



**RYVU THERAPEUTICS S.A.**

**Q1 2022 report**



## TABLE OF CONTENTS

1	ECONOMIC AND FINANCIAL HIGHLIGHTS .....	1
1.1	Financial Results Obtained in the Reporting Period.....	1
1.2	Management Board comments to the financial results.....	2
1.3	The Company's Assets and the Structure of Assets and Liabilities .....	4
1.4	Current and Projected Financial Condition .....	5
2	MANAGEMENT BOARD INFORMATION ON ACTIVITES .....	6
2.1	The pipeline .....	6
2.2	Significant events in Q1 2022 .....	12
2.3	Unusual events occurring in the reporting period .....	15
3.	THE ISSUER'S CORPORATE BODIES.....	17
4.	INFORMATION ON THE SHAREHOLDERS HOLDING (DIRECTLY OR INDIRECTLY) AT LEAST 5% OF THE TOTAL NUMBER OF VOTES AT THE GENERAL SHAREHOLDERS' MEETING OF THE COMPANY AND ON SHARES HELD BY MEMBERS OF THE ISSUER'S MANAGEMENT BOARD AND SUPERVISORY BOARD....	18
5.	ADDITIONAL INFORMATION.....	20

# 1. ECONOMIC AND FINANCIAL HIGHLIGHTS

## 1.1 Financial Results Obtained in the Reporting Period

Financial Statements of Ryvu Therapeutics S.A. (“Company”, “Issuer”, “Ryvu”) for the period from January 1, 2022 to March 31, 2022 are prepared in accordance with the International Financial Reporting Standards.

Selected income statement data are as follows:

Ryvu Therapeutics S.A. Item	Data in PLN thousand		Data in EUR thousand	
	From 01.01.2022 to 31.03.2022	From 01.01.2021 to 31.03.2021	From 01.01.2022 to 31.03.2022	From 01.01.2021 to 31.03.2021
Revenues from sales	228	432	49	94
Revenues from subsidies	6.754	6.121	1.453	1.339
Revenues from R&D projects	-	-	-	-
Other operating revenues	111	93	24	20
Revenues from operating activities	7.093	6.646	1.526	1.454
Operating expenses	-33.847	-22.301	-7.283	-4.878
Operating expenses without Incentive Scheme	-25.698	-22.301	-5.530	-4.878
Depreciation	-3.375	-2.889	-726	-632
Valuation of Incentive Scheme	-8.149	-	-1.754	-
Profit/loss from operating activities (EBIT)	-26.754	-15.655	-5.757	-3.424
Profit/loss from operating activities (EBIT) without Incentive Scheme	-18.605	-15.655	-4.003	-3.424
Profit/loss before income tax	-26.583	-13.224	-5.720	-2.892
Net profit/loss	-26.536	-13.563	-5.710	-2.966
Net profit/loss without Incentive Scheme	-18.387	-13.563	-3.957	-2.966
EBITDA	-23.379	-12.766	-5.031	-2.792
EBITDA without Incentive Scheme	-15.230	-12.766	-3.277	-2.792
Net cash flows from operating activities	-21.807	-11.244	-4.693	-2.459
Net cash flows from investing activities	4.143	-2.038	892	-446
Net cash flows from financing activities	-768	-733	-165	-160
Total net cash flow	-18.432	-14.015	-3.966	-3.065
Number of shares (weighted average)	18.355.474	18.355.474	18.355.474	18.355.474
Profit (loss) per share (in PLN)	-1.45	-0.74	-0.31	-0.16
Diluted profit (loss) per share (in PLN)	-1.45	-0.74	-0.31	-0.16
Book value per share (in PLN)	8.23	11.45	1.77	2.46
Diluted book value per share (in PLN)	8.23	11.45	1.77	2.46
Declared or paid dividend per share (in PLN)	-	-	-	-

