programs focused on the continuous professional training of our staff but also on developing the necessary professional skills of our new employees. In 2019, the training courses for our employees were grouped in three main directions, as follows:

- **Training courses for developing the professional competences** - aimed at improving the specific professional skills: risk assessment, audit, chromatographic analyses and automation elements.
  
- **Training courses for developing the management skills**
  - The “Time Management” course for the staff with management and/or coordination positions in the following departments: Engineering & Service, Research - Development, Financial, Human Resources, Commercial & Logistics, Marketing & Domestic and International Sales.
  - “Project Management” course for our employees from various departments involved in managing the projects in our company.
  
- **Trainings for obtaining professional certificates**

Through the specific of the activities, trainings and certifications for the employees with responsibilities on technical equipment and installations, are monthly organized by ISCIR, ANRE, INSEMEX.

500 employees were included in 2019 in training programs with external lecturers. These programs followed the above-mentioned three directions, totaling 8,566 hours.

The average number of training hours with both external and internal lecturers per employee was 37.5 compared to the planned 35 hours.

Complementary, in 2019, a multidisciplinary pilot training project with internal lecturers was carried out, having as a target audience specialists from the Marketing & International Sales Unit. After identifying the training needs, internal courses on legislation and medicine authorization procedures were conducted. The program will continue in 2020 with quality assurance training courses and will evaluate the possibility of extending the pilot project to other teams.

### **Strategies and measures to increase our employees' motivation**

Actions were initiated in 2019 to improve the employee motivation system. Currently, this system has been containing a fixed and a variable component, in direct correlation with each employee's performance.

The reward system was redesigned following the development of the analysis project based on the hierarchy of positions, depending on their complexity and the current payroll system, compared to the levels of similar positions in the labor market. Our company also established through an Addendum to the Collective Labor Agreement, a program for aligning the wage levels that have to be carried out in several stages, of which the first stage took place starting with January 2019.

Along with the actions of attracting new staff and training our employees, the staff retention and motivation is very important for Antibiotice. Adapting the reward system and creating a consistent financial and non-financial motivation policy for employees aim at increasing our employees' satisfaction and improving the staff retention. Employee turnover (only the employees leaving our company voluntarily) was 4.6% in 2019, lower than the estimated percentage.

### **Ensuring a favorable working environment and an organizational culture oriented to innovation and performance**

For achieving this objective, our company elaborated the 2019-2020 Action Plan for improving the organizational climate, following the results of the study conducted in 2018 for measuring our employees's degree of satisfaction related to the positions occupied.



The Action Plan aimed at developing new communication channels, organizing internal events to ease and develop the interpersonal communication, improving the conditions in the common social areas of the production plants.

In order to monitor the evolution of the climate and satisfaction indicators, the diagnostic study will be resumed annually, the employee job satisfaction being a strategic indicator for our management.

## 5. Quality management in line with the legal national and international requirements specific for the pharmaceutical industry

The quality of our products is ensured by processes that comply with the latest good manufacturing practice requirements at European level, all of our eight manufacturing flows being EU GMP certified. The manufacturing flows for sterile injectable medicinal products and for the active substance Nystatin are also certified by the Food and Drug Administration (FDA), the American authority in the field of medicine and food safety.

The implementation of all the regulatory requirements and evaluation of the quality management system by the regulatory authorities and partners from all the areas of the world, result in maintaining the level of quality, efficiency and safety of the medicines produced by Antibiotice.

### Managementul calității



**EU-GMP** pentru cele 8 fluxuri de fabricație

**US FDA** pentru pulberi sterile injectabile și substanța activă Nistatină



**USP Standard Internațional Referința** pentru Nistatină

**CoS** (certificat de conformitate) pentru Nistatină micronizată eliberat de EDQM



**Sistem integrat de management al calității** (calitate, mediu, sănătate și securitate operațională)



World Health Organization

**OMS- precalificarea pentru medicamentele anti-TBC**

The trust capital in the Antibiotice products' quality increases by meeting the Good Manufacturing Practice requirements and by permanently monitoring and improving the Integrated Management System implemented in our company that was recertified by TUV Rheinland Romania (02.12-05.12.2019).

- Quality, ISO 9001:2015,
- Environment, ISO 14001:2015,
- Occupational health and safety, OHSAS 18001:2017

### **Certified quality**

Quality of the Antibiotice products was proved by the results of the inspections and audits conducted in 2019:

- Inspections conducted by authorities:
  - Inspection conducted by the Russian regulatory agency (STATE INSTITUTE OF DRUGS AND GOOD PRACTICES - Ministry of Industry and Trade of the Russian Federation), for certifying the manufacturing flow of suppositories, to support the re-authorization of the medicines manufactured on this flow in Russia (29-31.01.2019);
  - Inspection conducted by the National Agency for Veterinary and Food Safety, for assessing the compliance of the Quality Management System implemented in Antibiotice and of the manufacturing flows of veterinary medicines (parenterals and ointments) with the Good Manufacturing Practice requirements. The regulatory body issued the GMP certificate for the above-mentioned manufacturing flows (01-03.04.2019);
  - NAMMD inspection for evaluating the compliance of the Quality Management System implemented by Antibiotice and of the manufacturing flows of the parenteral products and the active substance Nystatin with the Good Manufacturing Practice requirements. (07-11.10.2019).
- Audits conducted by our customers:
  - three audits for requalifying the manufacturing and control flow of Nystatin;

