CELON PHARMA

Half-year report

of Celon Pharma S.A. for 1H2021

The Management Board's report on operations of Celon Pharma S.A. in 1H2022

Kiełpin, September 30, 2021

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1. Selected financial data, presented also in EUR, consisting of essential items from the half-year financial statements for 1H2021 and 1H2020, and in the case of the balance sheet – as at the end of the current financial year and as at the end of the previous financial year.

SELECTED FINANCIAL DATA	thousand PLN		thousand EUR	
	01/01-06/30/2021	01/01-06/30/2020	01/01-06/30/2021	01/01-06/30/2020
Net sales revenues	105,096	77,091	23,112	17,358
Sales profit	2,533	1,234	557	278
Operating profit	1,910	1,765	420	397
Gross profit	126	1,094	28	246
Net profit	302	982	66	221
Net cash flow from operating activities	-1,141	13,932	-251	3,137
Net cash flow from investing activities	-14,831	-14,650	-3,262	- 3,299
Net cash flow from financial activities	-3,002	-3,651	-660	-822
Total net cash flows	-18,974	-4,370	-4,173	-984
	06/30/2021	**12/31/2020**	**06/30/2021**	**12/31/2020**
Total assets	537,552	531,888	118,906	115,257
Liabilities and provisions for liabilities	171,221	187,356	37,874	40,599
Long-term liabilities	70,430	73,210	15,579	15,864
Short-term liabilities	100,791	114,145	22,295	24,735
Equity	366,331	344,532	81,032	74,658
Share capital	4,500,000	4,500,000	996	975
Number of shares (pcs.)	45,000,000	45,000,000	45,000,000	45,000,000
Net profit per one share in PLN	0.01	0.02	0.00	0.00
Book value per one share in PLN	8.14	7.66	1.80	1.66

The selected balance sheet items expressed in EUR have been calculated in accordance with the average EUR exchange rates announced by the National Bank of Poland on June 30, 2021 (PLN 4.5208/EUR) and on December 31, 2020 (PLN 4.6148/EUR). The selected items of the profit and loss account and the cash flow statement were calculated into EUR in accordance with the exchange rate announced by the National Bank of Poland which constitutes the arithmetic mean of the average exchange rates of EUR applicable on the last day of each ended month within the 6-month period ended June 30, 2021 and the 6-month period ended June 30, 2020 (PLN 4.5472/EUR and PLN 4.4413/EUR, respectively).

2. Comment on the Company's financial performance in 1H2021

In 1H2021, the Company continued to implement its global expansion strategy for Salmex. The total net sales revenues compared to 1H2020 results have increased by over PLN 28 m and amounted to over PLN 105 m.

The drug sales in the period in question increased by over 45% i.e., from PLN 63.3 m to PLN 91.8 m. This is the first period in the Company's history where export sales have a greater share in its total sales; it was an over twofold increase. The domestic drug sales result was slightly lower, i.e., by 11%. This was caused by reduced growth dynamics observed for the overall domestic drug market and one-off impact on sales growth in 1H20 caused by various sales channels stocking up in fear of the pandemic. No significant changed dynamics have been observed for our products' domestic market shares in 1H2021. Additionally, in 1H2020 the Company reported a significant one-off sale of license rights for the amount of PLN 6.4 m.

Revenues from grants in 1H2021 increased by PLN 11.5 m, which represents an over 50% increase compared to the same period in 2020. In line with the Company's strategy, investments in research and development of new drugs were continued, which is reflected in the increase of costs by type in the R&D segment from PLN 28.5 m to PLN 33.6 m.

The income statement indicates that the profit from sales in the analyzed period increased from PLN 1.2 m to PLN 2.5 m. It should be underlined that the profitability of domestic sales of finished products is greater than export sales, hence the disproportionate increase of profit resulting from the fact that the Company's sales growth is driven by export sales. Additionally, this lack of proportionality was affected by the one-off sale of license rights for the amount of PLN 6.4 m, which took place in 1H20, as well as the fact that the 1H21 financial result was burdened with provisions for disposal costs amounting to PLN 1.9 m and market withdrawal costs amounting to PLN 0.5 m caused by the Company's decisions not to sell certain batches of Valzek. The Management Board is of the opinion that the swift withdrawal of the product from the market and simultaneous launching of the manufacturing process for new batches which meet current qualitative requirements will allow the Company to make the product available on the market as early as at the beginning of October 2021.

The growth of revenues in the operating segment by over 45% and the increased number of ongoing innovative projects resulted in a natural increase of the Company's basic operating costs. Costs by type for the (generic) operating segment activity amounted to PLN 69.0 m, which constituted an increase by over 45% compared to 1H2020. The huge investment outlays generate increasing depreciation and amortization costs – over 47%. The increase of the cost of wages and salaries by approx. 30% is associated with increased employment rates, i.e., from 437 to 514 employees, and with the natural increase of individual salaries. Growing costs of raw materials and other materials, fueled mostly by the weakening of the Polish currency and the significant energy cost rise, has also been observed.

3. Information about the Company

3.1. The object of the Company

Celon Pharma Spółka Akcyjna, hereinafter also referred to as the Company, with its registered office in Kiełpin, ul. Ogrodowa 2A, was established on 25 October 2012, as a result of the transformation of the company under the name of Celon Pharma Sp. z o.o. Celon Pharma Sp. z o.o. was entered into the Register of Entrepreneurs in the National Court Register, on 20 June 2002, under KRS number: 117523, and was stricken therefrom by virtue of law, on the date of the company's transformation into a joint-stock company. Celon Pharma S.A. was entered into the Register of Entrepreneurs of the National Court Register on October 25, 2012 under the KRS no.: 0000437778, maintained by the Regional Court in Warsaw, 14th Commercial Division of the National Court Register.

The core activity – manufacture of drugs, PKD 21.20.Z.

Celon Pharma S.A. is CEE's leading integrated biopharmaceutical company. The Company's area of the business activity includes development, manufacture, distribution and marketing of specialized prescription-only generic drugs, as well as the widely understood scope of research and development works related with the projects of innovative drugs that will be able to address the key needs of modern medicine in the future. Celon Pharma S.A. has a diversified portfolio of drug candidates in the four key therapeutic areas – neuropsychiatry, metabolic diseases, oncology and inflammatory diseases. The Company is implementing 15 innovative projects in these areas, 5 of which are in the clinical phase. The Company's most advanced program is the Falkieri program, which concerns the use of esketamine in the treatment of treatment-resistant depression, both unipolar and bipolar affective disorder. The other highly advanced project is the CPL'36 program concerning the use of the PDE10a inhibitor in the treatment of schizophrenia and psychomotor disorders, the CPL'110 program concerning the use of the FGFR inhibitor in the treatment of solid tumors (bladder, lungs, stomach) and the CPL'280 program concerning the use of the GPR40 agonist in the treatment of diabetes and diabetic neuropathies. The advancement of the clinical projects is presented in the table below.

Table 1. Projects in clinical development

INDICATION	MOLECULAR TARGET	RESEARCH PHASE	PRECLINICAL DEVELOPMENT	CLINICAL DEVELOPMENT: PHASE I	CLINICAL DEVELOPMENT: PHASE II
Treatment-resistant depression (MBB/DB)	(unknown) Esketamine	FALKIERI			
Schizophrenia /psychomotor disorders	PDE10a inhibitor	CPL'36			
Solid tumours (bladder, lungs, stomach)	FGFR inhibitor	CPL'110			
Diabetes / diabetic neuropathy	GPR40 antagonist	CPL'280			
Autoimmune diseases	JAK/ROCK inhibitor	CPL'116			

* Idiopathic pulmonary fibrosis (IPF) / Pulmonary arterial hypertension (PAH) / Rheumatoid arthritis (RA) / Psioriasis

Moreover, the Company monitors and responds to the current medial challenges. In its response to the COVID-19 pandemic, the Company has decided to implement two new projects related to research on a drug against COVID-19 and other viral diseases: (1) a project on an innovative antiviral drug in the treatment of COVID-19, influenza infections and (2) a project to reposition CPL'116, i.e. JAK/ROCK dual inhibitor, which is currently in phase I trials conducted on healthy volunteers for the treatment of COVID-19-induced cytokine storm, which is largely dependent on data regarding COVID-19 morbidity.

The Company's R&D model is based on its own fully integrated competencies, starting from the development of the idea for a drug, all the way to its production for the needs of the clinical trials. The Company is developing the innovative projects up to phase II clinical trials in order to obtain a partner for phase III and subsequent licensing the commercialization of the drug. However, the Company does not exclude the possibility of conducting phase III trials and subsequent commercialization independently (full or partial) of the selected projects.

In 2020, the Company opened its new R&D Center in Kazuń, nearby Warsaw, thanks to which the Company's R&D area of increased from 10,000 m2 to 30,000 m2, thus allowing to expand the team of scientists from 160 to 350; the Company expects to reach this number over the next 2-3 years. In the Company's opinion, the investment in one of the largest biopharmaceutical R&D centers in Central and Eastern Europe allows for increasing the Company's capacities in terms of the number of research programs conducted at the same time from 15 currently conducted innovative programs to potentially 30 projects conducted simultaneously.

3.2. Composition of the managerial and supervisory bodies

As at June 30, 2021 and as at the day of this statement, the Management Board of Celon Pharma S.A. is composed of the following persons:

- Maciej Wieczorek – President of the Management Board,
- Jacek Glinka – Vice-President of the Management Board,
- Iwona Giedronowicz – Member of the Management Board.

There have been no changes in the composition of the Management Board during 1H2021 and up to the day of publishing this report.

Composition of the Supervisory Board

As at June 30, 2021 and as at the day of providing this statement, the Supervisory Board of Celon Pharma S.A. is composed of the following persons:

- Robert Rzemiński – Chairman of the Supervisory Board,
- Krzysztof Kaczmarczyk – Member of the Supervisory Board,
- Urszula Wieczorek – Member of the Supervisory Board,
- Bogusław Galewski – Member of the Supervisory Board,
- Artur Wieczorek – Member of the Supervisory Board.

The following changes occurred in the composition of the Company's Supervisory Board during 1H2021 and up to the day of publishing this statement:

On February 11, 2021, Michał Kowalczewski, a Member of the Supervisory Board, notified the Company about his resignation from the Supervisory Board of the Company, with effect from the opening of the Company's next General Meeting on February 16, 2021.

The Extraordinary General Meeting of the Company held on February 16, 2021 appointed Bogusław Galewski as a Member of the Supervisory Board.

The Company announced the aforementioned event in current reports No. 8/2021 dated February 11, 2021, and No. 10/2021 of February 16, 2021.

3.3. The share capital of the Company

As at June 30, 2021, the share capital of Celon Pharma S.A. amounted to PLN 4,500,000.00 and was divided into 45,000,000 shares with a nominal value of PLN 0.10 each, including:

- 15,000,000 A1-series registered shares, privileged as to voting in such a way that each share carries two votes at the General Meeting of the Company,
- 15.000.000 ordinary A2-series bearer shares,
- 15.000.000 ordinary B-series bearer shares,

The total number of votes arising from all shares issued by the Company is 60,000,000.

Changes in the share capital

On February 16, 2021, the Extraordinary General Meeting of Celon Pharma S.A. adopted a resolution No. 4/2021 on amending the Company's Articles of Association and authorizing the Company's Management Board to increase the share capital within the authorized capital with the possibility for the Management Board to exclude the share subscription rights issued within the authorized capital in whole or in part with the consent of the Supervisory Board. Pursuant to the adopted resolution, the Management Board of the Company is authorized to increase the share capital of the Company through issuance of ordinary bearer shares in a number not exceeding 15,000,000 and the total nominal value not exceeding PLN 1,500,000. Under the authorized capital, the Management Board has the right to conduct one or several subsequent increases of the Company's share capital. The Management Board is authorized to determine the number and the issue price of the shares, the terms, deadlines and conditions of conducting the issuance of shares and the manner of suggesting subscription of shares (public offer requiring preparing a prospectus within the meaning of applicable provisions of law or public offer exempt from the obligation to prepare and publish a prospectus). The authorization of the Management Board expires after 3 years since the registration of the amendment of the Company's Articles of Association adopted by the aforementioned resolution passed by the Extraordinary General Meeting in the National Court Register. Adoption of the Extraordinary General Meeting's resolution was motivated by the necessity to create conditions for an efficient increase in the Company's share capital and obtaining the capital at a time convenient for the Company. The obtained financing will allow in particular continued development of drugs from the Company's innovative portfolio, including obtaining the planned milestones in the conducted research programs. Adoption of the resolution will also enable the Company to offer investors to subscribe for shares that will contribute to the development of the Company's activity. Changes to the Company's Articles of Association made using, among others, the aforementioned resolution No. 4/2021 of the Extraordinary General Meeting were registered in the National Court Register on April 12, 2021.

