

# **ACTIVITY REPORT**

For the third quarter  
of 2017



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

TCHAIKAPHARMA HIGH QUALITY MEDICINES INC.

25.10.2017

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

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

#### **Legal and commercial name**

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

#### **Location and registration. Unique Identification Code (UIC)**

The Company was listed in the Commercial Registry by Decision from 14.03.2000 on the company case 1096/2000 of the Varna District Court as a joint stock company named TCHAIKA PHARMA INC.

By decision of the General Meeting of Shareholders from 04.07.2003, entered by Decision from 30.07.2003 on the company case 1096/2000 of the Varna District Court, the name was changed to TCHAIKAPHARMA HIGH QUALITY MEDICINES INC.

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

#### **Foundation date and duration in time**

The Company was founded and entered in the Commercial Registry by Decision from 14.03.2000 on the company case 1096/2000 of the Varna District Court as a joint stock company. The duration of the Company is not limited in time.

#### **Country of Company registration, headquarters and address pursuant to the Statute; legal form; legislation under which the Company operates**

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

The Company was incorporated in the Republic of Bulgaria.

The headquarters and registered office of the Company:

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

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

Telephone: (359 2) 960 3634

Internet site: [www.tchaikapharma.com](http://www.tchaikapharma.com)

#### **Important events in the development of the business of the Company**

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

- Tchaikapharma High Quality Medicines Inc. was not transformed.
- Tchaikapharma High Quality Medicines Inc. was not transferred or pledged.
- There were no significant changes in the scope of activity of Tchaikapharma High Quality Medicines Inc.
- There were no filed claims for opening of insolvency proceedings.
- By Decision of the General Meeting of 26.08.2014 the capital was increased by BGN 32 000 000 to BGN 43 500 000, by issuing 11 500 000 (eleven million five hundred thousand) new ordinary shares with a nominal value of BGN 1 (one). The capital increase was carried out by capitalization of profits pursuant to Art. 197 of the Commerce Act.
- By Decision of the General Meeting of 20.04.2015 the capital was increased from BGN 43 500 000 to BGN 49 600 000, by issuing 6 100 000 (six million and one hundred thousand) new ordinary shares with a nominal value of BGN 1 (one). The capital increase was carried out by capitalization of profits pursuant to Art. 197 of the Commerce Act.
- By Decision of the General Meeting of 23.06.2016 the capital was increased from BGN 49 600 000 to BGN 56 600 000, by issuing 7 000 000 (seven million) new ordinary shares with a nominal value of BGN 1 (one). The increase of the capital was done by capitalization of profits pursuant to Art. 197 of the Commercial Code. The capital increase was entered in the Commercial Register of 19.07.2016
- The capital of the Company became BGN 56 600 000 distributed in 56 600 000 ordinary dematerialized voting shares with a par value of BGN 1 (one) each.
- By Decision of the General Meeting of 08.06.2017 the capital was increased from BGN 56 600 000 to BGN 64 300 000 by issuing 7 700 000 (seven million and seven hundred thousand) new ordinary dematerialized shares with a nominal value of BGN 1 (one). The increase of the capital was done by capitalization of profits pursuant to Art. 197 of the Commercial Code. The capital increase was entered in the Commercial Register on 05.07.2017.

Tchaikapharma High Quality Medicines Inc. is one of the fastest growing Bulgarian company specialized in manufacturing high quality and affordable generic and original medicines. The production facilities of the company are built in accordance with European requirements. The company is focused of quality and safety of the production of medicinal products for human medicine. In the years in which the company has been on the market it has proved its honesty and patient care. In the second quarter of 2017 Tchaikapharma continued to update its product range, which at this stage is over 150 medicinal products. Its main goal is the renewal of current trends in the worldwide drug therapy. The main priority for the company are medicinal products for the treatment of diabetes, diseases of the central nervous system, cancers and it is mainly focused on medications associated with the treatment of cardiovascular diseases.

