# **ACTIVITY REPORT**

For the first quarter of 2019



TCHAIKAPHARMA HIGH QUALITY MEDICINES INC. 23.04.2019

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 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 3714

Internet site: 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 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
- 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) 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 11.07.2017
- By Decision of the General Meeting of 30.04.2018 the capital was increased from BGN 64 300 000 to BGN 72 200 000, by issuing 7 900 000 (seven million and nine hundred) 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 29.05.2018
- The current capital of the Company is BGN 72 200 000 distributed in 72 200 000 ordinary dematerialized voting shares with a par value of BGN 1 (one) each.

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 first quarter of 2019 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: 2016, 2017 and 2018.

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

Investments for the period	2016	2017	2018
Tchaikapharma High Quality Medicines Inc.			
I. Fixed tangible assets	1 331	2 762	924
1. Plant, property and equipment	1 312	2 760	924
2. Other fixed assets	19	2	
II. Fixed intangible assets	547	743	274
Industrial property rights	495	726	274
2. Software	9	4	
3. Patents and licenses	43	43	
Total amount of acquisition of fixed tangible and intangible assets	1 878	3 505	1 198

#### Major investments in progress

In the first quarter of 2019 there were no major investments.

### **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 first quarter of 2019 the preparation of one of the company's own dossiers for the medicinal product Ceftriaxon-Tchaikapharma 2 g powder for injection/infusion solution was completed, which will add to the list of injectable antibiotics of the company.

Tchaikapharma High Quality Medicines Inc. continuously maintains production facilities in accordance with the modern European standards of Good Manufacturing Practice of pharmaceuticals. Currently the factories of the company produce more than 150 medicinal products. The premises and equipment of the plant are in full compliance with the European requirements for manufacturing of sterile medicinal products.

The clinical study report BE-17001 with the product INN Irbesartan/Hydrochlorothiazide and a CoAprovel reference has been completed, which will become part of the Irbesartan/Hydrochlorothiazide INN dossier. The Modules 2.4, 2.5, 2.6, 2.7, Module 4 and Module 5 of the respective dossier, which will be property of Tchaikapharma High Quality Medicines Inc., are currently being prepared.

Pharmacoeconomic analyses have been prepared for the product pricing procedure of Amarhyton (flecainide), Pizona Combi (pioglitazone/metformin) and Bilamcar (candesartan/amlodipine). The renewal procedure for Amarhyton (flecainide) has been completed; the procedure for obtaining a price for Pizona Combi (pioglitazone/metformin) is at the final stage and the Bilamcar (candesartan/amlodipine) documents are due to be submitted.

A quality system has been developed for the Bioanalytical Laboratory of Tchaikapharma High Quality Medicines Inc. An audit is about to be scheduled to verify the compliance with the principles of Good Laboratory Practice by the laboratory. The report from this audit is a prerequisite for launching a GLP compliance procedure with the Bulgarian Accreditation Service.

#### **Employees**

As of 31.03.2019 the average number of employees in Tchaikapharma High Quality Medicines Inc. was 133 (133 as of 31.12.2018). In the table below detailed information about the employees in the company is provided

	31.03.2019	Share
Number of employees as of 31.03.2019	133	100%
Higher education	79	59%

Secondary education	53	40%
Primary education	1	1%
Employees under 30 years	38	29%
Employees 31 - 40 years	54	41%
Employees 41 - 50 years.	30	23%
Employees 51 - 60 years.	8	6%
Employees 60+ years	3	2%
Women	59	44%
Men	74	56%

# Significant events since the beginning of the year until 31.03.2019

In the first quarter of 2019 there were no significant events.

# **Key financial indicators**

Indicators	01-03/2019	01-03/2018	Change
	BGN '000	BGN '000	%
Sales revenue	9 332	9 164	1.83%
Earnings before interest, taxes and depreciation (EBITDA)	4 337	4 207	3.10%
Net profit	3 153	3 023	4.30%

	01-03/2019	01-12/2018	Change
	BGN '000	BGN '000	%
Non-current assets	33 178	33 594	-1.24%
Current assets	65 754	77 445	3.25%
Equity	97 153	94 000	3.35%
Non-current liabilities	1 531	1 563	-2.05%
Current liabilities	14 459	15 476	-6.57%

	01-03/2019	01-03/2018
EBITDA/Sales revenue	47%	46%
Net profit/Sales revenue	34%	33%

