

ACTIVITY REPORT

For the fourth quarter
of 2020



TCHAIKAPHARMA
HIGH QUALITY MEDICINES

TCHAIKAPHARMA HIGH QUALITY MEDICINES INC.

25.01.2021

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 3724

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 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.
- By Decision of the General Meeting of 08.04.2019 the capital was increased from BGN 72 200 000 to BGN 82 200 000, by issuing 10 000 000 (ten 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 10.05.2019.
- By Decision of the General Meeting of 22.06.2020 the capital was increased from BGN 82 200 000 to BGN 84 500 000, by issuing 2 300 000 (two million and three hundred) new ordinary shares with a nominal value of BGN 1 (one). The increase of the capital has not yet been entered in the Commercial Register, and therefore is not reflected in current reports.
- The current capital of the Company is BGN 82 200 000 distributed in 82 200 000 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 fourth quarter of 2020 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: 2018, 2019 and 2020.

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

Investments for the period	2018	2019	2020
Tchaikapharma High Quality Medicines Inc.			
I. Fixed tangible assets	924	2 715	13 861
1. Land and buildings	924	2 617	13 042
2. Property and equipment			667
3. Other fixed assets		98	152
II. Fixed intangible assets	274	661	1 152
1. Industrial property rights	274	637	919
2. Software		10	9
3. Patents and licenses		14	224
Total amount of acquisition of fixed tangible and intangible assets	1 198	3 376	15 013

Major investments in progress

The activities for expansion of the tablet workshop in Tchaikapharma Plovdiv continue. New equipment for granulation-mixer-granulator, vortex dryer and regranulator is installed. Qualification of the equipment and training of the staff has been performed. Qualification of the premises and Change in the production permit are forthcoming. Construction of additional warehouses for format parts is pending.

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

Tchaikapharma High Quality Medicines Inc. continuously maintains its production facilities in accordance with the contemporary European requirements for Good Manufacturing Practice in the production of medicines. At present, more than 150 medicinal products are produced in the company's factories. The premises and the equipment of the factories are executed in full compliance with the European requirements for the production of medicines and for the plant in Varna – also for sterile medicinal products.

Applications have been submitted for obtaining a MA for new products:
Rivaroxaban-Tchaikapharma 10 mg, 15 mg, 20 mg film-coated tablets - IAL-41997-98-99-09.10.2020;
Ramipril/Amlodipine/Hydrochlorothiazide-Tchaikapharma 5 mg/5 mg/12.5 mg; 5 mg/5 mg/25 mg; 10 mg/5 mg/25 mg - IAL-51717-19-21 / 27.11.2020.

4 variations in the MA for Bulgaria of products were submitted and 10 variations were allowed during this period.

The MA of 6 Dexketoprofen-Tchaikapharma 50 mg / 2 ml sol for inj products was renewed or conc. for sol./inf - Ren. - BG/MA/MP-51814/02.10.2020; Pretimectal 35 mg modified-release tablets - Ren. - BG/MA/MP-51848/05.10.2020; Aroba 100 mg tablets - Ren.- BG/MA/MP-52343/06.11.2020; Coolsart 20mg/12.5mg; 40mg/12.5mg film-coated tablets - Ren. - BG/MA/MP-52344-41/06.11.2020; Remifentanil-Tchaikapharma 5 mg powder for conc. for sol. for injection / infusion - Ren. - BG/MA/MP-52345/06.11.2020; Aripipa 15 mg tablets - Ren. - BG/MA/MP-52347/09.11.2020

A new submission - MoriVid 200 mg film-coated tablets are being prepared for Kosovo (CPP for MA - IAL-52187/30.11.2020).

Modules 2.5, 2.7 and module 5 of the dossier of the medicinal product Cefotaxime have been prepared, which will be owned by Tchaikapharma High Quality Medicines AD. Modules 2.4, 2.5, 2.6, 2.7, module 4 and module 5 of the dossier of the medicinal product Cefepime, as well as 2.4 and 2.6, module 4 of Cefotaxime are in preparation.

An article was published in an international journal reviewing the relationship between hydroxychloroquine use and KOVID-19 mortality.

The dossier of a medicinal product: fixed dose combination Vildagliptin / Metformin was evaluated.

A brochure of the researcher for clinical trial of hydroxychloroquine for prophylaxis of KOVID-19 has been prepared, sponsored by Tchaikapharma High Quality Medicines AD.

For a clinical trial for the bioequivalence of chlorthalidone, the following have been prepared:

- Researcher's brochure
- Protocol of the clinical trial with the participation of Statistics (draft version)
- Summary of ongoing clinical trials with INN Chlorthalidone
- An EudraCT number has been obtained from the European database for the above study

The full validation of chlorthalidone and olmesartan has been completed in the bioanalytical laboratory. A preliminary on-site inspection to verify compliance with GLP by the Bulgarian Accreditation Service was successfully completed. All discrepancies identified by the Bulgarian Accreditation Service after the inspection have been eliminated.

Employees

As of 31.12.2020 the average number of employees in Tchaikapharma High Quality Medicines Inc. was 147 (146 as of 31.12.2019). In the table below detailed information about the employees in the company is provided

	31.12.2020	Share
Number of employees as of 31.12.2020	147	100%
Higher education	92	62%
Secondary education	54	37%
Primary education	1	1%
Employees under 30 years	45	31%
Employees 31 - 40 years	55	37%
Employees 41 - 50 years.	39	27%
Employees 51 - 60 years.	5	3%
Employees 60+ years	3	2%
Women	68	46%
Men	79	54%

Significant events since the beginning of the year until 31.12.2020

In the fourth quarter of 2020 there were no significant events.