## Investments

## Major investments for each of the following financial years: 2014, 2015 and 2016.

Overview of the investments in fixed assets by type and year is presented in the following table.

Investments for the period	2014	2015	2016
<b>Tchaikapharma High Quality Medicines Inc.</b>			
I. Fixed tangible assets	199	2 906	1 331
1. Plant, property and equipment	196	2 782	1 312
2. Other fixed assets	3	124	19
II. Fixed 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 amount of acquisition of fixed tangible and 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 second quarter of 2017 are the system of serialization and tamper evidence with which we meet the requirements of the European **Directive 2011/62/EU**. From 9.02.2019 every package of a medicinal product can be marketed within the EU with unique coding and tamper evidence. The system will be implemented in cooperation with SoftGroup AD and for installation are planned 5 machines for printing and verification of 2D matrix code (with the unique code of the box) tamper evidence system in each cartoning machine, server: central and local, software for generating individual codes, storing and sending them to the European hub.

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

### Economic activity

The entered in the Commercial Register activity of the Company is: purchase of substances and formulations for the production and sale of pharmaceuticals in finished or processed form, (after Marketing Authorisation); primary and secondary packaging of formulations (after Marketing Authorisation); import, export, re-export and merchandising in original or processed form; barter transactions and commissions; commercial representation of foreign and domestic individuals and legal entities at home 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 third quarter of 2017 Tchaikapharma continued to be one of the leading pharmaceutical companies in Bulgaria, which continued to add new products to its diverse portfolio.

During this period the registration dossier for a medicinal product with INN Pioglitazone/Metformin was also prepared under the trade name Pizona Combi.

Audits of new dossiers to be submitted for registration both in Europe and targeted only to the Bulgarian market were carried.

Tchaikapharma High Quality Medicines Inc. has continuously maintained its production facilities in accordance with the contemporary European requirements for Good Manufacturing Practice 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, Module 4 and Module 5 have been developed and will be part of the dossier of the medicinal product with INN Irbesartan, which is owned by Tchaikapharma High Quality Medicines Inc. The preparation of the dossier modules of a medicinal product with INN Ceftriaxone is currently under way. 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 are under preparation.

The development and validation of methods for investigation of the concentration of drug substances in human plasma is a major task of the bioanalytical laboratory. An important part of the work of the laboratory is the creation of standard operating procedures to ensure the quality of the work and the reliability of the results. Based on the quality system under

construction in the bio-analytical laboratory, it will also be possible to initiate a Good laboratory practice (GLP) compliance procedure.

## Employees

As of 30.09.2017 the average number of employees in Tchaikapharma High Quality Medicines Inc. was 138 (126 as of 31.12.2016). In the table below detailed information about the employees in the company is provided.

	<b>30.09.2017</b>	<b>Share</b>
<b>Number of employees as of 30.09.2017</b>	<b>138</b>	<b>100%</b>
Higher education	78	56%
Secondary education	59	43%
Primary education	1	1%
Employees under 30 years	38	28%
Employees 31 - 40 years	53	38%
Employees 41 - 50 years.	32	23%
Employees 51 - 60 years.	9	7%
Employees 60+ years	6	4%
Women	54	39%
Men	84	61%

## Significant events since the beginning of the year until 30.09.2017

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

## Key financial indicators

<b>Indicators</b>	<b>01-09/2017</b>	<b>01-09/2016</b>	<b>change</b>
	<b>BGN '000</b>	<b>BGN '000</b>	<b>%</b>
Sales revenue	25 960	24 590	5.57%
Earnings before interest, taxes and depreciation (EBITDA)	8 691	10 359	-16.10%
Net profit	5 617	6 781	-17.17%

	<b>01-09/2017</b>	<b>01-12/2016</b>	<b>change</b>
	<i>BGN '000</i>	<i>BGN '000</i>	<b>%</b>
Non-current assets	35 603	35 558	0.13%
Current assets	58 267	55 529	4.93%
Equity	78 612	72 995	7.69%
Non-current liabilities	2 049	2 366	-13.40%
Current liabilities	13 209	15 726	-16.01%