On March 5, 2021, the Management board of the Company adopted a resolution on the issue of not more than 15,000,000 D-series ordinary bearer shares as a part of the intended increase of the Company's share capital, which is referred to above. The resolution of the Company's Management Board was intended to enter into force under the condition of the court registering the amendments of the Company's Articles of Association specified by the aforementioned resolution No. 4/2021 of the Extraordinary General Meeting of the Company, which took place on April 12, 2021. However, on May 10, 2021, the Management Board of the Company decided to repeal the resolution of March 5, 2021 on the issue of shares, which was adopted as a conditional resolution.
On May 5, 2021, the Regional Court for the capital city of Warsaw in Warsaw, 14th Commercial Division of the National Court Register (KRS) made the following entry in Section 8 of the KRS:

- Authorized capital of the Company in the amount of PLN 1,500,000, in relation to the Extraordinary General Meeting's resolution no. 4/2021 adopted on February 16, 2021,
- conditional increase of the share capital in the amount of PLN 200.000, in relation to the Extraordinary General Meeting's resolution no. 7/2021 of February 16, 2021 on the issue, for the purpose of implementing Incentive Programs for Members of the Management Board and other persons of key importance to the Company, of A series subscription warrants with exclusion of share subscription rights of existing shareholders, entitling them to subscribe for C-series shares and a conditional increase of the share capital through the issue of C-series shares with exclusion of share subscription rights of existing shareholders and an amendment to the Company's Articles of Association related thereto (amendments to the Company's Articles of Association introduced by way of this resolution were registered in the National Court Register on April 12, 2021).

On May 10, 2021, the Management Board of Celon Pharma S.A. adopted a resolution on the increase of the share capital within the above-mentioned authorized capital, by way of issuing not more than 15,000,000 ordinary D-series Company's bearer shares. It is assumed that the issue of new shares in such a number will allow the Company to obtain the funds to cover its 5-year investment program.

Next, on June 25, 2021, the Management Board of the Company adopted a resolution on the amendment of the above-mentioned resolution in such a way that it decided to issue a maximum of 6,000,000 ordinary D-series bearer shares in the Company. The decision to issue only 6 million shares and obtain approx. EUR 60 million was made to finance the Company's current investment needs over the course of the next 2 years, which, in the Management Board's opinion, is in line with the usual market practice observed in the segment of biotechnological companies.

Pursuant to the Management Board's resolution, the issue of D-series shares was to take place in the form of an open subscription within the meaning of Article 431(2)(3) of the Code of Commercial Companies conducted by way of a public offer covered by a prospectus within the meaning of applicable provisions of law or other information or offer document drawn up for the needs of such an offer. The issue price of the shares was to be specified by the Management Board of the Company with the consideration of the current market price and demand for the Company's shares and the situation on the financial markets, as well as the result of the conducted book-building process. The Management Board of the Company granted the pre-emptive right to subscribe for D-series shares before other investors to the shareholders, or a group of shareholders whose assets were being managed by one institution, who held, as of the end of the day of publishing the prospectus drawn up in relation to the public offering and admission of D-series shares and rights to D-series shares to trading on the regulated market, the Company's shares of the total nominal value constituting at least 1% of the Company's share capital, in accordance to which each of such shareholder, who correctly subscribed for D-series shares at a price not lower than the issue price, had the pre-emptive right to subscribe D-series shares in a number not lower than a number allowing to maintain – after the issue of shares – a share in the share capital of the Company not lower than the share held at the end of the aforementioned day. The D-series shares could be paid for using cash contributions only. Subject to the consent of the Supervisory Board, it was decided that it was in the best interest of the Company to exclude the current shareholders' pre-emptive right to subscribe for D-series shares. Subscriptions for the offered shares took place from July 2, 2021 to July 12, 2021.

On July 15, 2021 (event taking place after the balance sheet date), the Management Board of Celon Pharma S.A. allocated 6,000,000 ordinary D-series bearer shares, with the nominal value of PLN 0.10 each, issued as part of the authorized capital, pursuant to the resolution of the Extraordinary General Meeting of the Company no. 4/2021 and the resolution of the Management Board of the Company of June 25, 2021, which are referred to above. The issue price of D-series shares amounted to PLN 36 per share. The D-series shares were allocated to 71 investors, including 8 individual investors and 63 institutional investors. The required cash contributions were paid in full by every entity taking over the aforementioned D-series shares.

The Company plans to use the proceeds from the issue of D-series shares primarily to finance innovative drug projects, including financing of the Company's participation in phase III of the clinical trials for the Falkieri project, financing of the development of CPL'116 and the Company's other innovative projects, including phase II clinical trials of the most advanced innovative drug projects: CPL'36, CPL'280, CPL'110, and, to a small extent, to finance other general corporate purposes of the Company.

In accordance with the agreement of July 1, 2021 on underwriting, the Company and Glatton Sp. z o.o. undertook obligations towards the global coordinators of the offering indicated in the prospectus of Celon Pharma S.A. approved by the Polish Financial Supervision Authority on July 1, 2021; these obligations limit, among others, these entities' options to offer, sell or charge the Company's shares on the terms described in the prospectus to 365 days from the first listing of the Company's D-series shares on the WSE.

The Company's share capital increase by way of issuing D-series shares was registered in the National Court Register on September 9, 2021.

In view of the above, as at the day of this report, the share capital of Celon Pharma S.A. amounts to PLN 5,100,000.00 and was divided into 51,000,000 shares with a nominal value of PLN 0.10 each, including:

- 15,000,000 A1-series registered shares, privileged as to voting in such a way that each share carries two votes at the General Meeting of the Company,
- 15.000.000 ordinary A2-series bearer shares,
- 15.000.000 ordinary B-series bearer shares,
- 6.000.000 ordinary D-series bearer shares,

The total number of votes arising from all shares issued by the Company is 66,000,000.

On September 14, 2021, Krajowy Depozyt Papierów Wartościowych S.A. ("KDPW", the Central Securities Depository of Poland) issued a statement on conditional registration of 6,000,000 ordinary D-series bearer shares of the Company in the depository of securities under PLCLNPH00015 ISIN code; The registration of D-series shares was conditional upon their introduction to trading on the regulated market on which other shares of the Company bearing the aforementioned ISIN code have been introduced.

On September 15, 2021, the Management Board of the Warsaw Stock Exchange ("WSE") has adopted a resolution concerning the admission and introduction of the Company's ordinary D-series bearer shares to stock exchange trading on the WSE Main Market List. In its resolution, it stated that pursuant to § 19.1 and § 19.2 of the WSE Rules, 6,000,000 ordinary D-series bearer shares of the Company have been admitted to stock exchange trading on the primary market. At the same time, the WSE Management Board decided to introduce the above-mentioned shares of the Company to trading on the primary market as of September 22, 2021, subject to the registration of these shares and designating them with the PLCLNPH00015 ISIN code by the KDPW on September 22, 2021. Pursuant to the KDPW's statement on the registration in the securities depository of 6,000,000 of the Company's ordinary D-series bearer shares under PLCLNPH00015 ISIN code on September 22, 2021, the condition for the introduction of the aforementioned shares to trading on the primary market has been met.

The Company announced the aforementioned event in current reports No. 9/2021 of February 16, 2021, No. 14/2021 of March 15, 2021, No. 20/2021 of April 12, 2021, No. 21/2021 of May 6, 2021, No. 22/2021 of May 10, 2021, No. 29/2021 of June 25, 2021, No. 34/2021 of July 15, 2021, No. 35/2021 of July 29,2021, No. 37/2021 of September 9, 2021, No. 39/2021 and 40/2021 of September 16, 2021 and 42/2021 of September 22, 2021.

In connection with the provisions introducing the obligatory dematerialization of shares (the Act of August 30, 2019 amending the Code of Commercial Companies and certain other acts; Journal of Laws of 2019, item 1798, as amended from Journal of Laws of 2020, item 875), the Company's A1-series shares have been dematerialized and registered with Krajowy Depozyt Papierów Wartościowych S.A. (the National Depository for Securities S.A.) The binding force of the share documents issued by the Company expired by operation of law on March 1, 2021.

4. A short description of the Issuer's significant achievements or failures, together with a list of the most important events concerning the Issuer up to the day of publishing the statements.

Positive results of the phase II clinical trial of DPI esketamine (Falkieri) in bipolar treatment-resistant depression

On January 8, 2021, the Company received results of the phase II clinical trial of its esketamine-based drug (Falkieri) in patients with bipolar treatment-resistant depression. In the trial, the adopted primary endpoint, defined as a considerable, statistically and clinically significant reduction on the MADRS scale, compared to placebo at week 2, was achieved for all tested doses. The obtained results indicate that an extremely positive scenario has played out, i.e. a scenario in which the drug stands out against the placebo in regard to efficacy, and the difference compared to the placebo on the MADRS score scale is greater than 5 points, the differences in percentage responses and remissions are greater than 25% compared to the placebo group, and additionally the drug indicates an acceptable safety and tolerance profile.

The difference on the MADRS scale after placebo deduction on day 14 was -5.9 (95% CI: -10.2 to -1.5; p=0.009) for the 24mg dose; -6.7 (95% CI: -11.1 to -2.2; p=0.004) for the 36mg dose; and -8.2 (95% CI: -12.6 to -3.7; p<0.001) for the 48mg dose. Furthermore, patients receiving Falkieri demonstrated a considerable, statistically significant improvement on the HDRS scale, a second depression assessment scale used in the trial, in all tested doses. Moreover, positive results were observed also with regard to secondary endpoints measuring the drug's efficacy. Responses to treatment, defined as a reduction on the MADRS scale larger or equal to 50% on day 14 were identified in 48%, 52% and 68% of patients receiving 24, 36 and 48 mg esketamine doses, respectively, vs. 23% in patients receiving placebo. Remissions, defined as reaching a value lesser than or equal to 10 points on the MADRS scale on day 14 was identified in 44%, 43% and 46% of patients receiving 24, 36 and 48 mg esketamine doses, respectively, vs. 9% in patients receiving placebo. The drug tolerability was high. No cases of treatment discontinuation connected with the occurrence of adverse reactions in any patients have been reported. No severe adverse reactions have been reported. No deaths or suicide attempts have been reported. No cases of mania induced in patients receiving Falkieri have been reported. This risk is a highly recognized factor accompanying the use of antidepressants in the treatment of bipolar depression. Dissociation after drug administration was short-term and mild. Sedation after drug administration has not been observed.

On June 23, 2021, the organization tasked with organizing and monitoring of the trial provided the Company with an update on the course and results of the trial, taking into account the 6-week follow-up. As at that day, full data have been entered into the database, including the 6-week follow-up of 81 patients, which constitutes 92% of patients enrolled into the trial. Data from day 14 for the primary endpoint have been verified for 100% of patients. The data, including the 6-week follow-up, have been verified in full for 39 patients, which constitutes 44% of patients participating in the study.

As at June 23, 2021 the Company assessed the long-term effect of the response and remission obtained in the active treatment phase. The assessment covered data available as at June 23, 2021; in line with the above-listed information, some of the data is still subject to verification by clinical monitors. The clinical response obtained in the active treatment phase (day 14) was continued over the course of subsequent 6 weeks in 11 of 11 patients in the Esk 24mg arm, in 9 of 11 patients in the Esk 36mg arm and in 15 of 15 patients in the Esk 48mg arm vs continued response in 3 of 5 patients in the placebo arm. Remission obtained in the active treatment phase (day 14) was continued over the course of subsequent 6 weeks in 9 of 10 patients in the Esk 24mg arm, 7 of 9 patients in the Esk 36mg arm and in 9 of 10 patients in the Esk 48mg arm vs continued response in 1 of 2 patients in the placebo arm. No serious adverse effects, deaths or suicide attempts have been reported in the study. Treatment discontinuation by day 14 has been reported in 3 patients in the placebo arm and 1 patient in the Esk24 arm. No treatment discontinuations have been reported in the Esk36 and Esk48 arms.