### Selected balance sheet data are as follows:

Ryvu Therapeutics S.A. Item	Data in PLN thousand		Data in EUR thousand	
	31.03.2022	31.12.2021	31.03.2022	31.12.2021
Total assets	<b>201.402</b>	228.813	<b>43.289</b>	49.748
Short-term receivables	<b>9.574</b>	11.741	<b>2.058</b>	2.553
Cash and cash equivalents	<b>64.804</b>	83.236	<b>13.929</b>	18.097
Other financial assets	-	4.994	-	1.086
Total liabilities	<b>50.368</b>	59.392	<b>10.826</b>	12.913
Long-term liabilities	<b>25.975</b>	23.192	<b>5.583</b>	5.042
Short-term liabilities	<b>24.393</b>	36.200	<b>5.243</b>	7.871
Total equity	<b>151.034</b>	169.422	<b>32.463</b>	36.836
Share capital	<b>7.342</b>	7.342	<b>1.578</b>	1.596

### Selected financial data presented in the Quarterly report were converted to Euro as follows:

1. Items relating to the profit and loss statement and the cash flow statement were converted using the exchange rate constituting the arithmetic average of the exchange rates, applicable as of the last day of every month in the given period, based on the information published by the National Bank of Poland (NBP):
  - for the period from 01/01/2022 – 31/03/2022: PLN 4.6472;
  - for the period from 01/01/2021 – 31/03/2021: PLN 4.5721;
2. Balance sheet items were converted using the average exchange rate announced by the NBP applicable as at the balance sheet date; which were:
  - as of 31 March 2022: PLN 4.6525;
  - as of 31 December 2021: PLN 4.5994.

## 1.2 Management Board comments to the financial results

In the first quarter of 2022, Ryvu Therapeutics S.A. recognized the total operating revenue of PLN 7,093 thousand, which constitutes an increase compared to the corresponding period in 2020, when the total operating revenue amounted to PLN 6,646 thousand. This results from the increase in revenues from subsidies (increase of PLN 633 thousand), partially compensated by the decrease in revenues from sales (decrease of PLN 204 thousand) compared to the corresponding period in 2021.

In the first quarter of 2022, Ryvu reported a net loss as well as an operating loss. The net and operating losses are the result of the new Company's strategy of Ryvu published on June 15, 2020 for the years 2020-2022, which develops and revises the assumptions of the strategy adopted by the Company for 2017-2021, published in the current report No. 27/2017 of August 2, 2017 (before the corporate split

of the Issuer). According to the Strategy, the Company focuses currently on increasing the value of the ongoing projects, that will be commercialized at a later stage of development.

The Company's net loss for period ended March 31, 2022, amounted to PLN 26,536 thousand in comparison to the net loss of PLN 13,563 thousand in the corresponding period of 2021. The bigger loss in 2021 is related to non-cash cost of valuation of incentive program for its employees of PLN 8,149 thousand (described below) as well as higher expenditure incurred on research and clinical projects.

## Valuation of shares in NodThera Inc.

### Valuation of shares

Three types of shares exist in NodThera Inc: ordinary (stock) and preferred stock (Junior Preferred Stock, Series A1 and A2 Preferred Stock and Series B Preferred Stock). Ryvu is a holder of the Junior Preferred Stock.

Associated with the Series A and B Preferred Stock is the right to receive dividends in the form of cash or the issuance of shares of the same class. The payment of dividends may be made in cases specified in the investment agreement, in particular in the event of a sale of the company or the admission of its shares to trading on a stock exchange. As of December 31, 2021, in aggregate, shareholders of Series A and Series B preferred stock were entitled to receive 4,041,698 shares of NodThera stock as dividends. Accordingly, as a consequence of the dividend payments in the form of a share issue, Ryvu share in the share capital of NodThera decreased (from 4.73% to 4.30%). In light of the above, as of December 31, 2021, the Management Board of Ryvu has decided to include in the valuation of the shares held by Ryvu in NodThera, a 10.01% discount to the price at which they were subscribed under the last share capital increase, i.e. series B2 and the above approach continues as of March 31, 2022.

Therefore, a share valuation of GBP 2.8069/share (share price including a discount corresponding to the class of shares held by the Issuer) should be used as a basis for the calculations. As of 31.03.2022 Ryvu holds 4.19% shares in NodThera on a fully diluted basis and the total valuation of Issuer's shares in NodThera Inc. amounts to PLN 29,401,822 (at the average NBP exchange rate of 5.4842 PLN/GBP).