- Antibiotice was audited as an API supplier. All the three audits were completed without finding non-conformities, the requalification of our company as an API supplier being recommended.
  - the parenteral manufacturing and control flow was audited for requalifying Antibiotice as a supplier of finished products. The audit was completed without finding critical non-conformities, the requalification of our company as a supplier of parenteral products being recommended.
- Audits conducted by our specialists to the premises of our suppliers of raw materials/ primary packaging materials/ finished products. These audits were conducted in compliance with the 2019 Annual Audit Plan: one of them to an API manufacturer for requalifying it as a supplier of non-sterile active substances and the other one to a contract beneficiary. No non-compliances were identified.

### **Environmental responsibility**

Antibiotice has an Environmental Protection Department in charge of the pollution prevention and continuous improvement of the environmental performance, acting in order to comply with the requirements of the environmental legislation. By obtaining the Integrated Environmental Authorization no. 1/10.01.2011, issued by the Regional Environmental Protection Agency Bacau (revised in 2018 and valid for 10-year period), Antibiotice proves that it is a company that meets the environmental requirements related to the emissions of pollutants in air, water and soil, being below the limits provided by the applicable norms in the field. Our company obtained also the Water Management Authorization no. 303/20.12.2010 issued by the National Administration of Romanian Waters, Basin Water Administration Prut- Barlad (valid until 31.12.2020).

In order to comply with the environmental protection legislation, our company provided the necessary specific equipment and qualified personnel. The entire activity is regulated by operating procedures of the environmental management system and specific working instructions.

The environmental factors were monitored according to the requirements of the Integrated

Environmental Authorization, both through our own laboratories and through a laboratory authorized by the Romanian Accreditation Association (RENAR).

- Specific consumption and use of energy

The activity developed in the Biosynthesis Plant that produces the active substance Nystatin falls within the scope of the European Directive for Integrated Pollution Prevention and Control (IPPC). In 2019, the Biosynthesis Plant was within the planned specific consumptions.

- Air quality

In 2019, our own laboratory monitored the air quality conducting analyzes regarding emissions / imissions of air pollutants for nitrogen oxides, ammonia, suspended powders and sedimentable powders.

There were no exceedances of the maximum allowed concentrations specified in the Integrated Environmental Authorization.

Also, we express a permanent concern for reducing the effects of emissions of technological odors, by their supervision and monitoring, as well as by using different technical solutions to limit them ( filter equipment).

- Water quality

Water quality was monitored through analyzes regarding the quality of the water entered the own wastewater treatment plant and discharged into the municipal sewage system, quality of the conventional clean water discharged into the natural stream, as well as the quality of groundwater.

There were no exceedances of the maximum allowed concentrations established by the Integrated Environmental Authorization, the Water Management Authorization and H.G.R. no. 352 of 2005 (NTPA 001 and NTPA 002).

- Soil protection and groundwater

From the total area of the land in the property of Antibiotice, about 40% is covered with green spaces.

Quality of the groundwater was monitored by monthly collecting and analyzing the samples obtained from the perimeter observation wells. There was no accidental pollution or

environmental incident leading to the degradation of soil quality in the area of influence of the company's activity.

- **Waste management**

Antibiotice implemented a selective waste collection system, each production plant and auxiliary activity being equipped with containers suitable for collection.

The recyclable waste were sold to the authorized economic operators.

The non-valuable waste was incinerated in our own incineration plant or stored to the municipal landfill.

Antibiotice complies with the requirements for the packaging waste management (corresponding to the quantity of packaging introduced in the market) established by the specific legislation, namely the recovery / recycling of 60% of the quantity of packaging placed in the national market.

### **Occupational health and safety**

By maintaining and developing an effective occupational health and safety management system within the company we create an optimal framework for managing and eliminating work-related risks, as well as for improving the environment and the relationships between employees.

The principles and measures of the occupational safety system are established and followed, through the Prevention & Protection Plan, by the Occupational Safety and Health Committee (CSSM), organized in our company.

In 2019, the Prevention & Protection Plan included several measures aimed at permanently improving the working conditions and prevention of work accidents and occupational diseases.

Thus, 3 meetings of the Safety & Health Committee were organized and the representatives of the Work Safety Committee were consulted for identifying new professional risks as well as granting / replacing the work and protection equipment and all the measures included in the Prevention & Protection Plan, as follows:

- in order to reduce the physical effort, the Parenteral Product Plant and the Storage Department were equipped with electrical equipment for transporting and lifting the raw materials and the finished product.

- in order to reduce the exposure to chemical agents, the chemical reagents from the laboratories of the Research & Development Unit were transferred in exhaust reagent cabinets (which ensure a constant aeration) and are fire-resistant.