Moreover, the Company was informed that the results for day 14 (i.e. conducted as at January 8, 2021, assessment for the primary endpoint and some of other endpoints, as well as partial safety and tolerability results, including CADSS score over the 2-week drug administration period) have not changed, confirm the drug’s statistically significant efficacy and will constitute the basis for the drug’s basic assessment in terms of the offered clinical benefit.

The Company points out that the bipolar depression phase II study was participated by 88 patients diagnosed with bipolar treatment-resistant depression, which was defined as at least two mood-stabilizing treatment strategies with marketing authorizations or with proven efficacy in treatment of bipolar depression. The dug was administered in a dry-powder inhaler in 3 doses: 24 mg (N=23), 36mg (N=21) and 48mg (N=22), obtained by way of an increasing number of active inhalations. The drug was administered 4 times (twice a week) on days 1, 4, 8 and 11. Placebo was administered to 22 patients. The main efficacy scale adopted for the trial was the Montgomery Asberg Depression Rating Scale (MADRS).

In the opinion of the Company's Management Board, the current data confirm the drug's high efficacy, including its long-term effect, good tolerability and constitute a strong basis for continuing development in phase-III clinical research. In connection with the obtained data, the Company plans to continue talks with the regulators concerning phase III trials, as well as partnering talks in line with its innovative portfolio's commercialization strategy.

The Company announced the aforementioned event in current reports No. 1/2021 of January 8, 2021 and No. 27/2021 of June 23, 2021. Pursuant to the information received from the organization tasked with its organizing and monitoring, the delays in the clinical trial monitoring processes were caused by difficulties in access to source data in study sites resulting from the COVID-19 pandemic in 1Q2021 and 2Q2021.

Obtaining a patent for GPR40 receptor agonists and their use in T2D treatment in the US

On January 18, 2021, the Company received information that the Company was granted a patent covering GPR40 receptor agonists and their use in type 2 diabetes treatment in the US. The patent was granted by the United States Patent and Trademark Office and guarantees full legal protection of the compounds covered by the patent and their use in treatment of the above-mentioned conditions in the United States of America.

The Company is developing GPR40 (CPL'280) in treatment of type 2 diabetes and diabetic neuropathies; that compound completed phase I clinical trials successfully. The obtained patent protection reduces the risk associated with the project and increases the value of the Company's potential products in the therapeutic areas covered by patent protection. The Company announced the aforementioned event in current report No. 3/2021 dated January 18, 2021.

Successful completion of the phase I clinical trial of CPL409116, the drug based on an innovative JAK/ROCK inhibitor

On February 9, 2021, the Company received information on the completion of the phase IA clinical trial of the CPL'116 compound, a dual JAK/ROCK kinase inhibitor, administered once in various, increasing doses to healthy volunteers. The study was designed to assess the compound's safety profile and pharmacokinetic parameters, no adverse reactions related to the administration of the tested product have been observed in the trial.

Then, on August 9, 2021 (event taking place after the balance sheet date), the Company received information on the completion of the administration of the studied compound, i.e., CPL'116, to healthy volunteers in the phase IB clinical trial. In the above-mentioned phase, the study product was administered repeatedly (over the course of 14 days), at increasing doses. In addition to safety and pharmacokinetic parameters, the assessment included an analysis of key pharmacodynamic parameters related to the degree of JAK/ROCK kinase inhibition in biological material collected from healthy volunteers. No serious adverse events (SAE) have been observed in participants during the phase IB trial, and the drug tolerability was high.

The Management Board believes that the data and results collected in the phase I trial provide a strong foundation for the compound's development in the course of subsequent clinical phases in autoimmune diseases, including disorders for which no proven effective therapy exists.

CPL 116 is a dual JAK and ROCK kinase inhibitor that the Company is developing in autoimmune indications, i.e., RA, psoriasis, lupus and others. The available preclinical data indicate that it might also be possible to use the compound in the treatment of COVID-19. The compound is the first dual JAK and ROCK kinase inhibitor in the world which, thanks to the inhibition of ROCK, offers additional benefits associated with cardioprotection, as well as augmentation of the anti-inflammatory effect. CPL'116 will be used in the treatment of selected autoimmune diseases in which the desired effect consists in simultaneous inhibition of inflammation and fibrogenesis. The clinical development of CPL'116 will take place as part of the so-called fast track, which assumes an accelerated regulatory process.

The Company announced the aforementioned event in current reports No. 6/2021 of February 9, 2021 and No. 36/2021 of August 10, 2021.

Agreement to terminate cooperation with the company's current partner in development, manufacturing and commercialization of the Company's inhalation drug in the US

On March 2, 2021, the Company signed an agreement with Lupin Atlantis Holdings S.A. ("Lupin") on cooperation in the development, manufacturing and commercialization of an inhalation drug containing a combination of salmeterol and fluticasone for the markets of the USA and Australia, Canada, Mexico and South Africa, concluded on February 4, 2015 (License and Development Agreement).

The Agreement provided for Lupin to take all steps to obtain the US Food and Drug Administration (FDA)'s approval of the application (Abbreviated New Drug Application) for the licensed product in the US and to conduct the entire registration process and to communicate with the FDA as well as to be responsible for completing all post-registration requirements in the licensed territory. As part of the Agreement, the Company had also concluded a Supply Agreement with Lupin under which the Company was required to supply Lupin with an FDA-approved pharmaceutical product for marketing in the US as well as in Australia, Canada, Mexico and South Africa. The termination of the above-mentioned agreements did not entail any claims against the Company and also enabled the Company to start searching for new partners for cooperation on the above-mentioned markets. The Company announced the aforementioned event in current report No. 12/2021 dated March 2, 2021.

Conclusion of a license agreement with Glenmark Pharmaceuticals Ltd.

On March 2, 2021, the Company signed a license agreement with Glenmark Pharmaceuticals Ltd with its registered seat in India ("Glenmark") to cooperate in the area of registration, sale and distribution of a product that constitutes a combination of fluticasone and salmeterol in a dry powder inhaler (sold under the name Salmex in Poland) in the following markets: Saudi Arabia, United Arab Emirates, Kuwait, Qatar, Bahrain, Oman, Libya, Algeria, Morocco, Iraq, South Africa, Mexico, Peru, Ecuador, Argentina, the Caribbean Islands, Philippines, Malaysia, Thailand, Singapore and Hong Kong. The agreement was concluded for a period of 10 years from the date of sales commencement in the respective markets, with the possibility of extension. The agreement gives Glenmark the exclusive right to sell the product in the above markets and gives the Company the exclusive right to manufacture the product for sale in the above markets.

The Company also has a license agreement for the aforementioned product with Glenmark Pharmaceuticals Europe Ltd. with its registered seat in the UK regarding the licensing agreement, with respect to 15 European countries. The Company announced the aforementioned event in current report No. 13/2021 dated March 2, 2021.

Conclusion of an agreement with the National Center for Research and Development for the co-funding of the project dedicated to the development of a drug based on GPR40 receptor agonists in the treatment of neuropathic pain

On March 23, 2021, the Company was informed that the National Center for Research and Development ("NCBR") signed the agreement on co-funding of the project. "Development and implementation into clinical trials and the company's activities of a drug based on GPR40 receptor agonists in the treatment of neuropathic pain (GRAPPA)", submitted to a competition under the Smart Growth Operational Program 2014-2020, measure 1.1/submeasure 1.1.1. The Company's application for co-funding of the project was recommended by the NCBR on January 18, 2021.

Pursuant to the co-funding agreement, the total cost of the project amounts to PLN 42.3 million, and the amount of co-funding granted amounts to PLN 22.2 million. The period of cost eligibility for the project ends on December 31, 2023.

Chronic pain conditions are experienced by patients suffering from physical injuries and lifestyle diseases; the latter are increasingly prevalent. The latest scientific discoveries have confirmed that GPR40 agonists play a key role in the modification of inflammatory and neuropathic pain. The final objective of this project is to evaluate the drug candidate in the treatment of neuropathic pain as part of phase II clinical trials. The CPL207208 compound is a specific GPR40 receptor agonist. The compound is being developed by the Company for treatment of type 2 diabetes and diabetic neuropathies and has successfully completed phase I clinical trials. The Company announced the aforementioned event in current report No. 2/2021 of January 18, 2021 and No. 15/2021 of March 24, 2021.

Signing of a co-funding agreement with the National Center for Research regarding a project for an inhaled drug candidate for the treatment of inflammatory and fibrotic lung diseases, including COVID-19 complications

On March 30, 2021, the Company was informed of the NCBR signing the agreement on the co-funding of the following project: "In vivo validation, toxicological development and implementation into clinical trials and the Company's activities of an inhalation drug candidate for the treatment of inflammatory and fibrotic lung diseases including COVID-19 complications", submitted to a competition under the Smart Growth Operational Program 2014-2020, measure 1.1/submeasure 1.1.1. The Company's application for co-funding was recommended by the NCBR on February 10, 2021.

Pursuant to the co-funding agreement, the total cost of the project amounts to PLN 46.9 million, and the amount of co-funding granted amounts to PLN 27.2 million. The period of cost eligibility for the project ends on December 31, 2023.

The aim of the project is non-clinical and clinical confirmation of the efficacy and safety of the CPL116 compound – a JAK/ROCK kinase inhibitor developed by the Company, administered by inhalation for the following indications: asthma, chronic obstructive pulmonary disease (COPD) and idiopathic pulmonary fibrosis (IPF). Chronic inflammatory and fibrotic respiratory diseases affect millions of people around the world. It is expected that administration by inhalation will help reduce the dosage and limit the occurrence of adverse effects. The scope of works covered by the project includes the manufacture of an Active Pharmaceutical Ingredient (API) according to GMP (Good Manufacturing Practice) standards, as well as conducting pre-clinical trials to confirm the drug's efficacy and pharmacokinetic profile when administered by inhalation. In subsequent stages, the Company plans to develop a formulation using a modern dry powder inhaler (DPI) and to conduct a toxicological study on administration of the compound by inhalation. The final stage of the works will be the evaluation of the developed inhalation drug in phase I and II clinical trials. The Company announced the event above in current reports No. 7/2021 of February 10, 2021 and No. 17/2021 of March 31, 2021.

Completion of phase I clinical trial of CPL'280, a second generation GPR40 receptor agonist

On April 1, 2021, the Company received information from the clinical center on the completion of the stage of administration of the drug to volunteers, in the so-called repeated administration, at the highest dosing, under the conducted phase I clinical trial of the GPR40 receptor agonist (hereinafter referred to as CPL'280). Therefore, the Company confirmed the completion of the active clinical part of the phase I study.

The purpose of the study was to determine the safety and tolerability of the drug, as well as its pharmacokinetic properties after single and repeated administration and interaction with metformin and food. A total of 68 healthy volunteers were involved in the phase I study. The drug has demonstrated a favorable safety profile; no disturbing adverse effects, after either single or repeated administration, have been observed. Earlier, no interactions of CPL'280 with either metformin or food have been identified which provides the comfort of flexible and safe dosing in the chronic management of metabolic diseases. Laboratory studies conducted to date on volunteers participating in the phase I study have not identified any adverse effects of CPL'280 on monitored parameters that may indicate hepatotoxicity, including changes in ALT and AST liver enzyme levels.

CPL280 represents the latest generation of drugs used in diabetes and metabolic disorders. The drug has previously demonstrated an extremely favorable safety profile in preclinical studies, which distinguishes it from other drugs in its class. The above study was conducted under the GATE project, for which the Company received PLN 24.7 million of co-funding from the NCBR. The Company announced the aforementioned event in current report No. 18/2021 dated April 1, 2021.

Submission of an application for consent to commence a phase II trial of CPL'280 in treatment of type 2 diabetes.