### Valuation of shares in NodThera Inc. according to fair value:

new share issue price (in GBP)	2.8069
average NBP exchange rate from March 31, 2022	5.4842
new share issue price (in PLN)	15.39
the number of the Company's shares in NodThera Inc.	1.910.000
value of shares in the balance sheet as of March 31, 2022	29.401.822
value of shares in the balance sheet as of December 31, 2021	29.403.922
change in valuation – gross impact on valuation of shares	-2.100
deferred tax	-399
net impact on valuation of shares	-1.701

## Incentive Scheme

On May 17, 2021, the General Shareholders Meeting adopted the non-dilutive Stock Grant Program for 2021-2024 for all employees in the form of the right to acquire shares of the Company. Subject of The Stock Grant Program is comprised of 1,247,720 ordinary shares of the Company that have been donated free of charge by Mr. Paweł Przewięźlikowski – founder, President of the Management Board and Company's largest shareholder to the Company, constituting a total of 25% of the Company's shares held by Mr. Paweł Przewięźlikowski. The Stock Grant Program provides employees with the right to acquire shares at a preferential price of PLN 0.19 per share, covering the Company's administrative costs incurred to execute the Stock Grant Program. The fair value of the shares granted is determined as of the grant date and recognized over the vesting period in remuneration costs in correspondence with the capital increase at the time of vesting by employees during the program. For the period ending March, 2022 the Company recognized the non-cash cost of valuation of this incentive program of PLN 8.149 thousand – more details are described in note 36 to the financial statements.

### 1.3 The Company's Assets and the Structure of Assets and Liabilities

As of March 31, 2022, the value of the Company's assets was PLN 201,402 thousand and decreased by PLN 27,411 thousand compared to the end of 2021 (PLN 228,813 thousand), mainly due to expenditures on R&D projects. At the end of March 2022, the highest value of current assets is cash which amounted to PLN 64,804 thousand (at the end of 2021 it was PLN 83,236 thousand). The decrease in cash resulted from the aforementioned spending incurred on R&D projects and corporate income tax payment for converting shares held in NodThera Ltd. into NodThera Inc. in the amount of PLN 5,458 thousand. Fixed assets are mainly Research and Development Centre for Innovative Drugs (named 'CBR') and laboratory equipment and the valuation of NodThera of PLN 29,402 thousand. The value of non-current assets decreased in comparison to December 31, 2021, by PLN 2,278 thousand. The decrease consists mainly of the depreciation of fixed assets partially compensated by expenditures on equipping CBR.

The main item in Ryvu's equity and liabilities is equity, which amounted to PLN 151,034 thousand as of March 31, 2022, and decreased by PLN 18,388 thousand compared to December 31, 2021. The decrease in equity is mainly a result of the net loss recognized for the period. The other source of assets' funding is long-term liabilities which amounted to PLN 25,975 thousand at the end of March 2022. Long-term liabilities mainly related to deferred income related mainly to the infrastructure subsidy for CBR.

The assets structure demonstrates the Company's high financial liquidity, which is confirmed by the following ratios:

	31.03.2021	31.12.2021
<b>Current ratio</b>		
<b>current assets/current liabilities including short-term provisions and accruals (excl. deferred revenues)</b>	4.26	3.83
<hr/>		
<b>Quick ratio</b>		
<b>(current assets-inventory)/current liabilities including short-term provisions and accruals (excl. deferred revenues)</b>	4.16	3.75

Cash surpluses, not used in the operating activities, are deposited in the low-risk financial instruments like short term bank deposits, Pekao Leasing S.A.'s bonds.

#### 1.4 Current and Projected Financial Condition

The Company's financial position as of the report date is good. As of March 31, 2022, the value of the Company's cash amounted to PLN 64,804 thousand, and as of May 12, 2022, it was PLN 57,800 thousand. The decrease in cash has resulted from expenditure on R&D projects.

The Company meets its obligations in a timely manner and maintains sustainable cash levels ensuring its financial liquidity. Cash inflow from previous share issues, funds obtained from subsidies from EU funds supporting R&D projects and cash generated from the commercialization of projects allow the Company to execute its planned investments, in particular, the development of the ongoing and new innovative projects and expansion of laboratory infrastructure. Future Company's revenue depends strongly on the ability to commercialize the research projects.

