

# MANAGEMENT REPORT

For the fourth quarter  
of 2017



**TCHAIKAPHARMA**  
**HIGH QUALITY MEDICINES**

TCHAIKAPHARMA HIGH QUALITY MEDICINES INC.

26 January 2018

## **General information about Tchaikapharma High Quality Medicines Inc.**

### **History and development of Tchaikapharma High Quality Medicines Inc.**

#### **Legal and corporate name**

The legal and corporate name of the company is Tchaikapharma High Quality Medicines Inc.

#### **Address details and registration. Unique Identification Code (UIC)**

The Company was registered as a joint stock company with the Commercial Register by virtue of Decision dated 14 March 2000 of the Varna District Court on company file 1096/2000. The corporate name was TCHAIKA PHARMA INC.

By resolution of the General Meeting of Shareholders dated 04 July 2003, registered by virtue of Decision dated 30 July 2003 on company file 1096/2000 of the Varna District Court, the corporate name was changed to TCHAIKAPHARMA HIGH QUALITY MEDICINES INC.

The Company is registered with the Commercial Register of the Registry Agency at the Ministry of Justice under **UIC 103524525**.

#### **Date of incorporation and duration of the existence**

The Company was incorporated as a joint stock company and registered with the Commercial Register by virtue of Decision dated 14 March 2000 on company file 1096/2000 of the Varna District Court. The existence of the Company is of unlimited duration.

#### **Country of establishment, head office and registered address pursuant to the Articles of Association; legal form; legislation governing the activity of the Company**

Tchaikapharma High Quality Medicines Inc is a joint stock company, which operates in compliance with the legislation of the Republic of Bulgaria.

The Company is incorporated in the Republic of Bulgaria.

The head office and registered address of the Company is as follows:

Republic of Bulgaria, 1172 Sofia, 1 G.M. Dimitrov Blvd.

Contact Address: 1172 Sofia, 1 G.M. Dimitrov Blvd.

Telephone number: (359 2) 960 3634

Website: [www.tchaikapharma.com](http://www.tchaikapharma.com)

## Important events in the development of the Company

Important events in the development of the Issuer for the last three years:

- Tchaikapharma High Quality Medicines Inc has not been subject to transformation.
- Tchaikapharma High Quality Medicines Inc has not been transferred or pledged.
- No significant changes in the scope of activity of Tchaikapharma High Quality Medicines Inc have taken place;
- No claims for opening of insolvency proceedings have been submitted.
- By Decision of the General Meeting of 26 August 2014, the capital was increased from BGN 32,000,000 to BGN 43,500,000 through the issuance of 11,500,000 (eleven million five hundred thousand) new ordinary dematerialised shares with nominal value of BGN 1 (one) each. The capital increase was effected by way of capitalisation of profits pursuant to Art. 197 of the Commercial Act.
- By Decision of the General Meeting of 20 April 2015, the capital was increased from BGN 43,500,000 to BGN 49,600,000 through the issuance of 6,100,000 (six million one hundred thousand) new ordinary dematerialised shares with nominal value of BGN 1 (one) each. The capital increase was effected by way of capitalisation of profits pursuant to Art. 197 of the Commercial Act.
- By Decision of the General Meeting of 23 June 2016, the capital was increased from BGN 49,600,000 to BGN 56,600,000 through the issuance of 7,000,000 (seven million) new ordinary dematerialised shares with nominal value of BGN 1 (one) each. The increase of the capital was effected by way of capitalisation of profits pursuant to Art. 197 of the Commercial Act. The capital increase was registered with the Commercial Register on 19 July 2016.
- Currently, the capital of the Company amounts to BGN 56,600,000 split into 56,600,000 ordinary dematerialized voting shares with nominal value of BGN 1 (one) each.
- By Decision of the General Meeting of 08 June 2017, the capital was increased from BGN 56,600,000 to BGN 64,300,000 through the issuance of 7,700,000 (seven million seven hundred thousand) new ordinary dematerialized shares with nominal value of BGN 1 (one). The increase of the capital was effected by way of capitalisation of profits pursuant to Art. 197 of the Commercial Act. The capital increase was registered with the Commercial Register on 05 July 2017.

Tchaikapharma High Quality Medicines Inc is one of the fastest growing Bulgarian companies, specialised in manufacturing high quality and affordable generic medicines. The production facilities of the company are built in compliance with the European requirements. The company is focused on the quality and safety of production of medicinal products for human use. In the years, in which the company has been on the market, it has proved its integrity and the care for the patient. In the fourth quarter of 2017, Tchaikapharma continued to upgrade its product range, which at this stage consists of more than 150 medicinal products. Its main goal is to incorporate current trends in the worldwide drug therapy in its products.