On June 22, 2021 the Company submitted an application to the Polish Office for Registration of Medicinal Products, Medical Devices and Biocidal Products (URPL) along with preclinical and phase I clinical trial documentation regarding the commencement of a phase II trial, where CPL'280 will be tested in patients with diagnosed type 2 diabetes. The study will be a randomized, double-blind, placebo-controlled clinical trial conducted on a group of approx. 80 patients, with the drug administered orally in 4 doses over the course of 2 weeks. The main endpoint will be fasting glucose control assessed using oral glucose tolerance tests conducted after 14 days of using CPL'280. Additionally, patients will be subject to a therapy safety assessment, including safety of the drug's impact on the liver function, as well as a pharmacokinetic assessment.

The application along with the developed documentation concludes a broad preclinical and early phase-I clinical program, where the drug demonstrated exceptional efficiency in terms of glycemic control and was characterized by a very favorable safety profile. CPL'280 was designed in the Company's laboratories as the latest-generation GPR40 agonist, with particular focus on safety, in particular regarding the risk of hepatotoxicity. Notably, compared to first-generation GPR40 agonists, CPL'280 does not block bile acid transporters and does not form toxic reactive metabolites. Additionally, in animal models, CPL'280 demonstrated a benefit in terms of diabetic neuropathy, i.e., the most common long-term complication of type 2 diabetes. Diabetic neuropathy is another indication for which the Company is planning the clinical development of CPL'280. The phase-2 clinical development of CPL'280 is co-funded by the National Center for Research and Development under the GATE project grant The Company announced the event above in current report No. 26/2021 dated June 22, 2021.

Signing of a letter of intent on commencing cooperation with Tarchomińskie Zakłady Farmaceutyczne S.A.

On June 24, 2021 the Company and Tarchomińskie Zakłady Farmaceutyczne S.A. (TZF) signed a letter of intent, in which the parties declared that, taking into account that the Company has both the competences and technical capabilities to develop innovative pharmaceuticals with potential use in the treatment and prevention of COVID-19, treatment of cancer, neurological diseases, diabetes and other metabolic diseases, and taking into account the investment commenced by TZF in

the form of creating a research and production center for highly active substances, in order to take full advantage of the synergy of experience of the two teams and technological advancement of both companies, the Company and TZF declare their intention to initiate cooperation in the area of development (R&D) and production (fill & finish) of medicinal products based on modern technologies (m-RNA), a platform of highly active drugs with particular emphasis on new technologies for sterile forms of the drug, in the areas of infectious diseases, cancers and metabolic diseases. The detailed scope of cooperation is to be specified in the potential cooperation agreement. The Company announced the aforementioned event in current report No. 28/2021 dated August 10, 2021.

5. The indication of factors and events of unusual nature of significant impact on the condensed financial statements

There were no factors and events other than the ones indicated in the other points of the report, including factors and events of unusual nature that would have significant impact on the condensed financial statements of the Company in 1H2021.

6. Description of changes in the organization of the issuer's capital group, including as a result of a merger of entities, gaining or losing control over subsidiaries and long-term investments, as well as division, restructuring or discontinuation of activities, and indication of entities subject to consolidation, and in the case of the issuer being the dominating entity, which, on the basis of applicable provisions, is not required or may not prepare consolidated financial statements – additionally an indication of the reason and legal basis for the lack of consolidation.

Celon Pharma S.A. did not have subsidiaries and it was not making up a capital group during the reporting period.

7. Position of the Management Board regarding the possibility of meeting previously published performance forecasts for the given year, in the light of the results presented in the periodic report in relation to the performance forecasts,

The Company has not published forecast results for 2021.

8. Indication of shareholders holding, directly or indirectly through subsidiaries, at least 5% of the total number of votes at the issuer's general meeting as at the date of submitting the report, along with an indication of the number of shares held by these entities, the percentage share of these shares in the share capital, the number of votes resulting therefrom and the percentage share of these shares in the total number of votes at the general meeting, as well as an indication of changes in the ownership structure of significant blocks of the issuer's shares in the period from the date of submitting the previous periodic report.

After registration of the increase of the Company's share capital on September 9, 2021, as a result of the issue of ordinary D-series bearer shares of the Company, to the best knowledge of the Company, the ownership structure of significant blocks of the Company's shares as at the date of publication of this report is as follows:

Shareholder	Number of shares	Share in the share capital	Number of votes	Share in the total number of votes
Maciej Wieczorek indirectly through Glatton Sp. z o.o.* (100% of shares)	30,003,531	58.83%	45,003,531	68.19%
Other Shareholders	20,996,469	41.17%	20,996,469	31.81%
Total	**51,000,000**	**100%**	**66,000,000**	**100%**

* Glatton sp. z o.o. holds 15,000,000 registered shares privileged to vote.

To the best knowledge of the Company, the ownership structure of significant blocks of the Company's shares as at the date of publication of this report, i.e., for 1Q2021 published on May 20, 2021, is as follows:

Shareholder	Number of shares	Share in the share capital	Number of votes	Share in the total number of votes
Maciej Wieczorek indirectly through Glatton Sp. z o.o.* (100% of shares)	30,003,531	66.67%	45,003,531	75.01%
Other Shareholders	14,996,469	33.33%	14,996,469	24.99%
Total	**45,000,000**	**100%**	**60,000,000**	**100%**

* Glatton sp. z o.o. Held 15,000,000 registered shares privileged to vote.

9. Information on the issuer's shares or rights to shares held by persons sitting on the issuer's managing or supervisory bodies as at the date of submitting the report, along with an indication of changes in the ownership status, in the period from the date of submission of the previous periodic report, separately for each of these persons.

Shareholder	As at the day of publishing the report for 1Q2021 (May 20, 2021)	As at the day of publishing the report for 1H2021 (September 30, 2021)
Management Board		
Maciej Wieczorek*	-	-
Jacek Glinka	-	-
Iwona Giedronowicz	-	-
Supervisory Board		
Robert Rzemiński	-	-
Krzysztof Kaczmarczyk	-	-
Bogusław Galewski	-	-
Urszula Wieczorek	-	-
Artur Wieczorek	5.937	1.330

* Maciej Wieczorek holds shares in the Company indirectly through Glatton Sp. z o.o., as indicated in the relevant table presenting shareholders of Celon Pharma S.A. who hold at least 5% of the total number of votes at the General Meeting of the Company (point 8 – above).

Members of the Management Board and of the Supervisory Board do not have rights to the Company's shares.

On February 16, 2021, the Extraordinary General Meeting of the Company adopted a resolution on the introduction of Incentive Programs for Members of the Management Board and other persons of key importance to the Company for the financial years 2021-2030. As a part of implementing the Incentive Programs, the eligible persons will have the right to acquire subscription warrants which give the right to acquire shares in the Company issued under a conditional share capital increase. The subscription warrants will be subscribed for by indicated eligible persons and in the amount specified in the resolution of the Supervisory Board (in the case of the Incentive Program for Members of the Management Board) or by the President of the Management Board (in the case of the Incentive Program for the Company's Officers), subject to the provisions of the regulations of the aforementioned Programs. Persons who are shareholders holding, directly or indirectly, over 33% of the votes in the Company and their family members will not have the right to acquire subscription warrants. At the same time, the Supervisory Board or the President of the Management Board respectively will be specifying the maximum number of subscription warrants granted to each eligible person in each year of duration of the Incentive Programs and will approve the eligible persons meeting i.a. managerial targets or targets of the officers in a given financial year. The Incentive Programs will be implemented through the issuance and allocation of up to 2,000,000 A-series subscription warrants entitling the eligible persons to subscribe to up to 2,000,000 shares in the Company, whereas the total number of A-series subscription warrants offered in a given financial year under both Incentive Programs shall not exceed 200,000 (in particularly justified situations the Supervisory Board may decide to increase that number, however to a maximum of 400,000 warrants). An eligible person exercising the right under the A-series subscription warrants and subscribing C-series shares will require the eligible person to submit a statement in which they undertake not to sell the C-series shares within 1 year.

Therefore, on February 16, 2021, the Extraordinary General Meeting of the Company adopted a resolution on the issue of up to 2,000,000 A-series registered subscription warrants with exclusion of the existing shareholders' pre-emptive right, entitling them to subscribe for 1 C-series share each and a conditional increase of the share capital by an amount not exceeding PLN 200,000 through the issue of C-series shares with the exclusion of the existing shareholders' pre-emptive right and an amendment to the Company's Articles of Association related thereto. The subscription warrants will be issued free of charge. Exercising the rights under A-series subscription warrants will be possible until February 16, 2031. The issue price of C-series shares will be specified by the Management Board (and in relation to shares subscribed for by the Members of the Management Board – by the Supervisory Board), whereas the issue price in the case of holders of A-series subscription warrants will amount to at least PLN 0.10 per each C-series share. The C-series shares will be the subject for application for admission and introduction to the stock exchange trading on the market operated by the Warsaw Stock Exchange.

No subscription warrants under the adopted Incentive Programs have been issued as at the day of publishing of this report.

10. Identification of significant proceedings pending before a court, a competent arbitration authority or a public administration authority concerning the issuer's liabilities and receivables with identification of significant proceedings pending before a court, a competent arbitration authority or a public administration authority concerning the issuer's liabilities and receivables.

There were no significant proceedings pending before a court, a competent arbitration authority or a public administration authority concerning the Company's liabilities or receivables in 1H2021.

In terms of the remaining proceedings, on 29 June 2021, a claim for payment was filed against the Company by Polfarmex S.A. with its registered office in Kutno before the District Court in Warsaw, 22nd Intellectual Property Division. The plaintiff in the above-mentioned case filed a claim for an amount of PLN 658,776.72, with statutory interest calculated from 30 December 2020
until the payment date, adopting the remuneration allegedly resulting from the implementation of the joint venture agreement of September 28, 2010 and the subsequent amendments thereto as the grounds for the claim. In particular, the purpose of the agreement and its amendments was the joint commercialization in the French market of a medicinal product comprising a combination of salmeterol and fluticasone. In its response to the claim dated August 26, 2021, the Company motioned that the claim be dismissed in its entirety on the grounds that it was unfounded, and that the plaintiff pay the costs of the proceedings.

11. Information on the issuer concluding one or more transactions with affiliates, provided they were concluded on conditions other than market conditions along with an indication of their value, whereas the information on individual transactions can by divided by type, with an exception when the information of individual transactions are necessary to understand their impact on the issuer’s assets, finances and financial result.

The Issuer did not conclude transactions with affiliates on conditions other than market conditions during 1H2021.

12. Information on the issuer granting loan or credit guarantees or underwriting – jointly to one entity or its affiliate if the total value of the existing guarantees or underwriting is considerable.

In 1H2021, the Company did not grant any loan or interests and did not grant any underwritings – jointly to one entity or its affiliate, where the total value of the existing guarantees or underwriting would be considerable.

13. Other information which, in the issuer's opinion, is significant for the assessment of its situation in terms of personnel, assets, finances, financial performance and changes thereto, and information which is significant for the assessment of the issuer's capacity to meet its liabilities.

There is no information, other than the information indicated below and in the other sections of this report, which is significant for the assessment of the Company's situation in terms of personnel, assets, finances, financial performance and changes thereto as well as the Company's capacity to meet its liabilities.

Change of accounting policies

On February 16, 2021, the Extraordinary General Meeting of the Company adopted a resolution on changing the accounting policy and commencing the preparation of the Company's financial statements in accordance with the International Accounting Standards, International Financial Reporting Standards and related interpretations announced in the form of regulations of the European Commission (jointly "IFRS"). The first period for which the Company's annual financial statements will be prepared for statutory purposes in accordance with IFRS is the financial year starting on January 1, 2021 and ending on December 31, 2021.

At the same time, for the purposes of drawing up a prospectus in connection with the public offering of the Company's D-series shares issued as authorized capital and applying for the admission of newly issued shares to trading on the regulated market operated by the Warsaw Stock Exchange, the Company prepared additional financial statements for Celon Pharma S.A. , drawn up in accordance with the IFRS, including with data for the financial years 2018-2020, made public in the current report no. 19/2021 dated April 7, 2021.

Payment of dividends to shareholders

On June 29, 2021, the Ordinary General Meeting of the Company adopted a resolution on the distribution of profit for the financial year 2020, in accordance to which it was decided that the net profit of the Company for 2020 in the amount of PLN 21,494,827.07 will be allocated as follows:

a) PLN 18,344,827.07 is to be allocated to the Company’s reserve capital,
b) PLN 3,150,000.00 is to be paid out to shareholders as dividend (i.e., PLN 0.07 per share).