## 2 MANAGEMENT BOARD INFORMATION ON ACTIVITES

### 2.1 The pipeline

Ryvu Therapeutics is advancing a broad pipeline addressing emerging targets in oncology.

Ryvu's pipeline includes candidates with differentiated therapeutic mechanisms, including programs directed at kinase, synthetic lethality, immuno-oncology and immunometabolism pathways.

These research and development projects are represented below.

#### CLINICAL PROJECTS

PROGRAM / TARGET NAME	INDICATION	DISCOVERY	PRECLINICAL	PHASE I	PHASE II	PARTNER	ANTICIPATED MILESTONES
SEL24 (MEN1703) PIM/FLT3	AML					MENARINI	Phase II data 2022
RVU120 CDK8/19	AML/MDS					LEUKEMIA & LYMPHOMA SOCIETY	Additional Phase Ib data mid 2022
	SOLID TUMORS						Initial Phase I data H1 2022

#### DISCOVERY & PRECLINICAL PROJECTS

PROGRAM / TARGET NAME	INDICATION	DISCOVERY	PRECLINICAL	PHASE I	PHASE II	PARTNER	ANTICIPATED MILESTONES
<b>SYNTHETIC LETHALITY</b>							
PRMT5	SOLID TUMORS						
WRN	SOLID TUMORS						
NOVEL TARGETS	ONCOLOGY						
<b>IMMUNO-ONCOLOGY</b>							
HPK1	SOLID TUMORS						
STING	SOLID TUMORS						
DISCOVERY COLLABORATIONS						Galápagos	MERCK

Source: Company's own data.

### SEL24(MEN1703)

SEL24 (also known as MEN1703) is a selective, small molecule, dual inhibitor of PIM and FLT3 kinases, two enzymes that are strongly implicated in malignant transformation of hematopoietic cells. The compound has been discovered by Ryvu and is currently in development in collaboration with Menarini Group as a therapeutic option for cancers including acute myeloid leukemia (AML). The licensing contract with Menarini was executed in March 2017 and currently Menarini is the sole sponsor of the ongoing phase I/II clinical study. Details of this study can be found at [ClinicalTrials.gov](https://ClinicalTrials.gov/under-the-identifier/NCT03008187) under the identifier [NCT03008187](https://ClinicalTrials.gov/under-the-identifier/NCT03008187).

The successful completion of a Phase I clinical study of SEL24 in AML was announced by Menarini in March 2020 and the results were presented at the 25th Annual Meeting of the European Hematology Association (EHA) 2020. Subsequently a Cohort Expansion study in relapsed/refractory AML patients has been initiated in the United States and Europe. The aim of the Phase II study is to further investigate the single agent activity and expanding safety profile of SEL24.



The data that have been generated in the SEL24. Cohort Expansion part of the study were presented in June 2021 during the American Society of Clinical Oncology (ASCO) and European Hematology Association (EHA) Virtual Congresses. Data reported in the posters confirmed the manageable safety profile of the drug at the recommended dose and showed preliminary single agent efficacy in relapsed/refractory AML, particularly in patients with IDH mutant disease either naïve or previously exposed to IDH inhibitors.

In the above mentioned posters, that a total of four objective responses across the dose escalation (n=25) and cohort expansion (n=23) in patients with AML were reported, with 3 of those 4 responders harboring an IDH mutation. Notably, three out of five patients with IDH mutations treated at doses of 75-125 mg achieved a CR/CRi, including a patient that previously relapsed on the IDH-inhibitor enasidenib. Furthermore, one patient with an IDH1 mutation achieved a CRi and underwent allogeneic-HSCT.

Menarini stated that these results warrant further investigation of SEL24 in AML, with a potential to focus in the IDH mutated subset. A subsequent study in this patient population started in July 2021.

Moreover, on November 4, 2021 Menarini announced that the U.S. Food and Drug Administration (FDA) has granted orphan drug designation (ODD) to SEL24 for the treatment of AML.