Our company took also actions to inform and raise awareness of its employees on topics regarding the aging in health conditions and prevention of the health problems during their professional life.

### **Antibiotice - a responsible company involved in the sustainable development of the community**

Development of a sustainable business, ethics and transparency, economic, social and environmental impact of the Antibiotice company represent strategic directions followed also in 2019. Acting sustainably, Antibiotice creates long-term value for both itself and stakeholders while respecting the environment, being concerned about the health and safety of its employees, supporting the community in which it operates.

“Responsible for a better life” is the concept through which Antibiotice elaborated in 2019 its second non-financial report (<https://bit.ly/2ttuAuT>). The document, which reflects the construction of a performing and responsible company for all the categories of stakeholders, represents a transparency step, including relevant data that contribute to the understanding of the company's environment, economic and social footprint. In this way, another dimension of the company's performance is presented, that of the value and impact it creates by assuming good practices in all its areas of activity.

Within the legal term imposed by the Order of the Minister of Public Finance 1938/2016, Antibiotice SA undertakes to publish the 2019 Non-Financial Report, which will be made available to the public on the company's website ([www.antibiotice.ro](http://www.antibiotice.ro)).

In terms of community involvement, this is achieved through social responsibility programs based on four strategic pillars: health, education, environment and social matters.

## 1. Health

*We develop social responsibility programs to improve the health of our employees, but also the health of the community in which we operate. These programs have been developed to educate and inform the population about health prevention*

### 1.1. " Donate blood! Put your soul to life! "- a voluntary blood donation campaign

Under this urge, the Antibiotice employees have participated since 2010, in the blood donation campaigns, organized internally, by the "Science and Soul" Foundation in partnership with the Regional Blood Transfusion Center (CRTS) Iași. Performed biannually, this action responds both to the need to increase the blood reserves needed in hospitals and to the employees' desire to do a good deed for their fellow citizens, donating blood to solve the urgent medical cases.

Our company organized two campaigns "Donate blood! Put your soul to life!" on April 7, 2019, on the occasion of the World Health Day and on October 2019. A number of 120 Antibiotice employees donated 60 liters of blood, saving this way 300 lives.

The "Science and Soul" Foundation was awarded three times in 2019 for its efforts to continuously organize (9 years in a row) blood donation campaigns in which Antibiotice employees were the donors. Our Foundation received the first prize for this program within the CSR Awards Gala organized by CSR Media and the Blood Donor Gala organized by the Voluntary Emergency Service Iași. The Foundation was also given the "Rescue Hero" distinction granted by the National Institute of Transfusion Hematology Bucharest.

### 1.2. "Each of us can save a life!" - first aid courses for the Antibiotice employees

First aid courses make the difference between life and death and health education increases a person's chances of survival if those around him/her know how to intervene until the ambulance arrives.

To this end, for the second year in a row, our company organized, on the occasion of World Heart Day, a first aid course attended by 100 employees willing to learn the basic first aid measures. This action was carried out in partnership with the Emergency Receiving Unit of

SMURD Iasi and Emergency Medicine Department within Gr. T. Popa University of Medicine and Pharmacy.

The campaign entitled "Each of us can save a life!" was awarded at the Romanian CSR Award 2019 Gala in the "Support for employees" category and promotes the responsible behavior among the Antibiotice employees.

## 2. Education

*We invest, with science and soul, in the education of young people who, like our employees, can be highly performant in their career and become responsible behavior models. We recognize and support the role of the local community in forming and developing the company's main source of value - the well trained people.*

**2.1. „Science and Soul” Scholarships** - an annual scholarship program for supporting 5 pupils from the rural area

For 18 years running, through its “Science and Soul” Foundation, Antibiotice has been supporting together with the Pro Ruralis Association 5 pupils from the rural area by granting them annual scholarships. This way, our company contributes to the education of children with special abilities and a higher intelligence coefficient but without material possibilities, supporting them to continue their studies at the secondary and high school, thus giving them the chance for professional achievement and personal development.

## 3. Environment

*Antibiotice develops a sustainable partnership with the community by carrying out activities meant to protect the environment, being permanently concerned with improving its environmental performance.*

**3.1. Be Pro-Nature! Put your Soul!** This is an environmental protection project encompassing more programs developed by our company in 2019:

- **”Orchard at school”** is a program through which, year by year, the volunteer employees from Antibiotice plant a fruit orchard around the rural schools. Thus, in the month of April, 70 volunteers from Antibiotice planted fruit trees at the Day Care Center for children at



risk in the Cornești Village, Miroslava commune as well as at the "Constantin Păunescu" Special Gymnasium School Iasi for pupils with different mental disabilities.

In 2019, in addition to its mission of instilling respect for environment in the young generation and maintaining a healthy lifestyle, the "**Orchard at school**" project also aimed at offering therapy activities for children with special needs such as planting and caring the young orchard.

- "**We plant oxygen in the community**" is a tree planting program for our employees that involved the greening of an area near the company. Thus, in November 2019, 60 volunteer employees from Antibiotice planted 200 saplings in the immediate vicinity of our company.
- **Earth Hour** - our company's participation in the Earth Hour campaign is part of the program "Be Pro-Nature! Put a soul!" and involves the symbolic turning off the non-essential electric lights in our company for one hour.