45,000,000 shares in the Company were subject to the dividend. The Management Board set July 15, 2021 as the dividend record date, and for the dividend to be paid out on August 5, 2021.

The resolution of the Ordinary General Meeting was in line with the recommendation of the Company's Management Board, in accordance to which the payment of the divided in the above-mentioned amount was in the Management Board's opinion justified, and at the same time allows the Company to finance its further development.

The dividend was paid by the Company on the scheduled date (event taking place after the balance sheet date).

The Company reported on the Management Board's recommendation and the resolution of the Company's Ordinary General Meeting regarding the payment of dividends in current reports No. 24/2021 of 31 May 2021 and No. 31/2021 of 29 June 2021.

Withdrawal of Valzek 80mg and 160mg drug batches from the market

On 23 September 2021, by way of a decision issued at the request of the Company, the Chief Pharmaceutical Inspector withdrew the currently available batches of Valzek nationwide. The product unavailability is temporary and short-term. Newly manufactured Valzek batches will be distributed to wholesalers at the beginning of October 2021 and subsequently will be made available to patients in pharmacies.

The purpose of the procedure implemented by the Company is to adapt the product to the new qualitative specifications set by regulators regarding azide impurities. These can occur as a by-product at certain synthesis steps during the manufacture of sartan active substances. The role of the relevant EU and Polish regulatory authorities is to issue guidelines for pharmaceutical manufacturers on the control and determination of various impurities in the products they manufacture. Following the receipt of such guidelines, regarding the mutagenicity of azide impurities, the Company implemented its own validated method for determining this impurity, tested all Valzek batches available on the market and, after receiving the results, took action to withdraw the product from the market. At the same time, it launched a manufacturing process based on the active substance valsartan, which complies with the new qualitative guidelines with regard to the control of this type of impurity, which will enable the rapid and efficient launch of new Valzek batches to the market.

In the opinion of the Company's Management Board, the situation in question is a common occurrence in the pharmaceutical industry and remains without significant impact on the Company's financial result as well as on its current business operations.

Epidemiological situation related to COVID-19

In the face of the global COVID-19 pandemic and the introduction of the state of epidemic emergency in Poland, the Company performed a multifaceted analysis regarding this risk in relation to its business operations. In view of the epidemiological situation in the country and abroad, bearing in mind the necessity to ensure continuity of all operational and business processes, as well as the safety of the Company's employees, business associates and partners, the Company's Management Board took actions which it found appropriate. As at the date of publication of this report, all operational activities are carried out by the Company without interruption. The Company's Management Board continuously endeavors to implement, on an ongoing basis, all the guidelines of the state authorities, in particular the public health authorities with regard to the Company's operational activities. Special internal procedures have been introduced at the Company's premises, prepared in consultation with the competent local public health authorities. On that basis, the Company has tightened to a minimum the possibility of visitors and outsiders entering all company locations and has provided additional points with personal disinfection materials for visitors and employees. Additional procedures for self-monitoring of employees by supervisors have been introduced in the manufacturing, development and quality assurance areas. These are additional activities introduced to the existing work system under the Good Manufacturing Practice (GMP) regime. The undertaken activities are aimed at minimizing the impact of the epidemic in Poland on the Company's production capacity. Furthermore, the Company has cancelled employee participation in overseas conferences and cancelled business trips that could involve an increased risk of spreading the virus. Internal and external meetings involving the Company's representatives with guests, business associates and partners are now predominantly held by tele- and videoconference. Research and development work is carried out without disruption. Where possible, given the nature of their duties, Employees have been given the option of remote working solutions. Additional points of personal disinfection materials have been organized and launched at each of the Company's locations, and additional responsibilities have been introduced for individuals who are the first line of contact. Regarding the promotion of medicinal products, in view of the need to ensure continuity of activities to effectively market manufactured medicinal products, while ensuring safe working conditions for employees, the burden of operational activities was redirected from the medical facilities which were temporarily inaccessible to pharmacies and pharmacy chains. The range of activities was supported by marketing tools using modern communication technologies while maintaining the ability to measure the representatives' activity. In connection with the COVID-19 pandemic, the Company's Management Board carried out a multifaceted analysis of the impact of current and anticipated risks related to the current, as well as the

anticipated epidemiological situation in Poland and abroad. In the Company's opinion, the impact of the COVID-19 epidemiological emergency on the risk of ensuring the necessary raw materials for the Company as at the date of publication of this report is marginal. It should be noted that securing the key components for the Company's most important products, i.e., for Salmex and Ketrel, which make up approximately 80% in the Company's sales, as at the date of publication of this report covers a period of between a few and more than 9 months. The Company's Management Board has taken additional steps to diversify suppliers of raw materials required to manufacture the Company's products with the aim of eliminating this risk in the future. The Company has a long-standing policy of addressing supply risks by authorizing at least two independent alternative suppliers for key components, thus significantly reducing the risk of supply interruption.

14. Identification of factors which, in the issuer's opinion, will affect its performance in the perspective of at least the next quarter

The Company believes that its performance is primarily affected by the following market factors and trends, some of which the Company anticipates will continue to be significant drivers of the Company's financial results in the future. The Company divides these factors into (1) market trends and external factors such as (i) the development of the market for innovative medicines, (ii) the development of the market for generic medicines, (iii) the costs of complying with applicable regulations, (iv) changes in currency exchange rates and (v) applicable tax regulations, as well as (2) factors related to the Company's business activity, such as (i) export sales of Salmex, (ii) partnering transactions, (iii) R&D expenditure, (iv) sales and distribution costs, as well as (iv) revenues from subsidies and grants.

Commercialization of innovative drugs

The Company believes that the development of innovative medicines and their further commercialization will become one of the main drivers of the Company's growth in the future. Once the critical milestones of the phase II clinical trials have been reached, the Company will work to identify the best commercial solutions, including acquiring commercial partners to pursue phase III clinical development and commercialization of its projects.

While the Company generally intends to grant full licenses for the commercialization of its medicines, the Company is also considering retaining commercialization rights for selected medicines (which require limited investment in this area) sold in Europe and possibly the United States of America. The Company is in the early stages of developing key commercial relationships in this area. In particular, the Company expects to look for a potential commercialization partner for its most advanced Falkieri program in the short or medium term. The Falkieri program is also designed to eventually enable treatment in both clinical and home conditions, for both acute and conservative treatment, respectively. Given the promising safety and bioavailability profile of Falkieri, as well as the exceptionally positive Phase II results in bipolar depression, the Company believes it will generate significant interest from potential external partners for further collaboration in phase III and commercialization of the medicine.

In the event that the other innovative projects of the Company reach advanced stages of clinical development, the level of patent protection of the compounds and technologies developed by the Company, as well as the results of preclinical and clinical trials, including the most important phase II studies, will constitute an important factor for such activities. The Company believes that its compounds, which are being developed in preclinical and clinical trials, have multiple advantages over most of compounds currently available on the market or those under development, which provides a competitive advantage and favorable commercialization of such drugs in the future.

Further dynamic development of the generic drugs segment, including in particular further growth in global reach and sales of Salmex

The Company will continue to support its activity in the area of generic drugs. The Company is currently working on the development of several medicines in related disease areas, using the Company's current position in the market of generic medicines in Poland and its experience in building leading brands of generic drugs. The Company also plans to further develop its inhalation technologies on the basis of the experience gained from the development of Salmex. Salmex will remain the main export product. It is currently sold in 18 European countries, as well as in some non-European countries, including i.a. the Dominican Republic, Guatemala and Kazakhstan. The commercialization of Salmex outside Poland is done exclusively through business partners such as Glenmark, Viatris (formerly Mylan), Genericon. The Company is actively seeking new partners in various markets worldwide, convinced that Salmex has the potential to become the Polish pharmaceutical industry's first global product. Other countries where further geographical expansion is planned include the United States of America, China, Mexico, South Africa, Greece, Israel and numerous countries in Latin America, the Middle East and South-East Asia.

Medium-term development targets

In terms of the development of innovative drugs, supported by the launch of the infrastructure of the new R&D center, the Company aims to achieve the following medium-term targets:

- the introduction of at least two drug candidates into clinical development per year,
- the completion of phase II drug trials in at least 6 therapeutic indications,
- initiation of phase III programs (independently or in collaboration with other partners) for at least three therapeutic indications,
- the completion of phase III trials of Falkieri (esketamine DPI) and submission of applications to the FDA and EMA,
- the signing of significant partnership agreements.

In terms of the segment of generic medicines, the Company aims to achieve the following medium-term targets:

- continued geographical expansion of Salmex;
- strengthening the market position in the main EU markets;
- achieving a double-digit CAGR growth rate in export sales between 2021 and 2025;
- completing clinical development and obtaining marketing authorization for Salmex in China and the US.
- expansion of the portfolio of generic medicines in key therapeutic areas (respiratory diseases
- and central nervous system diseases).

15. The principles for the preparation of the half-year condensed financial statements.

The accounting principles (policies) applied in the preparation of the interim condensed financial statements are consistent with the principles applied in the preparation of the Company's historical financial data for the year that ended on December 31, 2020, except for the application of new or amended standards and interpretations effective for annual periods beginning on or after January 1, 2021.

The amended standards and interpretations that are applicable for the first time in 2021 have no material impact on the Company's half-year condensed financial statements.

Amendments to IFRS 9, IAS 39, IFRS 7, IFRS 4 and IFRS 16: Interest Rate Benchmark Reform – phase II – official translation from the OJ of the EU.

The proposed changes include temporary exceptions addressing the results of replacing the Interbank Offered Rates (“IBOR”) with an alternative benchmark close to the risk-free rate (“RFR”) and their effect on the financial reporting. The changes include the following practical solutions:

- practical solution which requires that changes to an agreement or changes of cash flows which are a direct consequence of a reform are treated as changes to the floating interest rate, which is tantamount to the change of the market interest rate,
- permission to adjust the hedge accounting documentation in terms of designating and documenting hedging relationships without dissolving them, if such changes were necessitated directly by the IBOR reform,
- granting entities temporary exemption from the requirement to meet the separate identification criterion, if the RFR instrument has been designated as a hedging of the risk component.

The Company has not opted for early application of any standard, interpretation or amendment that has been published but has not yet become effective under the legislation of the European Union.

16. Description of main threats and risks

Risks associated with clinical trials and innovative drug projects

The main characteristics of research projects, particularly with regard to innovative drug development projects, involve a high degree of uncertainty regarding the feasibility of achieving the anticipated results, the relatively frequent need to modify the original research assumptions, and the different and time-varying development potential of the projects related to the possibility of commercializing the compound in question.

The Company's know-how and experience, as well as the extensive literature in this area, suggest that, depending on the therapeutic group, an average of 3 to 5 out of 10 research projects in the field of innovative medicines development reach the clinical trial phase where commercialization is possible, and an average of only 1 to 2 out of 10 reach the registration phase (based on a study by Kimmitt et al., “Time and Success Rates of Pharmaceutical R&D”, 2020). The development of innovative medicines is associated with a number of risks, the two main ones being:

i) delays in the execution of the project, for instance as a result of a change in the original assumptions, which reduce the possible market potential of the compound and limit the possibility of its commercialization, and

ii) failure to achieve the intended research outcomes as a result of failure to achieve the expected pharmacological and clinical parameters of the selected compound or drug candidate.

Should such events occur, the Company may face termination of the research project at a stage prior to its commercialization and thus may not receive a return of its research and development expenditures. At the moment, five of the Company's 15 research projects are at the clinical trial phase. Clinical trials conducted on humans constitute a very important stage of work related to preparation for registration and commercialization, which is subject to significant risks. In particular, it is possible that the results of clinical trials are not consistent with the anticipated results, which may give rise to the need for conducting additional clinical trials or developing new protocols for such trials. Such events may delay the drug registration and therefore delay the point at which the Company will start generating revenues from the sale of the drug and may lead to the project's failure. In particular, in the case of projects discontinued at the clinical trials phase or earlier, the scale of the costs incurred to execute them may prove to be significant, which could have a negative impact on the Company's business activity, financial performance or prospects.

As at the date of preparation of this report, the Company assesses the relevance of this risk factor to be high, that the probability of the occurrence of this risk is moderate and that, should this risk occur in the future, the scale of its negative impact on the Company's business activity, financial performance or prospects would be significant.