	<b>01-09/2017</b>	<b>01-09/2016</b>
EBITDA/Sales revenue	34%	42%
Net profit/Sales revenue	22%	27%

## Review of the risk factors

- The Company's activities could be affected by any change in the regulatory requirements for the production of pharmaceutical products.
- Changes to the legislation regulating the Company's business are possible, and these can potentially increase the costs of compliance or have another effect on its operations.
- The production processes of the Company are subject to stringent requirements and approvals by regulatory authorities which may delay or 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 conditions and is exposed to potential liabilities related to the environment.
- The Company is exposed to strong competition.

The Company operates in active exchange with foreign suppliers and customers. It is therefore exposed to currency risk, mainly against the US dollar. Currency risk is related to the adverse movement in the exchange rate of the US dollar against the Bulgarian lev in future business operations, recognized foreign currency assets and liabilities. The rest of the company's operations are usually denominated in Bulgarian lev and/or in euros.

## Sales by types of dosage forms

<b>Revenue by dosage forms</b>	<b>01-09/2017</b>	<b>01-09/2016</b>
	<i>BGN '000</i>	<i>BGN '000</i>
Tablets	21 663	21 772
Ampules	1 327	998
Vials	2 876	1 739
<b>Total:</b>	<b>25 866</b>	<b>24 509</b>

<b>Revenue by therapeutic groups</b>	<b>01-09/2017</b>	<b>01-09/2016</b>
	<i>BGN '000</i>	<i>BGN '000</i>
Cardiovascular system	20 413	19 836
Musculoskeletal system and connective tissue	72	213
Respiratory system and antibiotics	2 543	1 732
Nervous system	788	812
Endocrine system	860	609
Other products	449	778
Digestive system and metabolism	528	221
Oncology	213	306
<b>Total:</b>	<b>25 866</b>	<b>24 509</b>

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

**246**

**302**

<b>Other operating income</b>	<b>01-09/2017</b>	<b>01-09/2016</b>
	<i>BGN '000</i>	<i>BGN '000</i>
<b>Income from rent</b>	32	39
<b>Other income</b>	62	42
<b>Total:</b>	<b>94</b>	<b>81</b>

<b>Financial income</b>	<b>01-09/2017</b>	<b>01-09/2016</b>
	<i>BGN '000</i>	<i>BGN '000</i>
Income from interest	-	138
Income from exchange rate differences	84	38
Other financial income	-	-
<b>Total:</b>	<b>84</b>	<b>176</b>

## Core activity expenses



<b>Operating expenses</b>	<b>01-09/2017</b>	<b>01-09/2016</b>
	<i>BGN '000</i>	<i>BGN '000</i>
Book value of sold products	1 465	3 120
Materials	6 957	5 854
External services	5 841	2 769
Salaries	2 059	1 912
Social security costs	420	370
Depreciation costs	2 294	2 655
Other	795	452
<b>Total:</b>	<b>19 831</b>	<b>17 132</b>

<b>Cost of materials</b>	<b>01-09/2017</b>	<b>01-09/2016</b>
	<i>BGN '000</i>	<i>BGN '000</i>
Basic material	6 298	5 403
Electricity	297	235
Fuels and lubricants	46	25
Spare parts and laboratory materials	131	168
Water	13	8
Other materials	172	15
<b>Total:</b>	<b>6 957</b>	<b>5 854</b>

<b>Costs of external services</b>	<b>01-09/2017</b>	<b>01-09/2016</b>
	<i>BGN '000</i>	<i>BGN '000</i>
Rents	157	129
Security	159	62
Insurance	24	47
Telephone and postage expenses	22	28
Equipment maintenance and subscription	45	9
Fees	79	41
Transport costs	37	31
Other costs for external services	5 318	2 422
<b>Total:</b>	<b>5 841</b>	<b>2 769</b>