2019 was the 11<sup>th</sup> consecutive year in which Antibiotice symbolically turned off the lights inside its facilities, joining this way the Earth Hour campaign, the largest environmental manifestation of all times, which draws attention to the effects of global warming and to the measures to be taken, at any level, to stop the phenomenon.

#### **4. Social matters**

*Antibiotice, through the "Science and Soul" Foundation engages itself in the community life by supporting disadvantaged groups through social programs, some of which have become traditional.*

##### **4.1. "Power of deed"- Charity in the Easter holidays**

Around Easter, the "Science and Soul" Foundation made a humanitarian gesture for 23 needy families, which together have 121 children, from remote localities of the Iași County (Zmău Village, Lungani Commune, Dumești and Cosițeni villages from the Dumești Commune). Each family received a package containing basic foods, traditional products, cleaning products and stationery for children.

#### **4.2. We prepare the Future - Celebration of the International Children's Day at the Antibiotice headquarters**

It has already become a tradition for Antibiotice to offer gifts every year to the employees' children on the occasion of the International Children's Day. In 2019, the company offered the children the opportunity to enter the traditional Moldavian world full of life and humor created by the greatest Romanian storyteller, Ion Creangă. The children were invited to the "Amintiri din copilărie" show held at the National Athenaeum in Iași.

#### **4.3. „Be generous, Be Santa Claus!”**

In 2019, for the seventh year in a row the “Science and Soul” Foundation organized the „Be generous, Be Santa Claus!” campaign in partnership with Pro Vita Department of the Iasi Archdiocese Mission Sector.

The campaign was organized for a number of 100 children from families with reduced material opportunities, from 12 rural localities of Iasi County.

The children aged between 1 and 13 expressed their wishes in letters addressed to Santa Claus. Their emotional rows animated our colleagues who became the Santa Claus's elves, fulfilling the children's wishes.

On December 18, 2019, Santa Claus rushed to appear at a festivity organized in our company. The kids enjoyed meeting him, many of them for the first time. As a sign of thanks, the little ones staged short artistic moments, singing Christmas carols.

### **IV Corporate governance**

Antibiotice has been continuing the process of implementing the good corporate governance practices, strictly meeting the principles and recommendations of the Corporate Governance Code of the Bucharest Stock Exchange (CGC-BVB) that was adopted in 2012.

By applying these principles, our company makes its activities and processes more transparent and effective, offering this way in the long run the proper framework for maximizing the value of its shares and for increasing its attractiveness towards the investors.

The Antibiotice management considers the Corporate Governance Code an important tool for achieving sustainable performance, ensuring the accuracy and transparency of the decision-making process through equal access of all the shareholders to relevant information about the company.

The Antibiotice corporate governance system is based on the following pillars:

- Corporate Governance Code
- Code of Ethics
- General Meeting of Shareholders
- Management Board
- Advisory Committees
- Executive Management
- Internal audit, Inventory Financial Control and Risk Management

### **Corporate Governance Code**

The Code of Corporate Governance of Antibiotice SA included the principles and recommendations of the Bucharest Stock Exchange and represents the tool through which Antibiotice implements these principles and recommendations.

The Corporate Governance Code creates the necessary framework for establishing strong relationships with the shareholders and stakeholders, as well as for an effective and transparent, trust-based communication.

The Corporate Governance Code of Antibiotice SA is divided into four chapters:

Chapter I - Responsibilities of the Management Board

Chapter II - Risk Management and Internal Control System

Chapter III - Fair reward and motivation

Chapter IV - Investor relations

It also has two annexes:

Annex I - Management Board's Rules of Procedure

Annex II - Rules for evaluating the Antibiotice's administrators

**Chapter I - Responsibilities of the Management Board** - defines the role of this body while setting the guidelines in terms of competence, experience, knowledge and independence of its members, which enable them to effectively perform their specific duties and responsibilities.

**Chapter II - Risk Management and Internal Control System** - demonstrates that the company's activity is supervised by certain risk management and internal control systems set up for this purpose. Also, internal audits are conducted in order to assess independently and periodically the safety and effectiveness of the risk management and internal control systems.

**Chapter III - Fair reward and motivation** - establishes the general principles and conditions that are the foundation of the method for setting the level of remuneration for the Board members and company's management team.

**Chapter IV- Investor relations** - states the fact that Antibiotice must make constant efforts to provide the shareholders with updated information on events of interest to them (e.g. general meetings of shareholders, shareholder-related rights, etc)

In conclusion, The Corporate Governance Code of Antibiotice SA and its annexes draw the general framework under which the Management Board develops its activity in accordance with the rules and principles of corporate governance established by the Bucharest Stock Exchange, in order to create an attractive capital market, based on the best practices, transparency and trust.

The stage of compliance with the provisions of the new Corporate Governance Code of the BVV<sup>1</sup> 1 at December 31, 2019 is presented in Annex no.1 to this report.