Risks associated with reliance on and collaboration with suppliers

The Company relies, and expects to continue to rely, on third parties to purchase machines, equipment and components for the production of particular drugs, including active substances and chemical reagents as well as laboratory equipment used in research and development. Given the risk of supply chain disruption, the Company sources active substances from Poland, Germany, Italy, Canada, Israel, and India. The main suppliers of both active substances and reagents provide the Company with 80% of its resource needs. The replacement of any of the Company's major suppliers may impose significant efforts on the Company's part and could potentially result in delays in the delivery of materials, additional costs or involve the suspension of sales of the Company's products. In the case of active substances subject to registration in the Company's product registration dossier, supply disruptions may significantly affect the ability to produce the finished product. Almost all active substances included in the registration dossiers of the Company's products have at least two qualified and registered suppliers, thus the risk is reduced. However, replacing any of the suppliers, e.g., in the case of contamination of active substances, may require significant efforts on the Company's part and potentially cause delays in the delivery of materials, additional costs or involve the suspension of sales of the Company's products. A part of the Company's machinery park, in particular the equipment used in the manufacture of dry powder inhalers, is of a unique nature. These are customized machines individually designed to meet the needs of the Company's production processes. Given that the vast majority of investment tasks related to the construction of a machinery park to secure current and future (in the perspective of the next few years) production needs have already been completed, the risk of reliance in this case relates to being able to smoothly and timely service and repair such equipment, particularly the unique equipment. Any delays in servicing and repairing the Company's machinery park may cause delays in the production of the Company's products or the Company's ongoing research projects.

Furthermore, if suppliers fail to meet their contractual obligations, fail to meet expected deadlines or fail to comply with regulatory requirements, the development of potential drugs and the commercialization of drugs produced by the Company may be suspended, delayed or become less profitable, which could have a negative impact on the Company's business activity. Moreover, if the suppliers fail to comply with employment, social and recognized ethical standards or other standards, the Company's reputation, image and the perception of its products may be adversely affected or harmed.

As at the date of preparation of this report, the Company assesses the relevance of this risk factor to be high, that the probability of the occurrence of this risk is low and that, should this risk occur in the future, the scale of its negative impact on the Company's business activity, financial performance or prospects would be significant.

Risk associated with losing key wholesalers or distributors of generic drugs, and as a consequence – final customers

Due to the regulations regarding the trade in pharmaceutical products, the Company cannot directly influence the purchasing decision of the final customers, i.e., patients, through advertisement. That is why, in terms of the scope of marketing products, the Company is dependent on wholesalers or distributors. In Poland, the Company sells its generic drugs mostly to pharmaceutical wholesalers. The Company cooperates with and delivers its products to 14 pharmaceutical wholesalers that account for over 95% of the Company's turnover from pharmaceuticals in Poland. Such wholesalers supply drug stores and hospitals directly or indirectly; most of them are sold nationwide. The three biggest wholesalers in Poland account for approx. 70% of the Company's revenue generated in Poland. The fact that the majority of these wholesalers operate in drug stores across Poland limits the risk of a significant sales decline of Company's products to drug stores across Poland in the event of ceasing cooperation with one of such wholesalers. Outside of Poland, the distribution of the Company's products takes place through external business partners who are responsible for marketing and sale of the Company's drugs on foreign markets. The Company gives the partners the rights to distribute and sell the Company's products on territories which usually cover one or more countries, based on the concluded license agreements. Partners rarely withdrew from such a cooperation voluntarily. However, discontinuing cooperation with a partner may result from situations such as the partner's bankruptcy or being taken over by a different entity that may have its own competitive product and might want to replace the Company’s product. In such a case, the Company will be forced to look for a new partner, which – depending on the market – might be connected with a temporary decrease in sales of products on the given territory or might delay the Company’s entrance on the given market.

The Company limits dependence on its key wholesalers or distributors of generic drugs by diversifying such partners. There is a risk of losing one or more of such wholesale recipients. Losing one or more of such wholesale recipients or business partners may temporarily disrupt the process of distributing and selling drugs, and in consequence negatively impact their availability to final customers, meaning patients, which may negatively impact the Company’s financial situation. Moreover, lower revenues from generic drugs may have a negative impact on the financing of the Company's research activity.

As at the date of preparation of this report, the Company assesses the relevance of this risk factor to be high, that the probability of the occurrence of this risk is low and that, should this risk occur in the future, the scale of its negative impact on the Company's business activity, financial performance or prospects would be significant.

Risk associated with recruiting patients for clinical trials

The Company is dependent on recruiting patients for clinical trials for its new generic and innovative drugs. Patient recruitment depends on numerous factors, including the size and nature of the patient group, qualification criteria for a given trial, proximity of the clinics, the draft clinical trial protocol, the existence of competitive clinical trials, availability of new drugs approved for the indication that is the subject of the clinical trial and the clinician's and patient's perception of potential benefits of the researched drug compared to other available therapies. As some of the drugs developed by the Company focus on rare diseases and disorders, the Company can engage a limited number of patients in order to complete its clinical trials in a timely and cost-effective manner. In the case of rare diseases or disorders, the Company is competing also for patients with competitive programs conducted by other entities. Additionally, studies performed on patients in clinical trials may also be limited or discontinued due to additional guidelines of regulators, including ethical committees that might require a change to the method of conducting trials, which in consequence may influence the timely completion of the clinical trial. The above events constitute a permanent risk in the Company's activity, and they did happen in the past, resulting in a delay of innovative projects implemented by the Company in relation to their original schedule; such delays might also occur in the case of the currently implemented innovative projects.

Moreover, the Company's efforts aiming at establishing a relation with patient organizations as a part of recruiting patients for clinical trials might prove unsuccessful due to varying standards of care in different countries or varying opinions of the ethics committees analyzing the trials, which might cause delays in enrolling patients for such clinical trials. Moreover, any negative effects of the clinical trials for one of the potential drugs of the Company may hinder or make it impossible to recruit and keep patients in other clinical trials for this potential drug, as well as impact other projects of the Company due to the risk of a tarnished reputation.

As at the date of preparation of this report, the Company assesses the relevance of this risk factor to be high, that the probability of the occurrence of this risk is moderate and that, should this risk occur in the future, the scale of its negative impact on the Company's business activity, financial performance or prospects would be significant.

Risk of underestimation of costs related with development and commercialization of drugs

The Company estimates the costs of each R&D project concerning a new drug taking into consideration different scenarios, including the level of financing from own funds as well as external funds (e.g., grants), and the possibility of establishing relations with potential distributing partners. The possibility that the actual amount of costs of R&D projects conducted by the Company will be significantly higher than originally expected cannot be excluded. The potential reasons for underestimation of costs of development of drugs and introduction of the developed drugs to the market might include: (i) changes of provisions of law resulting in, among others, the necessity of changing the technology used by the Company or necessitating the incurring of additional expenditure and time for the Company to adjust to the new regulations, (ii) the necessity to expand the scope of clinical trials, (iii) the increase of costs related to the purchase of raw materials or active substances, as well as (iv) shortage or decrease of the quality of raw materials and materials used for manufacturing drugs. The above-mentioned events constitute a constant risk in the Company's activity and in the past, there were indeed cases when the planned budged for a given project was exceeded in relation to, for instance, underestimation of costs or increasing the scale of the project during its course. This risk may also concern the Company's currently implemented innovative projects, whereas the possible scale of underestimation of costs can be estimated only after the projects in question have been completed. Moreover, as the development stages of the Company's innovative projects are becoming more advanced and time-consuming, the frequency of these events may increase in the future.

As at the date of preparation of this report, the Company assesses the relevance of this risk factor to be high, that the probability of the occurrence of this risk is moderate and that, should this risk occur in the future, the scale of its negative impact on the Company's business activity, financial performance or prospects would be significant.

Risk of withdrawal of marketing authorization of certain drugs manufactured by the Company or of their marketing being suspended

Prior to the introduction of each drug to the market, the Company must obtain marketing authorization for each drug, separately for each market where the Company is planning to distribute the given drug, including from the appropriate national body in the case of authorization in EU member states, of the European Medicines Agency (EMA) in the case of marketing authorization in the entire territory of the EU (centralized procedure) or of the Food and Drug Agency (FDA) in the US. There is committee concerned with safety of medicinal products operating in EMA. In the event of issues with the safety of a medicinal product that was authorized for marketing in more than one member state, within the entire EU territory, the same regulatory activities are undertaken, and the patients and health care workers in all member states receive identical guidelines. In cases specified by the law, the competent authority has the right to withdraw the marketing authorization of a drug. Withdrawal of the marketing authorization of a given medicinal product of the Company would have a negative impact on the Company's development perspective and the obtained financial results. Moreover, in certain circumstances (e.g., in the case of a justified suspicion regarding safety of the products), the appropriate supervisory authorities, including a voivodeship (regional) pharmaceutical inspectorate in Poland may issue a decision suspending the marketing of certain batches of a medicinal product, which may have a negative impact on the Company's development prospects and the obtained financial results.

As at the date of preparation of this report, the Company assesses the relevance of this risk factor to be high, that the probability of the occurrence of this risk is moderate and that, should this risk occur in the future, the scale of its negative impact on the Company's business activity, financial performance or prospects would be significant.

Risk associated with the Company being unable to enter new markets or to expand its presence on the existing markets

One of the main objectives of the Company is to sell drugs on the global markets, independently or through a pharmaceutical partner, that were developed and manufactured by the Company, including primarily markets of the UE member states and the United States of America. This is connected with the obligation for these drugs to be registered by the applicable authorities – EMA and FDA, respectively, as well as an obligation to use the applicable GMP quality system that describes the minimal standards to be met by the drug manufacturer during the manufacturing process. There is a risk that in the case of, for example, failure to adjust the products to the applicable requirements, procedural changes or mistakes in documentation, the process of registering drugs might be delayed or end with a refusal. Moreover, there is a risk that the appropriate regulatory requirements adopted by each of the relevant authorities will be significantly changed, which might cause the Company to incur additional costs or face the risk of annulment of the marketing authorization. The factors above might negatively impact the Company's activity, financial performance or prospects. Moreover, there is a risk that cooperation with a partner responsible for registering the drug in a given territory will be unsuccessful, which might cause the necessity of finding a new partner and, as a result, a delay or withdrawal of the Company from entering such a new market. As at the date of preparation of this report, the Company assesses the relevance of this risk factor to be high, that the probability of the occurrence of this risk is moderate and that, should this risk occur in the future, the scale of its negative impact on the Company's business activity, financial performance or prospects would be significant.

Risk of adverse effects caused by the Company's products and the risk of liability for products

The Company cannot exclude a situation where some of the Company's drugs and medicinal products, as well as the potential new products, demonstrate undesired or unintended side effects, toxicity or other traits that might result in preventing the Company from receiving additional marketing authorizations, withdrawing marketing authorization or preventing or limit the commercial use of the given drug. If such adverse effects are identified during the development works on the potential products of the Company, the Company might be forced to refrain from further development works on such products. If the adverse effects occur after the drug registration, the marketing profile of such approved drug might be limited or the Company might face other significant consequences, such as claims due to the liability for the product. In the case of drugs authorized for marketing in the EU, based on the scientific assessment conducted by EMA, the European Committee may grant marketing authorization, refuse to grant it, change its terms, as well as suspend the marketing authorization, it may also undertake an activity on the European-wide scale in the event of issues with the safety of the product which had been granted a national marketing authorization. However, the Company notes that the risk of side effects caused by the Company products is constant and it might be one of the most significant risks for pharmaceutical companies, in particular due to the reason that some side effects may be revealed only after a relatively long time or their significance might be underestimated during the works on the drug.

In the cases in which using medicinal products of the Company will have negative impact on the client's health, the authorization for commercialization of the Company's products might be withdrawn or might result in the injured party claiming damages from the Company in the course of civil proceedings, which might result in the liability for damages. Moreover, in such a case, the Company may also be liable due to the sale of dangerous products. There are many factors that might cause the products to be deemed as dangerous, including the manner of introducing them to the market or the manner of providing information on the product characteristics to consumers. The necessity to satisfy all or part of the damage claims directed against the Company may have a negative effect on the Company's business activity, financial performance or prospects. Moreover, in certain circumstances, the Company or its Management Board may face administrative or criminal charges in the case when the Company's drugs cause harm to patients. All of the above-mentioned events may negatively affect the Company's reputation, its image and result in a negative perception of its products.