<b>Financial expenses</b>	<b>01-09/2017</b>	<b>01-09/2016</b>
	<i>BGN '000</i>	<i>BGN '000</i>
Interest expenses	206	307
Expenses from exchange rate differences	31	45
Other financial expenses	31	49
<b>Total:</b>	<b>268</b>	<b>401</b>

## Assets

	01-09/2017	01-12/2016
	<i>BGN '000</i>	<i>BGN '000</i>
<b>Non-current assets</b>		
Property, plant and equipment	26 072	25 888
Intangible assets	3 450	3 644
Investments with minority interest	1	1
Trade receivables	6 080	6 025
<b>Total non-current assets</b>	<b>35 603</b>	<b>35 558</b>

	01-09/2017	01-12/2016
	<i>BGN '000</i>	<i>BGN '000</i>
<b>Current assets</b>		
Inventories	5 561	5 082
Trade and other receivables	52 653	50 373
Financial assets with maturity		24
Current corporate tax	8	
Cash and cash equivalents	45	50
<b>Total current assets</b>	<b>58 267</b>	<b>55 529</b>
<b>Total Assets</b>	<b>93 870</b>	<b>91 087</b>

	01-09/2017	01-12/2016
	<i>BGN '000</i>	<i>BGN '000</i>
<b>Property, plant and equipment</b>		
Land and buildings	11 245	11 568
Machinery and equipment	12 997	13 988
Other	208	261
In the process of acquisition	1 622	71
	<b>26 072</b>	<b>25 888</b>

	01-09/2017	01-12/2016
	<i>BGN '000</i>	<i>BGN '000</i>
<b>Inventories</b>		
Materials	4 791	4 629
Production	439	138
Goods	264	192
Work in progress	67	123
<b>Total:</b>	<b>5 561</b>	<b>5 082</b>

## Equity and liabilities

	01-09/2017	01-12/2016
	<i>BGN '000</i>	<i>BGN '000</i>
Registered capital	64 300	56 600
Statutory reserve	8 695	7 810
Undistributed profit	5 617	8 585
<b>Total Equity</b>	<b>78 612</b>	<b>72 995</b>

## Liabilities

	01-09/2017	01-12/2016
	<i>BGN '000</i>	<i>BGN '000</i>
<b>Non-current liabilities</b>		

Long-term loans	698	1 015
Deferred tax liabilities	1 284	1 284
Liabilities to employees on retirement	67	67
<b>Total non-current liabilities</b>	<b>2 049</b>	<b>2 366</b>
<b>Current liabilities</b>		
Trade and other liabilities	2 752	2 909
Short term loans	9 777	11 349
Current part of long-term loans	571	869
Current corporate income tax		55
Other tax liabilities	109	544
<b>Total current liabilities</b>	<b>13 209</b>	<b>15 726</b>
<b>Total liabilities</b>	<b>15 258</b>	<b>18 092</b>
<b>Total equity and liabilities</b>	<b>93 870</b>	<b>91 087</b>

## Financial indicators

	01-09/2017	01-12/2016
Debt ratio	0.19	0.27
Financial autonomy ratio	5.15	3.73

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

The total amount of shares issued as of 30.09.2017 was 64 300 000 with a nominal value of BGN 1 per share. All issued shares are registered, dematerialized, ordinary and indivisible under the Statute of the Company. All issued shares are of the same type. Each share gives equal rights to its owner in proportion to the nominal value of the share. The shares of Tchaikapharma High Quality Medicines Inc. are traded on the official market of the Bulgarian Stock Exchange-Sofia.

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

	1-09/2017	1-09/2016
Total number of issued shares	64 300 000	56 600 000
Number of shares in circulation at end of period	64 300 000	56 600 000
Price per share at the end of the period in BGN	7.66	6.42
Market capitalization at the end of the period in BGN	492 538 000	363 372 000

Biser Georgiev

/Executive Director/