## Code of Ethics

The Code of Ethics of Antibiotice SA presents the ethical standards of conduct that establish and regulate the corporate values, the company's business responsibilities and obligations and how the company operates.

The Code of Ethics provides rules in the key areas relating to employees, human rights, environmental management, social responsibility and corporate governance.

The Code is binding and applies to all the structures and activities of the company.

The Code of Ethics is a fundamental commitment of our company to do its best in order to comply with the high ethical standards and applicable legal requirements wherever it operates.

The Code of Ethics is presented in detail on the website of our company: <https://bit.ly/2oOfRHT>

## General Meeting of Shareholders

General Meeting of Shareholders (GMS) represents the highest decision-making body of the company, where the shareholders participate directly in the decision-making process. Among other attributions, GMS decides the distribution of profit, elects the Management Board, appoints the auditors and sets the remuneration for the Management Board members.

During 2019, the Board convened two Ordinary General Meetings and two Extraordinary General Meetings of Shareholders, on *April 18, 2019 and September 10, 2019*.

All the necessary documents relating to the smooth conduct of the General Meetings were published in due time and as required by the law.

*The Ordinary General Meeting of Shareholders of April 18, 2019 approved:*

1. the company's financial statements for the fiscal year 2018, based on the Management Report and Financial Auditor Report;
2. distribution of the 2018 net profit, setting the gross dividend per share in value of 0.009991506 LEI/share and setting the payment date on 20.09.2019;
3. registration of the unclaimed and unpaid dividends for the financial year 2014 as revenues;
4. the 2019 Income and Expenditure Budget;
5. the degree of achieving the objectives and performance criteria for 2018 by the members of the Management Board;
6. the discharge of administration for the activity conducted in the fiscal year 2018, based on reports submitted.
7. the objectives of the Management Board's members set in the 2019 Administration Plan;
8. setting the remuneration of the Management Board's members, according to the provisions of GEO no. 109/2011 on the corporate governance of public enterprises and GD no. 722/2016 for the approval of the Methodological Norms for the application of certain provisions of the Government Emergency Ordinance no.109 / 2011 on the corporate governance of public enterprises;
9. modifying the composition of the Management Board by appointing Mr. Cristian Vasile Grasu in the position of interim administrator in accordance with the provisions of art. 641 of GEO no. 109/2011 on the corporate governance of public enterprises;
10. starting the process for selecting a new member of the Management Board, according to the provisions of the art. 64<sup>4</sup> of GEO no. 109/2011 on the corporate governance of public enterprises and art. 4, para. 3 of GD no. 722/2016 for the approval of the Methodological Norms for the application of certain provisions of the GEO no.109 / 2011 on the corporate governance of public enterprises as well as the empowering of the Management Board to select the new administrator in accordance with the provisions of art. 29, para 2 of GEO no. 109/2011 on the corporate governance of public enterprises and art. 4, para. 5 of GD no. 722/2016 for the approval of the Methodological Norms for the application of certain provisions of the GEO no.109 / 2011 on the corporate governance of public enterprises.

*The Extraordinary General Meeting of Shareholders of April 18, 2019 approved:*

1. a 12-month extension of the validity period of the multicurrency multiproduct credit amounting to 30 million LEI borrowed by SC Antibiotice SA from the Export Import Bank of Romania- Eximbank.
2. to maintain the guaranties related to the multi-product multi-currency credit amounting to 30 million LEI throughout the validity period (one calendar year starting with 26.06.2019) resulting from the extension under point 1 of the Agenda;
3. to issue a decision-commitment of Antibiotice not to divide itself, not to merge and decide the anticipated dissolution throughout the entire validity period of the multi-product multicurrency credit without the prior consent of the Export-Import Bank of Romania - EximBank SA..
4. to empower the General Director Mr. Ioan NANI and Financial Director Ms. Paula COMAN to sign on behalf of the company all documents related to the credit facility extension under paragraphs 1 and 2 of the Agenda, as well as documents related to obligations assumed by the company in accordance with paragraphs 3 of the Agenda.

*The Ordinary General Meeting of Shareholders of September 10, 2019 approved:*

1. the company's financial statements for the first semester of 2019, based on the Management Report and Financial Auditor Report.
2. the appointment of Mr. Cristian Vasile Grasu as a non-executive administrator for a 4-year term, in accordance with the provisions of art. 29 of GEO no. 109/2011 on the corporate governance of public enterprises.

*The Extraordinary General Meeting of Shareholders of September 10, 2019 approved:*

1. the extension of the grace period and the period of use of the investment loan related to the IAS3-20-2018/03.05.2018 contract, concluded with Unicredit Bank until 30.06.2020.