The medicinal products for the treatment of diabetes, diseases of the central nervous system, and cancers are a key priority for the Company, and it is mainly focused on medicines for treating cardiovascular diseases.

## Investments

### Major investments in the financial years of 2014, 2015 and 2016.

Overview of the investments in fixed assets by type and year:

Investments for the period	2014	2015	2016
<b>Tchaikapharma High Quality Medicines Inc.</b>			
I. Fixed tangible assets	199	2 906	1 331
1. Property, plant and equipment	196	2 782	1 312
2. Other fixed assets	3	124	19
II. Non-current intangible assets	1 031	532	547
1. Industrial property rights	1 031	531	495
2. Software		1	9
3. Patents and licenses			43
<b>Total costs of acquisition of fixed tangible and non-current intangible assets</b>	<b>1 230</b>	<b>3 438</b>	<b>1 878</b>

### Major investments in progress

The investments in the two factories of Tchaikapharma High Quality Medicines Inc for the year 2017, consist of the serialization and tamperevidence system aimed at meeting the requirements of the European **Directive 2011/62/EU**. Commencing 9 February 2019, in order to be sold within the EU territory every package of a medicinal product must bear a unique code and evidence of tampering. The system will be implemented in cooperation with SoftGroup AD; this involves the installation of 5 machines for printing and verification of 2D matrix code (with the unique code of the box) a tamperevidence system in each card boarding machine, server: centrally and locally, individual code generation software, storing and sending them to the European hub.

A small investment in the plant in Plovdiv is made in the system for optimizing the energy costs of heating and cooling of the production ventilation system.

## Economic activity

The scope of activity of the Company, as registered with the Commercial Register, is: purchase of substances and formulations for the production and sale of pharmaceuticals in treated or processed form, (after Marketing Authorisation); primary and secondary packaging of formulations (after Marketing Authorisation); import, export, re-export and merchandising in original, remade or processed type; barter and commission transactions; trade representation for foreign and domestic individuals and legal entities in the country and abroad; industrial and commercial management; consulting, marketing, brokerage, leasing, licensing, entrepreneurship, transport and shipping, research and development activities.

Currently, the main scope of activity of the Company can be summarized as follows:

- Production
- Packaging (primary and secondary)
- Marketing and promotion of medicines
- Research and development

In the fourth quarter of 2017, Tchaikapharma, being one of the leading pharmaceutical companies in Bulgaria, continued to add new products to its diverse portfolio.

At the end of 2017, an application for registration of a medicinal product with the trade name Pizona Combi, part of the group of anti-diabetic medicines, was filed.

New products to be prepared and submitted for registration at the beginning of 2018 were determined as a result of audits carried out.

Tchaikapharma High Quality Medicines Inc has continuously maintained its production facilities and equipment in accordance with the contemporary European requirements for Good Manufacturing Practice in respect of medicines. The Company built manufacturing facilities for aseptic products that meet the highest requirements for sterile products.

At present, more than 150 medicinal products are produced in the company's factories and in the development phase there are another 15 products.

Tchaikapharma High Quality Medicines Inc, as a high-quality manufacturer of medicinal products, began to produce its own dossiers of medicinal products. Modules 2.4, 2.5, 2.6, 2.7, of a dossier of a medicinal product with INN Ceftriaxone have been developed. The necessary documents, such as Protocol, Investigator's Brochure, Patient's Clinical Card, etc., required to obtain authorisation to conduct a second clinical trial to demonstrate the bioequivalence of a fixed combination of irbesartan/hydrochlorothiazide with the CoAprovel reference product have been prepared. The development and validation of methods for investigation of the concentration of drug substances in human plasma is a major task of the bio analytical laboratory. The creation of standard operating procedures to ensure the quality of the work and the reliability of the results of the bio analytical laboratory is under way. At present, the validation of the first method, which has been developed by the bio analytical laboratory in compliance with the requirements of current manuals EMA and FDA, is in progress. Based on the quality system currently being developed in the bio analytical

laboratory, it will also be possible to initiate a Good laboratory practice (GLP) compliance verification procedure.

## Employees

As of 31 December 2017 the average number of employees in Tchaikapharma High Quality Medicines Inc was 133 (126 as of 31 December 2016). In the table below, detailed information about the employees in the company is provided.