At the 63rd ASH Annual Meeting & Exposition, held on December 11 – December 14, 2021, in Atlanta, US, Menarini presented pharmacodynamic and genomic profiling data from the First-in-Human trial. Modulation of ribosomal protein S6 phosphorylation was used as a marker for target engagement. Meaningful target engagement was achieved in 50% of patients and inhibition was maintained even at later cycles of treatment.

On April 27, 2022 it was announced that the most recent project updates will be presented during 2022 ASCO Annual Meeting. Menarini's poster is entitled: "Phase 1/2 study of SEL24/MEN1703, a first-in-class dual PIM/FLT3 kinase inhibitor, in patients with IDH1/2-mutated acute myeloid leukemia: The DIAMOND-01 trial".

On May, 12 2022 it was announced that Ryvu's partner Menarini Group disclosed in its abstract submitted for the EHA 2022 the updated safety and efficacy results from an additional expansion cohort of the DIAMOND-01 trial in 20 patients with relapsed or refractory (R/R) IDHm AML treated with SEL24.

As of 10 January 2022 (cut-off date), 14 patients were enrolled in the IDHm cohort.

Seven patients had IDH2, 1 had IDH1/2, and 4 had IDH1 mutations. Concomitant mutations in FLT3-ITD were detected in 2 patients. Of the 7 patients who completed  $\geq 1$  treatment cycle and had  $\geq 1$  postbaseline assessment or clear disease progression, ORR was 28.6%; 1 patient achieved a complete response with incomplete blood count recovery (CRi) and underwent hematopoietic stem cell transplant, 1 patient had a partial response. Preliminary results in the IDHm cohort confirm that SEL24/MEN1703, has a manageable safety profile and single-agent activity in patients with R/R IDHm AML.

Updated results will be presented by Menarini at the poster "Phase 1/2 Study of SEL24/MEN1703, a First-In-Class Dual PIM/FLT3 Kinase Inhibitor, in Patients with IDH1/2-Mutated Acute Myeloid

Leukemia: The DIAMOND-01 Trial” at the EHA Hybrid Congress 2022 which will be held on June 9-17 2022 in Vienna, Austria and on-line.

Ryvu receives information on the study progress from Menarini during periodic technical and joint steering committee meetings. Ryvu has also been assisting directly in translational research on the program funded by Menarini.

## RVU120 (SEL120)

RVU120 (also known as SEL120) is a clinical stage, selective first-in-class dual inhibitor of CDK8/CDK19 kinases. RVU120 (SEL120) has demonstrated efficacy in a number of solid tumor *in vitro* and *in vivo* models as well as in hematologic malignancies. CDK8 and its paralog CDK19 are kinase submodules of the mediator complex, involved in both transcriptional activation and repression, having central roles in the maintenance of cancer cell viability and undifferentiated state for a variety of tumor types (Dannappel et al. 2019; Rzymiski et al. 2015; Philip et al. 2018). CDK8/19-mediator complex integrates basal transcriptional machinery with the activity of oncogenic transcriptional and epigenetic factors. Inhibition of CDK8/19 can repress key oncogenic transcriptional programs and induce lineage commitment genes in AML. CDK8 and CDK19 are also preclinically validated novel targets for the treatment of breast and prostate cancers. Targeting CDK8 and its paralog CDK19 using potent and selective CDK8/19 inhibitor RVU120, may be an effective treatment for both hematological malignancies and solid tumors with deregulated transcription.

RVU120 has been internally discovered by Ryvu and has received support from the Leukemia & Lymphoma Society Therapy Acceleration Program® (TAP), a strategic initiative to partner directly with innovative biotechnology companies and leading research institutions to accelerate the development of promising new therapies for blood cancers.

On March 25, 2020, the U.S. Food and Drug Administration (FDA) granted an orphan drug designation (ODD) to RVU120, for the treatment of patients with AML.

At present, Ryvu is conducting two clinical studies with RVU120: (i) Phase Ib in patients with AML/HR-MDS ([NCT04021368](#)) and (ii) Phase I/II in relapsed/refractory metastatic or advanced solid tumors ([NCT05052255](#)). Additionally, multiple translational research activities are underway, aimed at further confirmation of RVU120 mechanism of action, defining target patient population and potential combination partners as well as validating RVU120 in other hemato-oncology as well as solid tumor indications. As such, results of translational research are aimed at supporting the clinical development plan for RVU120.