2. the empowerment of Mr. Ioan Nani as General Director and Mrs. Paula Luminita Coman as Financial Director to sign on behalf of the company any additional document related to the present credit contract as well as any additional documents related to the credit contracts concluded with UniCredit Bank.
3. the empowerment of Mr. Ioan Nani as General Director - signature I and Mrs. Paula Luminita Coman as Financial Director - signature II to sign on behalf of the company the additional documents related to the facility contracts, the guarantee contracts and the related additional documents, the guaranteed promissory note, the requests for use/reimbursement, the requests for issuing letters of guarantee and opening letters of credit, in relation to ING Bank.
4. the establishment of the Antibiotice representative office headquarters in the Republic of Moldova at the following address: Office 705, 7<sup>th</sup> floor, with a total area of 62.20 sqm., in the building located on 5/4 Dimitrie Cantemir Blvd., Chişinău, Republic of Moldova.
5. the establishment of the Antibiotice representative office headquarters in Vietnam, at the following address: Room 807, 8<sup>th</sup> floor, Building 3A, 3 Lane 82 Day Tan, Can Giay District, City of Hanoi, Vietnam.

### **Management Board**

Antibiotice is administered by a Management Board responsible for fulfilling all the tasks necessary to achieve the company's object of activity, except those provided by law for the General Meeting of Shareholders. There is a clear division of responsibilities between the Management Board and Executive Management.

The Management Board aims as its own decisions, those of the company's management and of the General Meeting of Shareholders as well as the internal regulations be compliant with the legal requirements and properly implemented. The Board is responsible for monitoring the company's management on behalf of the shareholders.

The duties of the Management Board are described in the company's Articles of Association and in the relevant internal regulations available on our company's website under the *Corporate Governance* section.



In 2019, the Management Board met in 11 sedinte, registering a 100% presence each time, and adopted decisions that enabled it to carry out its tasks in an effective and efficient manner.

Thus, at the monthly meetings, the Board analyzed in detail the financial results obtained during the reporting and cumulative period from the beginning of the year as well as the economic performance in relation to the budget and compared to the similar period of the previous year.

The Board requested, depending on the situation, detailed explanations from the executive management related to the plans for increasing the production efficiency, investment plans, constituted provisions, liquidity management, operational and overall profitability. Following the detailed analysis of the results, the Board decided to approve them for publication and for sending them to the Bucharest Stock Exchange and the Financial Supervisory Authority, each time meeting the deadline included in the Financial Communication Calendar.

The 5 members of the Management Board guarantee the efficiency of the capacity to supervise, analyze and evaluate the activity of directors, as well as the fair treatment of the shareholders.

#### **Management Board of Antibiotice SA on December 31, 2019**

**Dan Octavian Alexandrescu, Physician, 44 years old**

**President of the Management Board and representative of the Ministry of Health**

At the Ordinary General Meeting of Shareholders held on September 29, 2018, Mr. Alexandrescu was elected as a member of the Management Board, for a 4-year period.

Mr. Dan-Octavian Alexandrescu is a primary physician with competence in laparoscopic surgery and the Coordinator of the Policy Directorate for Medicines and Medical Devices since March 2017.

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

**Ioan Nani, Economist, 60 years old**

**Executive member of the Management Board and General Director**

At the Ordinary General Meeting of Shareholders held on April 19, 2016, Mr. Nani was reconfirmed as a member of the Management Board, for a 4-year period, the members of the Management Board electing him as the Board's Vice President.

Mr. Nani is an economist specialized in management and chartered accountant, member of the Management Board since 2009 and General Director (1998 - 2008 and 2009 - present).

**Number of Antibiotice SA shares held - 1,513\***

**Cristian Vasile GRASU, Physiscian, 59 years old**

**Member of the Management Board and representative of the Ministry of Health**

At the Ordinary General Meeting of Shareholders held on September 10, 2019 Mr. Grasu was elected as a member of the Management Board, for a 4-year period.

Physician, Coordinator of the General Directorate of Public Healthcare of the Department for Monitoring and Coordination of Regional Hospitals, as well as of the priority actions of the Ministry of Health.

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

**Nicolae STOIAN, Economist, 63 years old**

**Member of the Management Board and representative of the shareholder SIF Oltenia and other shareholders - legal entities**

At the Ordinary General Meeting of Shareholders held on April 19, 2016, Mr. Stoian was reelected as a member of the Management Board for a 4-year period.

Mr. Stoian is a chartered accountant, tax consultant and financial auditor, representative of the Internal Control Department at SIF Oltenia.

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

**Elena CALITOIU, Engineer, 56 years old**

**Member of the Management Board and representative of the shareholder SIF Oltenia and other shareholders - legal entities**

At the Ordinary General Meeting of Shareholders held on April 19, 2016, Ms. Calitoiu was confirmed as a member of the Management Board, for a 4-year period.

Ms. Calitoiu is a mechanical engineer and Director of Placements & Risk Management Department, SIF Oltenia

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

*\*Number of Antibiotice (ATB) shares held on December 31, 2019 according to the latest database owned by Antibiotice for 2019.*

### **Advisory committees**

The specialized advisory committees in 2019:

- ***Audit Committee***: Mr. Cristian-Vasile Grasu, Mr. Nicolae Stoian and Ms. Elena Calitoiu;
- ***Nomination and Remuneration Committee***: Mr. Dan-Octavian Alexandrescu and Ms. Elena Calitoiu;
- ***Trade Policy Committee***: Mr. Dan Octavian Alexandrescu and Mr. Nicolae Stoian.