As at the date of preparation of this report, the Company assesses the relevance of this risk factor to be moderate, that the probability of the occurrence of this risk is moderate and that, should this risk occur in the future, the scale of its negative impact on the Company's business activity, financial performance or prospects would be significant.

Risk associated with other pharmaceutical companies discovering and marketing of other drugs used in the same indications as the Company's drugs

Neuropsychiatry, metabolic diseases, inflammatory diseases and oncology, which are the key areas of the Company's activity, are being heavily researched in biomedical sciences. The dynamic development in the area of genetics and molecular biology has a significant impact on the acceleration of efforts to develop next-generation drugs. This results in a risk that new drugs characterized by an advantage in terms of effectiveness or tolerability over the drugs which are currently manufactured or developed by the Company will be marketed within the next few years. Furthermore, there is a risk that new treatment methods are discovered – e.g., vaccines intended against disorders treated with the use of drugs offered by the Company, either currently or in the future. The emergence of new, more advanced, more effective or cheaper drugs and treatment methods in areas which are the focus of the Company's activity could have a negative impact on the Company's business activity, financial performance or prospects.

As at the date of preparation of this report, the Company assesses the relevance of this risk factor to be moderate, that the probability of the occurrence of this risk is moderate and that, should this risk occur in the future, the scale of its negative impact on the Company's business activity, financial performance or prospects would be significant.

Risk associated with lack of possibility to commercialize the Company's innovative drugs

The Company's activity in the area of innovative drugs is largely based on the identification of leading compounds which have the potential to be developed into innovative drugs. The value of the Company's innovative drug projects depends on whether therapeutic actions, administration methods, better tolerability, or new medical applications of such drugs are demonstrated compared to the currently available treatment options. As at today, results of those works on the projects in question are difficult to access. Therefore, there is a risk that they will not prove to be as beneficial as anticipated, and that their commercialization will be hindered. For example, the Company might not be able to grant licenses for its innovations or might come across difficulties in finding partners which would be suitable (in terms of geographic or trade aspects) to commercialize such projects or might find it difficult to agree on satisfactory cooperation terms with such partners. Furthermore, commercialized projects might fail to achieve the anticipated milestones or performance which might have a negative impact on the Company's business activity, financial performance or prospects. Moreover, the Company's innovative projects, including the Falkieri project, are, or might become, the subject of partnering talks with potential external partners. Negotiations with such partners might not be finalized within the initially assumed time frame or the

course of talks with partners might encourage the Company to analyze alternative commercialization scenarios, including independent commercialization directly by the Company in all or selected territories. This might have a negative impact on the Company's business activity, financial performance or prospects, in particular with regard to planning the financing of the Company's activity and other innovative projects in situations where the obtained financing proves to be insufficient.

As at the date of preparation of this report, the Company assesses the relevance of this risk factor to be moderate, that the probability of the occurrence of this risk is moderate and that, should this risk occur in the future, the scale of its negative impact on the Company's business activity, financial performance or prospects would be significant.

Risk associated with reimbursement of drugs

As at the date of this report, all drugs included in the Company's portfolio (with the exception of Lazivir) are listed as reimbursed drugs, i.e., drugs financed in part or in full from public funds, as determined by the Polish Minister of Health or other foreign regulatory bodies in certain other jurisdictions.

In most jurisdictions, the market of drugs, in particular reimbursed drugs, is subject to detailed regulations. On their basis the list of reimbursed drugs, the scope of reimbursement, including pricing and reimbursement level are determined. After marketing authorization has been granted on the EU level, pricing and reimbursement decisions are taken at the level of individual member states; this decision-making takes into account the potential role and application of the given medicinal product in the context of the given country's state healthcare system. Unfavorable changes of those regulations in individual member states (e.g., reducing the level of reimbursement or removing the Company's products from the list of reimbursed drugs) might have a negative impact on the sale of the Company’s products and thus negatively affect the Company's business activity, financial performance or prospects.

As at the date of preparation of this report, the Company assesses the relevance of this risk factor to be moderate, that the probability of the occurrence of this risk is low and that, should this risk occur in the future, the scale of its negative impact on the Company's business activity, financial performance or prospects would be significant.

Risk associated with disputes related to industrial and intellectual property rights

Regulations on industrial and intellectual property rights and protection of those rights play a significant role in the Company's business activity. The Company cannot guarantee that its business activity will not lead to the violation of third-party intellectual property rights. In such situations, it cannot be excluded that third parties will pursue claims against the Company for violation of industrial and intellectual property rights (in particular patents), in particular at the level of research and at the level of obtaining marketing authorization for the Company’s medicinal products. Such claims being pursued, even if they are groundless, might have a negative impact on the time needed to obtain the aforementioned marketing authorization and defending against such claims might necessitate the incurring of significant costs, which might have a negative impact on the Company's business activity, financial performance or prospects.

Effectively pursued claims on the violation of any third-party rights against the Company or the Company's failure to effectively pursue claims on the violation on the Company's rights by third parties might have a negative impact on the Company's business activity, financial performance or prospects. For instance, GSK's claims pursued in 2018 resulted in suspended distribution of Salmex on foreign markets in 2019 and reduced revenues of the Company from the sale of this drug on certain foreign markets. Although, in January 2020, the Company, GSK, and the Glenmark Group concluded a settlement under which the Company and Glenmark could continue sales of Salmex in Poland and on selected European markets, the Company cannot guarantee that it will not be sued for the violation of other trademark and copyright protection rights by companies in the GSK group or by other entities in the future.

As at the date of preparation of this report, the Company assesses the relevance of this risk factor to be moderate, that the probability of the occurrence of this risk is low and that, should this risk occur in the future, the scale of its negative impact on the Company's business activity, financial performance or prospects would be significant.

Risk associated with refusal to grant patent protection and risk associated with withdrawal of patent protection

Patents and other intellectual property rights held by the Company might not ensure sufficient protection of its technologies and products which might limit the Company's effective advantage on the market. The Company's success is to a certain extent dependent on its capacity to obtain, maintain and enforce patents and other intellectual property rights regarding the Company's technologies and products, in Poland, the EU and other countries. The Polish Patent Office, the European Patent Office and patent offices in other countries require the compliance with a number of provisions on the incurring of fees and other similar provisions in the course of applying for the patent. Although in many cases, accidental expiry of a protection right can be remedied by way of paying a fee for late payment or in a different manner, in accordance with applicable provisions of law, there are certain situations where failure to comply with provisions might result in the rejection or expiry of a patent or a patent application, which leads to the loss of patent rights in a given legal system either in part or in full. Violations of provisions which might result in the rejection or expiry in a patent of patent application include failure to

respond to official actions within a prescribed time frame, failure to make payments or irregularities in the actions taken to secure patent protection, including failure to submit all the formally required documents. Furthermore, the granting, scope, validity, enforceability and trade value of the Company's patent rights cannot be taken for granted because the Company's currently examined and future patent applications might not result in the granting of patent protection to the Company's technologies or products, in full or in part, or which would effectively prevent other companies from commercializing competitive technologies and products. Changes to patent law or interpretations of patent law in Poland and other countries might reduce the value of the patents held by the Company or reduce the scope of the patent protection they provide.

As at the date of preparation of this report, the Company assesses the relevance of this risk factor to be moderate, that the probability of the occurrence of this risk is moderate and that, should this risk occur in the future, the scale of its negative impact on the Company's business activity, financial performance or prospects would be significant.

Foreign exchange risk

Most machines and devices, laboratory equipment, active substances required for manufacturing and reagents for conducting research are bought from foreign suppliers at prices determined in foreign currencies, including in particular EUR and USD. Unfavorable currency exchange changes (the weakening of the Polish currency in relation to foreign currencies) might have a negative impact on the level of the Company's investment outlays and might result in increased costs of manufacturing products and conducting R&D works, which in turn may negatively affect the Company's financial performance. To date, usually the Company's revenues and expenditure in foreign currencies balance out, as the Company generates revenue in EUR on account of exporting its drugs. However, the Company's revenues in foreign currencies are on the rise and the Company anticipates that they will continue to increase as the Company's planned development on foreign markets continues. That will be associated with greater exposure to currency exchange changes in the future, in particular given the fact that most of the Company's costs are incurred and most likely will continue to be incurred in PLN.

As at the date of preparation of this report, the Company assesses the relevance of this risk factor to be moderate, that the probability of the occurrence of this risk is moderate and that, should this risk occur in the future, the scale of its negative impact on the Company's business activity, financial performance or prospects would be significant.

Risk associated with the loss of key employees

Effective operations of the Company and successful implementation of its strategy depend on the experience of its managers and key personnel. Given the specific nature of the Company's area of activity, it depends on highly qualified, technically skilled and creative employees whose high level of competencies and skills allow for developing new technologies and innovative products. The Company's actions are based on the know-how and experience of its highly qualified management, including the President of the Management Board – Maciej Wieczorek, Vice-President of the Management Board – Jacek Glinka and managers responsible for individual business areas (including R&D, production and supplies, sales and marketing, as well as finances and accounting). Competencies, loyalty and commitment of key employees are the main factors affecting the Company's everyday activity and its development. There is a risk that competition on the market where the Company operates, fueled by i.a. the shortage of experts with relevant qualifications, will result in resignations of employees of key importance to the Company, and the Company cannot guarantee that it will be able to recruit and retain such key employees in the future, including to obtain experts whose employment will prove necessary for the Company's future development, which might negatively affect Company's business activity, financial performance or prospects. In view of the above, the Company might also be forced to incur higher payroll costs. The Company is of the opinion that, to date, employee rotation in the Company was at a level typical for this industry, however, given the aforementioned factors, in particular the anticipated growing demand for such experts on the market, the Company cannot exclude such events happening more often in the future. Losing expert employees and key managers might have a negative impact on the Company's research capacities and the development of drug candidates, as well as on successful implementation of the Company's strategy.

As at the date of preparation of this report, the Company assesses the relevance of this risk factor to be moderate, that the probability of the occurrence of this risk is low and that, should this risk occur in the future, the scale of its negative impact on the Company's business activity, financial performance or prospects would be significant.

Risk associated with possible disclosure of trade and technological secrets

The successful implementation of the Company's plans in regard to i.a. innovative drug projects or details of conducted clinical trials might depend on whether confidential information held by the Company, in particular information regarding the conducted trials and technological processes, are kept secret. Only the Company's management and key employees and occasionally partners of projects implemented by the Company, such as academic establishments, have access to sensitive, confidential information regarding the Company's activity, such as its strategic plans, its planned business ventures and its key technologies. However, a situation where such information is disclosed and used by persons cooperating with the Company, in particular by its employees, cannot be excluded; as a result, such information could be used by the Company's competitors. In a such event, the measures protecting the Company's rights, in particular the claims which could be pursued by the Company, might prove insufficient to protect the Company against the negative effects of such events, which might have a negative impact on the Company's business activity, financial performance or prospects. The Company is of the opinion that this risk will become more significant in the future as the Company continues to develop its innovative project and as the Company develops its unique know-how in the course of its regular activity.

As at the date of preparation of this report, the Company assesses the relevance of this risk factor to be moderate, that the probability of the occurrence of this risk is low and that, should this risk occur in the future, the scale of its negative impact on the Company's business activity, financial performance or prospects would be significant.

Risk associated with granted co-financing

In relation to its innovative projects, the Company had implemented and is currently implementing projects co-financed from national and EU public funds, including programs implemented and managed by the National Center for Research and Development. Individual agreements on co-financing, terms of grant contests or applicable provisions of law determine detailed rules on i.a. applying for grants, using allocated funds, implementing projects, as well as interim reporting of their results. With regard to currently implemented projects, the Company applies due diligence to ensure that the projects are implemented in line with the agreements on co-financing, in particular with regard to schedules of works and expenditures. To the best of the Company's knowledge, there are no circumstances which would result in the Company's obligation to return the support obtained for the purpose of projects implemented with the use of public funds. However, the risk that competent national or EU bodies and institutions audit the Company with regard to the correctness of the project implementation, the achievement of their objectives and the use of the received funds as intended and identify possible deficiencies, and in consequence demand that a part of or the entire grant be returned with interest cannot be excluded. The possible requirement to return the co-financing might be associated with the risk of negatively affecting the Company's reputation and potential exclusion of the Company from participation in future grant contests on the basis of relevant provisions governing the allocation of funds in such contests. The above-mentioned entitlements of public bodies are usually subject to a 10-year period of limitation, calculated from the date on which the grant was awarded, i.e., the conclusion of individual agreements on co-financing. The possible demand to return the funds in part or in full might have a negative impact on the Company's business activity, financial performance or prospects.