	<b>31 December 2017</b>	<b>Share</b>
<b>Number of employees as of 31 December 2017</b>	<b>133</b>	<b>100%</b>
Higher education	72	55%
Secondary education	60	44%
Primary education	1	1%
Employees under 30 years	35	27%
Employees 31 - 40 years	53	40%
Employees 41 - 50 years.	31	24%
Employees 51 - 60 years.	9	6%
Employees 60+ years	5	3%
Women	51	39%
Men	82	61%

## Significant events since the beginning of the year until 31 December 2017

In the fourth quarter of 2017 there were no significant events.

## Key financial indicators

<b>Indicators</b>	<b>01-12/2017 BGN '000</b>	<b>01-12/2016 BGN '000</b>	<b>change %</b>
Sales revenue	33 359	33 076	0.85%
Earnings before interest, taxes, depreciation and amortisation (EBITDA)	13 320	13 382	-0.46%
Net profit	9 029	8 585	5.17%

	<b>01-12/2017 BGN '000</b>	<b>01-12/2016 BGN '000</b>	<b>change %</b>
Non-current assets	35 223	35 558	-0.94%
Current assets	61 061	55 529	9.96%

Equity	82 024	72 995	12.37%
Non-current liabilities	1 946	2 366	-17.75%
Current liabilities	12 314	15 726	-21.18%

	01-12/2017	01-12/2016
EBITDA/Sales revenue	39%	40%
Net profit/Sales revenue	27%	26%

## Review of the risk factors

- The Company's activities could be affected by changes in the regulatory requirements concerning production of pharmaceutical products.
- Amendments to the legislation regulating the Company's business are possible, and these could potentially increase the costs of compliance or may have another adverse effect on its operations.
- The production processes of the Company are subject to stringent requirements and approvals by regulatory authorities, which may delay or even interrupt the operations of the Company.
- The ability of the Company to pay dividends depends on a number of factors and there is no guarantee that in a year it will be able to pay dividends in accordance with its dividend policy.
- The Company is exposed to operational risk, which is inherent in its business activities.
- The Company is subject to multitude laws and regulations in the field of environmental protection and health and safety work conditions, and is exposed to potential liabilities in relation to environment.
- The Company is exposed to strong competition.

The Company operates in active exchange with foreign suppliers and customers. It is therefore exposed to foreign currency risk, mainly against the US dollar. The foreign currency risk is the risk that the exchange rate of US dollar: Bulgarian lev will fluctuate in future and thus, it will have an effect on the foreign currency assets and liabilities. The remaining part of the Company's operations is usually denominated in Bulgarian lev and/or in Euro.

## Sales by types of dosage forms

<b>Revenue by dosage forms</b>	<b>01-12/2017</b>	<b>01-12/2016</b>
	<i>BGN '000</i>	<i>BGN '000</i>
Tablets	28 980	29 263
Ampules	1 231	1 114
Vials	3 076	2 602
<b>Total:</b>	<b>33 287</b>	<b>32 979</b>

<b>Revenue by therapeutic groups</b>	<b>01-12/2017</b>	<b>01-12/2016</b>
	<i>BGN '000</i>	<i>BGN '000</i>
Cardiovascular system	26 414	26 358
Musculoskeletal system and connective tissue	72	249
Respiratory system and antibiotics	3 098	2 863
Nervous system	986	1 103
Endocrine system	1 118	912
Other products	858	795
Digestive system and metabolism	528	302
Oncology	213	396
<b>Total:</b>	<b>33 287</b>	<b>32 979</b>

**Changes in the stock of products and work in progress**

432

(107)

**Other operating income**

**01-12/2017**

**01-12/2016**

*BGN '000*

*BGN '000*

**Rental income**

47

43

**Other income**

82

65

**Total:**

129

108

**Finance income**

**01-12/2017**

**01-12/2016**

*BGN '000*

*BGN '000*

Income from interest

-

139

Income from exchange rate differences

88

38

Other finance income

-

-

**Total:**

88

177

## Operating expenses

<b>Operating expenses</b>	<b>01-12/2017</b>	<b>01-12/2016</b>
	<i>BGN '000</i>	<i>BGN '000</i>
Carrying amount of goods sold	1 719	3 379
Materials	9 696	8 275
Hired services	4 010	4 022
Personnel expenses	2 831	2 723
Social security expenses	573	520
Depreciation / amortisation expenses	2 294	3 532
Other expenses	1 681	553
<b>Total:</b>	<b>23 594</b>	<b>23 004</b>

<b>Costs of materials</b>	<b>01-12/2017</b>	<b>01-12/2016</b>
	<i>BGN '000</i>	<i>BGN '000</i>
Main materials	8 846	7 513
Electricity	391	322
Fuel and lubricants	63	40
Spare parts and laboratory materials	158	187
Water	19	13
Other materials	219	200
<b>Total:</b>	<b>9 696</b>	<b>8 275</b>