# 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

Revenue by dosage forms	01-03/2019	01-03/2018
	BGN '000	BGN '000
Tablets	8 555	7 809
Ampules	=	189
Vials	769	1 153
Total:	9 324	9 151

Revenue by therapeutic groups	01-03/2019 BGN '000	01-03/2018 BGN '000
Cardiovascular system	7 573	6 680
Musculoskeletal system and connective tissue	33	30
Respiratory system and antibiotics	710	1 085
Nervous system	241	394
Endocrine system	767	357
Other products	- ·	196
Digestive system and metabolism	-	300
Oncology	_	109

Total:	9 324	9 151
Changes in the inventories of products and work in progress	-454	-124
Other operating income	01-03/2019 BGN '000	01-03/2018 BGN '000
Income from rent	8	12
Other income	-	1
Total:	8	13
Financial income	01-03/2019 BGN '000	
Income from interest		
Income from exchange rate differences	2	4
Other financial income		1
Total:	2	5

# Core activity expenses

Operating expenses	01-03/2019	01-03/2018
	BGN '000	BGN '000
Book value of sold products	35	534
Materials	2 750	2 677
External services	1 307	908
Salaries	836	733
Social security costs	154	137
Depreciation costs	944	879
Other	335	82
Total:	6 361	5 950

Cost of materials	01-03/2019 BGN '000	
Basic material	2 433	2 453
Electricity	97	75
Fuels and lubricants	14	13
Spare parts and laboratory materials	32	41
Water	6	4
Other materials	168	91
Total:	2 750	2 677

Costs of external services	01-03/2019 BGN '000	
Rents	57	59
Security	65	53
Insurance	7	7
Telephone and postage expenses	8	7
Equipment maintenance and subscription	21	51
Fees	47	4
Transport costs	15	4
Other costs for external services	1 087	724
Total:	1 307	908

Financial expenses	01-03/2019	01-03/2018
	BGN '000	BGN '000
Interest expenses	56	59
Expenses from exchange rate differences	23	7
Other financial expenses	11	8
Total:	90	74

## Assets

Assets	01-03/2019	01-12/2018
Non-current assets	BGN '000	BGN '000
Property, plant and equipment	24 757	25 754
Intangible assets	3 452	2 871
Investments with minority interest	. 1	1.
Trade receivables	4 968	5 960
Total non-current assets	33 178	33 594
Current assets		
Inventories	6 179	5 491
Trade and other receivables	73 432	71 608
Treasury shares redeemed	_	92
Current corporate income tax	4	4
Cash and cash equivalents	350	250
Total current assets	79 965	77 445
Total Assets	113 143	111 039

	01-03/2019 BGN '000	01-12/2018 BGN '000
Property, plant and equipment	11 720	11 830
Land and buildings  Machinery and againment	11 145	11 759
Machinery and equipment Other	1 868	123
	24	2 042
In the process of acquisition	24 757	25 754
	24 /3/	23 134
Inventories	01-03/2019	01-12/2018
Inventories	BGN '000	BGN '000
Materials	5 033	5 065
Production	243	219
Goods	362	40
Work in progress	541	167
Total:	6 179	5 491
Equity and liabilities		
	01-03/2019	01-12/2018
	BGN '000	BGN '000
Registered capital	72 200	72 200
Statutory reserve	10 601	10 601
Undistributed profit	14352	11 199
Total Equity	97 153	94 000
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Liabilities	01-03/2019	01-12/2018
Non-current liabilities	BGN '000	BGN '000
Long-term loans	148	180
Deferred tax liabilities	1 264	1 264
Liabilities to employees on retirement	119	119
Total non-current liabilities	1 531	1 563
Current liabilities		
Trade and other liabilities	4 022	4 186
Short term loans	9 786	9 785
Current part of long-term loans	329	409
Current corporate income tax		217
Other tax liabilities	322	879
Total current liabilities	14 459	15 476
Total liabilities	15 990	17 039
Total equity and liabilities	113 143	111 039

### **Financial indicators**

01-03/2019 01-12/2018

Debt ratio

Financial autonomy ratio

0.16	0.18
6.08	5.52

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

The total amount of shares issued as of 31.03.2019 was 72 200 000 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.

	1-03/2019	1-03/2018
Total number of issued shares	72 200 000	64 300 000
Number of shares in circulation at end of period	72 200 000	64 300 000
Price per share at the end of the period in BGN	9.50	8.30
Market capitalization at the end of the period in BGN	685 900 000	533 690 000

Biser Georgie

/Executive Director/