As at the date of preparation of this report, the Company assesses the relevance of this risk factor to be moderate, that the probability of the occurrence of this risk is low and that, should this risk occur in the future, the scale of its negative impact on the Company's business activity, financial performance or prospects would be significant.

Risk associated with failure to secure grants for planned innovative projects

As part of the Company's development strategy, the Management Board adopted an investment program which covers in particular outlays on two areas of activity related to: (i) the development of inhaled drugs and their registration in European and North American markets and (ii) the development of new drug projects, including potential innovative drugs. EU subsidies which are estimated to account for approx. 50-60% of the planned project costs constitute a significant source of funds covering the Company's investment plans; the remaining costs are to be financed from the Company's own funds.

However, one cannot exclude the risk where the grant applications submitted by the Company are not successful due to the competitive nature of acquiring funds for innovative projects. To date, the Company has been successful in obtaining co-financing for the majority of its projects, however, should the application be rejected, it will be forced to search for other sources of financing its planned innovative projects; that might significantly delay their implementation and/or result in the need to engage the Company's equity or increase its debt. The actual options of the Company obtaining additional funds will depend on the financial, economic, market and other factors, over which the Company might have limited control or no control whatsoever. If the relevant funds are not available on acceptable commercial terms or if support from public funds is not granted within the required time frame and in the sufficient amount, the Company might be forced to delay, limit or discontinue the implementation of its strategy or might not be able to make the best of future business opportunities. The above risks might negatively impact the Company's business activity, financial performance or prospects.

As at the date of preparation of this report, the Company assesses the relevance of this risk factor to be moderate, that the probability of the occurrence of this risk is moderate and that, should this risk occur in the future, the scale of its negative impact on the Company's business activity, financial performance or prospects would be significant.

Risk associated with the use of hazardous substances and generating hazardous waste

The specific nature of the Company's activity which includes manufacturing of drugs and conducting research in this area is associated with the need to use chemical substances categorized as hazardous, such as oil, gas and benzine, including laboratory-scale use of carcinogenic and teratogenic substances, as well as the creation of hazardous waste. This is associated with potential exposure of the Company's employees to harmful effects of such substances and waste.

Given that the carcinogenic and teratogenic substances are used on a small scale, mainly for use in laboratories, and because relevant procedures are in place, the Company accesses this risk as low. However, one cannot exclude the risk where, in the event of a possible violation of the requirements related to the use of hazardous substances and the creation of such waste adopted by the Company, authorities will impose a penalty, including the order to discontinue or limit a given type of activity. Furthermore, the risk of a malfunction or other event resulting in harm to persons exposed to contact with substances or waste cannot be excluded; that might result in possible claims and the Company's liability, including financial liability. It is also possible that future legal regulations regarding requirements on handling hazardous substances will result in the need to limit the Company's current activity or to incur outlays to adjust the Company's activity to the new legal requirements; that might have a negative impact on the Company's business activity, financial performance or prospects. Violations of requirements regarding the handling of hazardous substances or creation of such waste might result in the Company incurring significant costs due to administrative fines or criminal penalties, as well as being liable for damages. Although the Company is insured against its employees' civil liability and such insurance covers the costs and expenses which the Company might be forced to incur in relation to injuries to its employees resulting from the use of hazardous materials or other work-related injuries, such insurance will not provide the required protection against potential liability.

As at the date of preparation of this report, the Company assesses the relevance of this risk factor to be moderate, that the probability of the occurrence of this risk is low and that, should this risk occur in the future, the scale of its negative impact on the Company's business activity, financial performance or prospects would be significant.

Risk associated with the competitive nature of the market in which the Company operates

Historically, the Company was focused on the production of generic drugs. In 2006, the Company started expanding its activity towards the development of inhalation drugs categorized as the so-called generics plus, biosimilars and innovative drug projects. The generic drug market is characterized by low barriers to entry and the possibility of generating stable revenues and achieving a significant market share over a short period of time. As a result, the first years after patent protection expires lead to a quick quantitative increase in the sale of generic drugs. However, as new generics to original drugs are introduced to the market over the course of a few years, the drug price erodes quickly and a systematic reduction of the cost-effectiveness of the generic drug sales on the given market is observed. One cannot exclude a risk where revenues from the sale of generics included in the Company's product portfolio drop more quickly than anticipated by the Company; that might result in the need to withdraw the given drug from the product portfolio and cause a temporary reduction of revenues from sales and financial performance.

The market of innovative therapeutics as characterized by relatively lower competitiveness, which results from the fact that registration and marketing of an innovative drug requires time-consuming and costly research and preparation of the full registration dossier. The process between the commencement of the research of such a drug and marketing it takes approx. 10 years. The Company cannot foresee how powerful and numerous the competition will be, however, greater competitiveness on the market is inevitable; this gives rise to the risk that the capacity to achieve the planned market share and the capacity for sales or commercialization of the pending innovative projects will be limited.

Publicly available information suggests that currently there are many entities on the market which are developing generics to the same original drugs targeted by the Company and that works on some of them are already very advanced. There is a risk that upon expiry of patent protection for the original drugs, some of those entities will be ready to market their own generics. This will increase the competition against the Company (e.g., the competitors might market their products sooner or introduce cheaper drugs etc.) and might force the Company to revise its assumptions as to the planned market share or the anticipated potential revenues.

The Company's commercial capacities might also be limited or eliminated if the competitors manage to develop and market products which are safer, more effective, are characterized by less frequent or significantly less severe adverse effects, are more convenient to use or cheaper than the products developed by the Company. It is also possible that the Company's competitors will obtain the necessary authorizations from regulatory bodies for their products sooner than the Company; this might lead to the Company's competitors achieving a strong market position before the Company manages to enter a given market. As a result, the actions aimed at discovering new potential drugs might prove not to be cost-effective for the Company; that might weaken its market position and have a negative impact on the Company's business activity, financial performance or prospects.

As at the date of preparation of this report, the Company assesses the relevance of this risk factor to be high, that the probability of the occurrence of this risk is moderate and that, should this risk occur in the future, the scale of its negative impact on the Company's business activity, financial performance or prospects would be significant.

Risk associated with national and international legal regulations

Frequent amendments of provisions to which the Polish legal system is prone may constitute a potential risk for the Company; the Management Board's assumptions with regard to its business activity might became out of date and its financial standing might deteriorate. The regulations which have the largest impact on the Company's operations include in particular pharmaceutical law, tax law and intellectual property law. Amendments to the aforementioned regulations might lead to a significant change to the provisions of law applicable to the Company and impact its financial performance, for example by way of increasing the operating costs (through a direct increase of tax burdens or additional expenditure required to meet new legal and administrative requirements), the extending of manufacturing and investment processes, the imposing of administrative fees and tax burdens on the Company in relation with non-compliance with provisions of law found by public administration bodies.

Another significant factor which might impact the Company's business activity, financial performance or prospects is the issue of discrepancies between interpretation of Polish and EU provisions of law. Inconsistent interpretation of provisions by Polish courts and public administration bodies, as well as EU courts might affect the Company both indirectly and directly.

The Company cannot guarantee that it will obtain the required administrative decisions for its drug development project, nor that no current or future administrative decisions will be questioned, withdrawn, amended, repealed or cancelled. Such situations may delay or change the original projects and have a negative impact on the Company's business activity, financial performance or prospects.

As at the date of preparation of this report, the Company assesses the relevance of this risk factor to be moderate, that the probability of the occurrence of this risk is moderate and that, should this risk occur in the future, the scale of its negative impact on the Company's business activity, financial performance or prospects would be significant.

Risk associated with tax policy

The Company is subject to complex tax legislation in both Poland and other countries where it is operational; this exposes it to frequent changes and lack of precision of tax regulations which often lack a consistent interpretation. Both the practices of tax offices and court decisions on tax issues which are based on ambiguous legal regulations increase the risk for business activities in Poland compared to more stable tax systems in place in more mature economies. The Company enjoyed a tax relief on account of its research and development activity, which allows the Company to deduct anew additional 100% of eligible expenditure incurred on such activity, which has already been classified as tax deductible cost from the tax base. Additionally, in line with the current tax regulations, it is also possible to use the so-called IP Box eligible IP rights mechanism, which makes it possible to apply a preferential tax rate, i.e., 5% from the tax base, that is the income. The Company can apply that preferential rate in the case of commercialization of certain projects. Possible new tax provisions or regulations might be introduced retroactively or non-retroactively; there might also be changes to the applicable interpretation and enforcement of such provisions or regulations, which might have a negative impact on the tax provisions currently applied by the Company.

As at the date of preparation of this report, the Company assesses the relevance of this risk factor to be moderate, that the probability of the occurrence of this risk is moderate and that, should this risk occur in the future, the scale of its negative impact on the Company's business activity, financial performance or prospects would be significant.

Risk associated with decisions taken by the Company's main shareholder

Glatton Sp. z o. o., a company where the sole shareholder is Maciej Wieczorek – the President of the Company's Management Board, holds 58.83% of shares in the Company's share capital; that gives it the right to 68.19% of the total votes in the General Meeting of Shareholders. As the dominating shareholder in the Company, Glatton Sp. z o.o. can significantly impact decisions of the General Meeting of Shareholders regarding payment and amount of dividends, and even decide not to make such a payment in particular financial years, or decide to vote in favor of payment of a dividend which is higher or lower than the amount recommended by the Company's Management Board, which might be contrary to the interest and expectations of the other shareholders and Management Board. Glatton Sp. z o. o. and its sole shareholder Maciej Wieczorek have decisive impact on the Company's affairs, including i.a. the shaping of the Company's policies and strategies, the directions in which the Company will develop, the selection of Supervisory Board members and, indirectly, the Company's Management Board. Resolutions of the General Meeting of Shareholders adopted with the majority shareholder's votes might not be consistent with the intentions or interests of minority shareholders. It is not possible to foresee whether the majority shareholder's policy and actions will be convergent with the interests of other shareholders of the Company.

As at the date of preparation of this report, the Company assesses the relevance of this risk factor to be moderate, that the probability of the occurrence of this risk is low and that, should this risk occur in the future, the scale of its negative impact on the Company's business activity, financial performance or prospects would be significant.

Risk associated with potential conflicts of interest

As at the publication of this report, the following relations between members of the Management Board and the Supervisory Board exist:

i) Maciej Wieczorek is indirectly the majority shareholder of the Company; he is the President of the Company's Management Board, the husband of a Member of the Supervisory Board, Urszula Wieczorek and the father of another Member of the Supervisory Board, Artur Wieczorek;

ii) Urszula Wieczorek, a member of the Supervisory Board, is the mother of another Member of Supervisory Board – Artur Wieczorek.

In view of the above, there is a potential risk of a conflict of interest among the above-mentioned individuals and between the above-mentioned individuals and the Company. This conflict could lead to a collision between the obligation to act in the best interest of the Company or to remain independent, and the personal interests of those individuals. The interest of each of the above-mentioned individuals might not be identical to the Company's interests, therefore the risk associated with a conflict of interest which might end unfavorably for the Company should be taken into account.

As at the date of preparation of this report, the Company assesses the relevance of this risk factor to be moderate, that the probability of the occurrence of this risk is low and that, should this risk occur in the future, the scale of its negative impact on the Company's business activity, financial performance or prospects would be significant.

Document signed by Maciej Wieczorek
Date: Date: 09.20.2021 16:17:35 CEST

Signature Not Verified
Document signed by Jacek Glinka
Date: 2021.09.30 15:54:34 CEST

The Management Board of Celon Pharma S.A.

Maciej Wieczorek - Prezes Zarządu

Jacek Glinka - Wiceprezes Zarządu

Iwona Giedronowicz - Członek Zarządu

Kiełpin, September 30, 2021

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