<b>Costs of hired services</b>	<b>01-12/2017</b>	<b>01-12/2016</b>
	<i>BGN '000</i>	<i>BGN '000</i>
Rents	220	181
Security	212	115
Insurance	29	55
Telephone and postage expenses	31	40
Equipment maintenance and subscription	76	55
Fees	70	82
Transport costs	43	49
Other costs of hired services	3 329	3 445
<b>Total:</b>	<b>4 010</b>	<b>4 022</b>

<b>Finance costs</b>	<b>01-12/2017</b>	<b>01-12/2016</b>
	<i>BGN '000</i>	<i>BGN '000</i>
Interest expenses	273	425
Expenses on exchange rate differences	48	81
Other finance costs	58	83
<b>Total:</b>	<b>379</b>	<b>589</b>

## Assets

	01-12/2017	01-12/2016
	<i>BGN '000</i>	<i>BGN '000</i>
<b>Non-current assets</b>		
Property, plant and equipment	26 264	25 888
Intangible assets	2 998	3 644
Minority interest investments	1	1
Trade receivables	5 960	6 025
<b>Total non-current assets</b>	<b>35 223</b>	<b>35 558</b>
	01-12/2017	01-12/2016
	<i>BGN '000</i>	<i>BGN '000</i>
<b>Current assets</b>		
Inventories	5 031	5 082
Trade and other receivables	55 997	50 373
Financial assets with maturity		24
Treasury shares redeemed	8	
Cash and cash equivalents	25	50
<b>Total current assets</b>	<b>61 061</b>	<b>55 529</b>
<b>Total Assets</b>	<b>96 284</b>	<b>91 087</b>

	01-12/2017	01-12/2016
	<i>BGN '000</i>	<i>BGN '000</i>
<b>Property, plant and equipment</b>		
Land and buildings	11 137	11 568
Machinery and equipment	13 076	13 988
Other assets	191	261
In progress	1 860	71
	<b>26 264</b>	<b>25 888</b>

	01-12/2017	01-12/2016
	<i>BGN '000</i>	<i>BGN '000</i>
<b>Inventories</b>		
Materials	4 225	4 629
Finished products	554	138
Goods	229	192
Work in progress	23	123
<b>Total:</b>	<b>5 031</b>	<b>5 082</b>

## Equity and liabilities

	01-12/2017	01-12/2016
	<i>BGN '000</i>	<i>BGN '000</i>
Registered (share) capital	64 300	56 600
Statutory reserve	8 695	7 810
Retained earnings	9 029	8 585
<b>Total Equity</b>	<b>82 024</b>	<b>72 995</b>

## Liabilities

	01-12/2017	01-12/2016
	BGN '000	BGN '000
<b>Non-current liabilities</b>		
Long-term loans	595	1 015
Deferred tax liabilities	1 284	1 284
Retirement benefit liabilities	67	67
<b>Total non-current liabilities</b>	<b>1 946</b>	<b>2 366</b>
<b>Current liabilities</b>		
Trade and other payables	1 839	2 909
Short-term loans	9 778	11 349
Current portion of long-term loans	486	869
Current corporate income tax		55
Other tax liabilities	211	544
<b>Total current liabilities</b>	<b>12 314</b>	<b>15 726</b>
<b>Total liabilities</b>	<b>14 260</b>	<b>18 092</b>
<b>Total equity and liabilities</b>	<b>96 284</b>	<b>91 087</b>

## Financial indicators

	01-12/2017	01-12/2016
Debt ratio	0.17	0.25
Financial autonomy ratio	5.75	4.03

## Information on the shares of Tchaikapharma High Quality Medicines Inc.

The total number of shares issued as of 31 December 2017 was 64,300,000, with nominal value of BGN 1 each. According to the Articles of Association of the Company, all shares issued are registered, dematerialized, ordinary and indivisible. All shares are of one class. Each share vests equal rights to its holder, in proportion to the nominal value of the share. The shares of Tchaikapharma High Quality Medicines Inc are listed on the official market of Bulgarian Stock Exchange-Sofia AD.

## Essential information on the shares of Tchaikapharma High Quality Medicines Inc.

	<b>1-12/2017</b>	<b>1-12/2016</b>
Total number of shares issued	64 300 000	56 600 000
Number of shares in circulation at the end of the period	64 300 000	56 600 000
Price per share at the end of the period in BGN	7.89	6.97
Market capitalisation at the end of the period in BGN	507 327 000	394 502 000

Biser Georgiev

/Executive Director/