The Advisory Committees carried out investigations, analyzes and elaborated recommendations for the Management Board in the specific fields and submitted periodically reports on their activity to the Management Board.

In 2019, the **Audit Committee** met in three sessions in order to fulfill its responsibilities on financial reporting, external and internal audit, risk management and internal control.

### **Nomination and Remuneration Committee**

In 2019, the **Nomination and Remuneration Committee** met in four sessions to evaluate the administrators' activity and followed the procedure for selecting a Management Board member.

The remuneration granted to the Management Board and Executive Management (General Director) in 2019 amounted to 4,233,682 LEI. This value represents the monthly fixed allowance and the variable allowance, according to the legislation in force:

- the monthly fixed allowance is established in accordance with the legal provisions, respectively the provisions of art. 37 paragraph (2) of GEO 109/2011
- the variable allowance is granted if the performance indicators and criteria included in the administration contracts and mandate contracts are properly fulfilled.

- The fixed and variable allowance for the Management Board members is approved by the General Meeting of Shareholders. The General Meeting of Shareholders also approves the general limits within which the directors with a mandate contract are remunerated; based on these general limits, the Management Board sets the remuneration of the directors with a mandate contract.

### **Executive management**

Antibiotice is represented by the General Director, according to the powers provided by law and by the company's Articles of Association. The Management Board represents the company in relationship with the appointed directors.

The Executive Management of Antibiotice is ensured by the General Director who is also the Vice-President of the Management Board and nine specialty executives.

### **Internal audit, Financial inventory control, Risk management**

The specialized internal control provided by the legislation in force is carried out by our own internal audit activity complemented by the financial inventory control and the inventory control.

The way of setting and achieving the objectives of the internal audit activity, the findings and recommendations resulting from all the internal control actions are presented quarterly to the Audit Committee within the Management Board, for assessing the activity and internal control exercised in the company.

So, in 2019, our specialized department conducted 10 audit missions having the following general objectives specific for each area:

- to examine the compliance of the audited activity with all the principles, specific procedural and methodological rules, internal notes and decisions;
- to examine the way in which the audited activity is organized;
- to evaluate the management and control system of the audited activity;
- other specific objectives.

The audit missions were carried out in compliance with the audit procedures, and internal audit reports were submitted to the General Director to be approved. The conclusions and recommendations of the audit reports were acknowledged by the audited structures.

The Internal Control Department monitored the implementation of the recommendations made during the internal audit missions. 50 recommendations were made in 2019. Out of 35 recommendations having as deadline 31.12.2019, 18 of them were implemented while for the remaining 17 an extension of the implementation deadline was requested.

As part of the inventory control activity, 21 inventory actions were carried out in 2019, involving the following structures:

- central warehouses for raw materials and consumables;
- places of consumption of raw materials and consumables where stock management is organized;
- departments where the inventory administrators were changed.

The inventory activity aimed at observing the legal framework established by the following normative acts:

- Accounting Law no. 82/1991, republished and updated;
- Law no. 22/1969 on the employment of warehouse operatives, the provision of guarantees and the liability for the management of goods;
- O.M.F. 2861 / 09.10.2009 for the approval of the Norms on organizing and performing the inventory of assets, debts and equity;
- Operating procedures, notes and internal decisions issued by the company's management.

The control actions found that the legal regulations and internal decisions regarding the stock management as well as the correspondence between the factual and the scriptic stocks as a result of the periodical check during the year between the quantitative and the quantitative-value evidence are properly observed.

The Financial inventory control actions in compliance with the provisions of G.D. 1151/2012, had the following objectives:

- to verify the compliance of the accounting registration of the economic-financial operations with the legal provisions;
- to verify if the Income & Expenditure Budget for 2018 was executed in compliance with the legal provisions;
- to verify if, in substantiating the draft of the Income & Expenditure Budget the legal requirements were met;
- to verify if the annual inventory of assets, liabilities and equity for the 2018 was made in compliance with the legal provisions and internal regulations;
- to verify if the receipts and payments in LEI and foreign currency, of any kind, in cash or by transfer were made in compliance with the legal provisions and internal regulations;
- to verify if the elaboration, circulation, preservation and archiving of primary, accounting and technical-operative documents were made in compliance with the legal provisions and internal regulations;

The financial inventory control actions were completed by drawing up control reports, in which findings and improvement measures were presented.

### **Risk management**

Our company complies with applicable legal and regulatory requirements for identifying, assessing, managing and reporting the risks:

- Government Secretary General Order (OSGG) no. 400/2015 modified and completed by OSGG no. 200/2016 and OSGG no. 600/2018;
- Requirements of the Corporate Governance Code of the Bucharest Stock Exchange.

The main purpose of risk management is to help people understand and identify the risks to which the organization is exposed so that they can anticipate and manage these risks without compromising the organization's effectiveness.

Antibiotice objectives on risk management:

- to understand the risks to which our company is exposed as well as their general and specific causes;
- to improve the risk profile of our company by managing the process of identifying, evaluating and managing risks and by implementing the control measures needed to maintain exposure to risk within the tolerable area.