The primary aim of the ongoing first-in-human (FIH) Phase I study with RVU120 in relapsed or refractory AML or high-risk MDS (CLI120-001, [NCT04021368](#)) is to evaluate the safety and tolerability of RVU120 as well as to establish the recommended dose for Phase II (RP2D). Secondary endpoints include measurements of pharmacokinetic (PK) properties and an assessment of signs of clinical activity. Response to RVU120 will be evaluated by individual response criteria per each disease predefined in the study protocol. In addition, the exploratory objective of the study investigates the relevant pharmacodynamic (PD) response by studying biomarkers of target engagement in patient samples, such as STAT5 phosphorylation, and identification of molecular markers that might point to a better response to treatment with RVU120.

The first patient in the CLI120-001 clinical trial was dosed on September 4th, 2019. The study is currently enrolling at seven investigational sites in the US and in Poland. Ryvu will present updated data of this ongoing study at the European Hematology Association Congress in June 2022. Final results of the dose escalation part of the study are expected in 2022.

The other ongoing clinical study (RVU120-SOL-021, NCT05052255) is a Phase I/II aiming to investigate the safety and efficacy of RVU120 in patients with relapsed/refractory metastatic or advanced solid tumors. The study is designed in two parts. Part 1 of the study (Phase I) is a dose escalation part according to a standard 3+3 design and is aimed at enrollment of adult patients with solid malignancies who have failed available standard therapies. The primary objective of the Phase I part is to determine safety, tolerability and the RP2D. The secondary objectives include determination of the pharmacokinetic (PK), pharmacodynamic (PD) and preliminary anti-tumor activity of RVU120 as a single agent. The Phase II part is aimed both at safety and efficacy expansion. Part 2 (Phase II) will enroll patients with specific tumor types, either as a single agent or in combination with standard anticancer medicinal agents. Additional translational and biomarker studies are currently ongoing to confirm which target patient populations will be selected.

The first patient was dosed on August 25<sup>th</sup>, 2021 at the 75 mg dose. The study is currently enrolling at five investigational sites in Poland and Spain. Preliminary data of the dose escalation part will be presented as an abstract at the Annual Meeting of the American Society of Clinical Oncology in June 2022. Final results of the dose escalation part of the study are expected in 2022.

#### **Key achievements in RVU120 clinical development:**

- **Data disclosure at the 63rd ASH Annual Meeting & Exposition**, held on December 11 – December 14, 2021, in Atlanta, US. Data of the first treated patients in the ongoing Phase Ib clinical trial in AML/HR-MDS were presented. In a difficult-to-treat population with a median of three prior lines of therapy, RVU120 showed a tolerable safety profile and preliminary signs of efficacy. No DLTs and no study drug-related SAEs were reported. A 82 year old patient with HR-MDS achieved hematologic improvement of the erythroid lineage at the 50 mg dose level. At the 75 mg dose level, a 62 year old patient with AML achieved a complete remission. Four patients were still ongoing at the time of data cut-off.
- **Data presentation at the American Association of Cancer Research (AACR) Annual Meeting 2022**, held on April 8 – April 13 2022, in New Orleans, US. A Trials-in-Progress poster for a Phase I/II clinical trial of RVU120 in patients with metastatic or advanced solid tumors (NCT05052255), currently on-going in Poland and Spain, was presented. The study is designed in 2 parts: Part 1 follows a 3+3 dose escalation design, and the primary objectives are to characterize the safety and tolerability of RVU120 as a single agent in patients with different tumors types and determine the RP2D. Part 2 will primarily explore the anti-tumor activity of RVU120 as a single agent in different patient populations. As of a data cut-off of 11 Feb 2022, five patients have been enrolled in part 1 at the 75 mg and the 100 mg dose levels, and have completed their first cycles of treatment without dose-limiting toxicities (DLTs) – what further supports manageable safety profile of RVU120. Apart from the clinical poster, translational research data on RVU120's efficacy against hormone-independent breast cancer cells in vitro and in vivo, were presented.