Key financial indicators

Indicators	01-12/2020	01-12/2019	Change
	BGN '000	BGN '000	%
Sales revenue	39 747	34 443	15.40%
Earnings before interest, taxes and depreciation (EBITDA)	5 018	6 702	-25.13%
Net profit	344	2 568	-86.62%

	01-12/2020 <i>BGN '000</i>	01-12/2019 <i>BGN '000</i>	Change %
Non-current assets	46 142	35 056	31.62%
Current assets	70 578	82 824	-14.78%
Equity	96 887	96 543	0.36%
Non-current liabilities	3 129	3 504	-10.70%
Current liabilities	16 704	17 833	-6.33%

	01-12/2020	01-12/2019
EBITDA/Sales revenue	13%	19%
Net profit/Sales revenue	1%	7%

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	01-12/2020 <i>BGN '000</i>	01-12/2019 <i>BGN '000</i>
Tablets	30 641	30 951
Ampules	876	304
Vials	8 163	3 137
Total:	39 680	34 392

Revenue by therapeutic groups	01-12/2020 <i>BGN '000</i>	01-12/2019 <i>BGN '000</i>
Cardiovascular system	27 178	26 149
Musculoskeletal system and connective tissue	59	92
Respiratory system and antibiotics	4 420	2 810
Nervous system	1 166	1 573
Endocrine system	3 227	2 748
Other products	2 448	628
Digestive system and metabolism	980	197
Oncology	203	195
Total:	39 680	34 392

Changes in the inventories of products and work in progress	(784)	1 734
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Other operating income	01-12/2020 <i>BGN '000</i>	01-12/2019 <i>BGN '000</i>
Income from rent	26	38
Other income	324	294
Total:	350	332

Financial income	01-12/2020 <i>BGN '000</i>	01-12/2019 <i>BGN '000</i>
Income from interest	505	344
Income from exchange rate differences	68	40
Other financial income	-	1
Total:	574	385

Core activity expenses

Operating expenses	01-12/2020	01-12/2019
	<i>BGN '000</i>	<i>BGN '000</i>
Book value of sold products	817	748
Materials	14 317	12 017
External services	14 083	12 061
Salaries	4 034	3 683
Social security costs	742	676
Depreciation costs	4 231	3 526
Other	658	803

Total: 38 883 33 514

Cost of materials 01-12/2020 01-12/2019
BGN '000 BGN '000

Basic material	13 248	10 841
Electricity	420	501
Fuels and lubricants	34	59
Spare parts and laboratory materials	187	95
Water	21	20
Other materials	407	501

Total: 14 317 12 017

Costs of external services 01-12/2020 01-12/2019
BGN '000 BGN '000

Rents	-	6
Security	385	355
Insurance	28	23
Telephone and postage expenses	26	29
Equipment maintenance and subscription	199	117
Fees	271	166
Transport costs	64	57
Other costs for external services	13 110	11 308

Total: 14 083 12 061

Financial expenses 01-12/2020 01-12/2019
BGN '000 BGN '000

Interest expenses	233	224
Expenses from exchange rate differences	-	-
Investments with minority interest	98	83
Other financial expenses	53	59

Total: 384 366

Assets

	01-12/2020	01-12/2019
	<i>BGN '000</i>	<i>BGN '000</i>
Non-current assets		
Property, plant and equipment	37 729	26 981
Intangible assets	3 254	2 725
Investments with minority interest	210	420
Trade receivables	4 949	4 930
Total non-current assets	46 142	35 056
Current assets		
Inventories	10 525	8 763
Trade and other receivables	60 006	74 020
Treasury shares redeemed	-	-
Current corporate income tax	1	1
Cash and cash equivalents	46	40
Total current assets	70 578	82 824
Total Assets	116 720	117 880

	01-12/2020	01-12/2019
	<i>BGN '000</i>	<i>BGN '000</i>
Property, plant and equipment		
Land and buildings	23 985	11 390
Machinery and equipment	9 503	11 971
Other	272	164
In the process of acquisition	3 969	3 456
	37 729	26 981

	01-12/2020	01-12/2019
	<i>BGN '000</i>	<i>BGN '000</i>
Inventories		
Materials	8 982	6 473
Production	639	891
Goods	294	250
Work in progress	610	1 149
Total:	10 525	8 763

Equity and liabilities

	01-12/2020	01-12/2019
	<i>BGN '000</i>	<i>BGN '000</i>
Registered capital	82 200	82 200
Statutory reserve	11 775	11 775
Undistributed profit	2 912	2 568
Total Equity	96 887	96 543

Liabilities	01-12/2020	01-12/2019
	BGN '000	BGN '000
Non-current liabilities		
Long-term loans	1 662	2 037
Deferred tax liabilities	1 308	1 308
Liabilities to employees on retirement	159	159
Total non-current liabilities	3 129	3 504
Current liabilities		
Trade and other liabilities	6 165	7 095
Short term loans	9 783	9 784
Current part of long-term loans	610	616
Current corporate income tax		142
Other tax liabilities	146	196
Total current liabilities	16 704	17 833
Total liabilities	19 833	21 337
Total equity and liabilities	116 720	117 880

Financial indicators

	01-12/2020	01-12/2019
Debt ratio	0.20	0.22
Financial autonomy ratio	4.89	4.52

Information on the shares of Tchaikapharma High Quality Medicines Inc.

The total amount of shares issued as of 31.12.2020 was 82 200 000 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.

	1-12/2020	1-12/2019
Total number of issued shares	82 200 000	82 200 000
Number of shares in circulation at end of period	82 200 000	82 200 000
Price per share at the end of the period in BGN	13.50	10.90
Market capitalization at the end of the period in BGN	1 109 700 000	895 980 000

Biser Georgiev 
/Executive Director/