The responsibilities regarding the risk management are fulfilled by the Risk Management Department together with the Antibiotice's risk managers and employees.

Our Risk Management Department annually analyzes and prioritises the significant risks that may affect the achievement of the company's overall goals, by establishing the risk profile and tolerance limit approved by the management of the company. They also draw up the "Plan for implementing the control measures for significant risks related to our company's business" and submit it for approval to the General Director.

In 2019, the General Risk Register was prepared and approved in order to minimize the significant risks to which Antibiotice is exposed, with a high impact on its objectives.

Specific risks identified for the organizational structures within Antibiotice SA were submitted to the Audit Committee:

The main risks identified:

### **1. Financial risks**

In terms of financial risk management, the risks to which our company is exposed are: currency risk, liquidity risk and commercial (non-payment) risk.

**1.1. Currency risk**, a component of the financial risk which occurs frequently in the current market economy where monetary rates fluctuate under the supply and demand rule. Exchange rate fluctuations are reflected both in the costs of imported raw materials, as well as in the prices of finished goods for export.

During 2019 there were periods with higher volatility, with depreciation periods of our currency, LEU.

In order to reduce the exposure to the currency risk, our company took a series of measures such as: synchronization of import and export activities by correlating payment and collection terms, as well as correlating the weight of currencies so that the payment for the imported goods be made as close to or even simultaneous with the collection of money for the exported products.

**1.2. Liquidity risk** arises from the company's failure to honor, at any time, the short-term payment obligations.

Liquidity risk may occur in the following circumstances: lack of cash-flow generated by the gap between receipts and payments determined by the collection of receivables at maturities exceeding 300 days, fluctuations in interest rates and currency rates, volume of investments, level of taxation (clawback tax), price of raw materials.

Our company's policy on **liquidity risk** is to maintain, as far as possible, sufficient liquid resources to meet the payment obligations as they reach maturity and to obtain necessary financing through credit lines.

**1.3. Commercial risk** is the risk of incurring losses or not-reaching the estimated profits due to lack of financial liquidity of the borrowers and their failure to pay upon maturity. Circumstances of non-payment risk: the large exposures of the company to the major national distributors, long payment periods caused mainly by delays with which the invoices for health services are settled by the National Health Insurance House.

The measures taken by our company to control and reduce the commercial risk include: monitoring the customer creditworthiness, diversifying the customer portfolio and requesting guaranties.

## **2. Legislative risk**

Legislative changes regarding the pharmaceutical market lead to the occurrence of legislative risk, which must be continuously managed.

Pharmaceutical market is a regulated market, with clear legislative requirements elaborated for controlling the quality and therapeutic efficiency of the medicines present in the market and for avoiding counterfeiting.

Our effort for complying with these provisions is reflected in additional costs related to updating the documentation, in line with the latest quality standards.



Our company's strategy of managing these risks involves a permanent concern for obtaining international certifications for the manufacturing flows, updating the authorization documentation for the products in the portfolio, continuous monitoring legislative changes at international level, constantly adapting our policies, rules and procedures to changes.

### **3. Human resource risk**

The main human resource risk is the lack on the labor market of candidates properly trained in fields specific for the pharmaceutical industry. The measures taken to control and reduce this risk: "Summer School + a" attended by the best students, promotion of our company in faculties, study visits for students in our company and partnerships concluded with the university institutions (Grigore T. Popa University of Medicine and Pharmacy (UMF) through "Perform a+).

**4. Reputational risk** is defined as the current or future risk of negatively affecting the company's profits and equity determined by the unfavorable perception on the company's image.

In order to effectively manage the events that could lead to a reputational risk, the following measures are envisaged: monitoring the image of the company in the media in order to identify any rumors that could generate image risks, periodical press releases with positive information, control of risks that may affect the image of the company, continuous training of personnel, rapid adaptation to the legislative requirements in the field, compliance with procedures.

**5. Operational risk** is the risk of loss that results either from the use of some inadequate processes, persons or internal systems that did not perform their function properly, or from external events.

Operational risks can materialize in equipment failures, human errors, faulty operational processes which can lead to unplanned shutdowns.

Antibiotice constantly monitors the operational risks in order to take measures to maintain them at an acceptable level that does not threaten its financial stability, interests of creditors, shareholders, employees, partners.

The Management Report was prepared based on the financial data submitted according to the legal requirements of the external financial audit.

## Conclusions:

- Sales income higher by 7% compared to 2018;
- The international sales amounted to 152.1 million LEI, up 25% compared to the value recorded in 2018;
- 2019 - the first year in which the international sales of finished products significantly outperformed the sales of the active substance Nystatin, up 65% compared to the previous year;
- Operating profit amounted to 41.56 million LEI, up 6% compared to the value recorded in 2018;
- Pre-tax profit amounted to 35.2% million LEI whereas the clawback tax reached the value of 42.2 million LEI;
- The product Moldamin® returns in the medical practice in a new formula and represents the first-line medicine in infections for which prolonged antibiotic concentrations are necessary.

General Director,  
Ioan Nani

Financial Director,  
Paula Coman