More detailed initial data will be presented in an abstract for the Annual Meeting of the American Society of Oncology that will become available on May 27.

- **In a poster presentation at the European Hematology Association Congress to be held in Vienna in June 2022**, Ryvu will present data from the ongoing Phase 1b dose-escalation study of RVU120 (SEL120) in patients with AML or high-risk myelodysplastic syndromes (HR-MDS). Preliminary data of the first 6 cohorts demonstrate a favorable safety profile. No DLT and no drug-related SAE have occurred. The PK profile of RVU120 is predictable and meaningful pharmacodynamic changes have been observed. Dose escalation is continuing and enrolment into the 85 mg cohort was ongoing at the time of abstract submission. Updated efficacy results will be presented at the congress.

Further translational research showed that patient-derived AML cells with DNMT3A and NPM1 mutations are more sensitive to RVU120 treatment both *in vitro* and *in vivo*. This observation is consistent with the clinical responses to RVU120 in study CLI120-001 in two patients that harbored DNMT3A and NPM1 mutations. Anti-cancer efficacy of RVU120 was associated with transcriptomic reprogramming and lineage commitment.

## PRECLINICAL AND DISCOVERY STAGE PROJECTS

### Synthetic lethality projects

Ryvu is carrying out several research stage projects in the area of synthetic lethality. The most advanced project in this field is focusing on cancers with a deletion of the metabolic gene MTAP, which occurs in 10 to 15% of all human tumors.

MTAP deletion results in massive accumulation of methylthioadenosine (MTA) in cells. MTA in high concentrations is a very selective inhibitor of PRMT5 methyltransferase, competitive for the substrate: S-adenosylmethionine (SAM). Accumulation of MTA in cells with MTAP deletion causes a partial inhibition of the methylation activity of PRMT5, which in turn reduces the level of symmetric arginine dimethylation of the whole proteome, and thus an increased sensitivity of cells to modulation of methylosome activity. The Company's strategy is to develop MTA-cooperative PRMT5 inhibitors, which will selectively inhibit the growth of MTAP-deleted cancer cells. The work carried out in H1 2022 focused on the expansion of the main chemical series into a lead series with the main aim to demonstrate *in vivo* proof of concept, which would then allow for nomination of preclinical candidate by the end of Q1 2023. Pilot efficacy studies with lead compound synthesized in Q4 2021 resulted in demonstrating ~44% tumor growth inhibition in MTAP -/- model that is accompanied by ~60% of target proximal PD biomarker inhibition. Number of efficacy studies with more optimized compounds synthesized and characterized in Q1 2022 are currently planned or in progress. Ryvu chemical series already reached desired range of potency in cellular models, currently the optimization focuses on improvement of ADME properties that would drive stronger responses *in vivo*.

New results on the development of MTA-cooperative PRMT5 inhibitors were presented at the annual AACR (American Association for Cancer Research) conference in New Orleans, United States. The publication can be found under following link: <https://ryvu.com/investors-media/publications/>.

The second disclosed project focuses on development of first-in-class small molecule inhibitors of the Werner Syndrome helicase (WRN). The protein is a member of the RecQ helicase family and plays an important role in controlling DNA repair mechanisms and maintaining integrity of the genome. WRN helicase has been identified to be indispensable in tumor cells with microsatellite instability (MSI), where inhibition of the protein's helicase/ATPase activity leads to impairment of cellular viability. This therapeutic strategy holds promise for patients with MSI tumors across multiple indications, such as colorectal, ovarian, endometrial and gastric cancers.

Ryvu carried out several high throughput screening campaigns which led to the identification of a number of small-molecule WRN-inhibiting compounds. Most promising chemotypes were selected for further expansion and profiling. In recent months major focus was put on further compound profiling, validation and exploration of the mode of action as well as expansion and improvement of key properties of the selected chemical series.

In addition to the two disclosed projects, Ryvu is currently leading multiple internal initiatives focused on identification and validation of new targets and respective hit matter in the synthetic lethality space. One of the key assumptions for the selected targets is first-in-class potential. So far, several new targets have been identified which potentially meet this criteria. Following positive target validation studies for two targets, the company has initiated a hit finding campaign aiming at identification of pharmacologically active compounds for these potentially first in class targets. At the same time, work is underway on the selection and experimental validation of further molecular targets with first-in-class drug potential. Therapeutic targets for which active molecules can be identified and validated will be included in the company's project pipeline as they progress from target validation to successful hit stage.

On top of ongoing target validation and hit identification efforts, Ryvu is implementing an innovative platform for discovery of novel biological targets for oncology drugs based on genome-wide knockout screens in cancer cells with defined phenotype. The planned work includes modeling the impact of the microenvironment (cellular stress conditions, 3D cell culture) and utilization of primary cells during the screening. By systematically analyzing the frequency of genomic alterations in clinical databases, the platform is being applied to genomic alterations with potentially the greatest unmet medical need allowing introduction of unique molecular targets in the area of synthetic lethality to Ryvu project portfolio. These efforts are aimed at building in mid-term a robust portfolio of projects differentiated from competitor approaches by predictive biomarkers for sensitivity to target modulation and patient stratification opportunities.

### **Immuno-oncology projects**

Currently, the Company conducts research two projects in the immunooncology space: immunoactivation by STING agonists and HPK1 inhibitors, which have the dual potential of both activating the immune response and protecting cells of the immune system against immunosuppression.

The most advanced project within the immune-oncology portfolio focuses on development of small-molecule agonists of Stimulator of Interferon Genes, known as STING. The protein is one of the intracellular sensors of nucleic acids and has been shown to play a pivotal role in activating

the immune response to pathogen-derived or self-DNA. Activation of the STING signaling pathway leads to production of type I interferons, mobilizing the immune system response and promoting cancer neoantigen presentation by dendritic cells which in turn enhances antitumor T cell response.

The proprietary chemical series developed by Ryvu are potent STING activators with robust *in vitro* cellular activity, which translates to *in vivo* antitumor efficacy leading to inhibition of tumor growth and their regressions in mouse syngeneic tumor models. Advanced profiling allowed to narrow down a shortlist of compounds and finally select a front-runner molecule as the preclinical candidate, which has been optimized to reach superior agonist activity in human immune cells while at the same time maintaining a good overall safety profile.

In Q1 2022 Ryvu continued analysis of advanced PK/PD and preliminary toxicology studies. Currently, the work focuses on completion of advanced studies on compound administration in order to progress into further toxicology assessment.

The second project in the field of immune-oncology focuses on small molecule inhibitors of HPK1 kinase (MAP4K1), which has been reported to serve as a critical negative feedback regulator of T-cells. HPK1 triggered phosphorylation of the adaptor protein SLP76 in the TCR complex, leading to its degradation and thus blockage of the signal transduction - required to induce an immune response and fight cancer. In the first quarter of 2022, optimization of chemical series was continued, with particular focus on improving the safety profile, i.e., increasing the therapeutic window and reducing the potential risk of cardiotoxicity. Moreover, considering the previous results, molecule characterized by high selectivity, metabolic stability, good solubility, and, importantly, not toxic at the cellular level was selected, and PK and PK / PD experiments were performed. Received results confirmed *in vivo* target engagement with dose-dependent pSLP76 modulation. Further studies planned in Q2 2022 include MTD and *in vivo* efficacy studies in mice with the frontrunner molecule.

## **OTHER PROJECTS**

Ryvu carries out also other research and development projects, details and status of which are currently confidential due to intensive competitive environment and company obligations.

## **2.2 Significant events in Q1 2022**

### **A) DURING THE REPORTING PERIOD**

#### **Delivery of a lawsuit for payment in connection with the construction of the Research and Development Center**

On January 19, 2022 Issuer informed about having been served with a lawsuit for payment filed to the Regional Court in Kraków by the Contractor in connection with the performance of the general contractor agreement for the project entitled: "Construction of the Research and Development Center for Innovative Drugs Selvita S.A.". In the lawsuit the Contractor is claiming damages for the costs incurred in connection with prolonged performance of the Contract, the unpaid portion of the lumpsum fee as well as supplementary remuneration for additional, replacement and omitted works (PLN 5.391.425,63) as well as damages resulting from the Company's unauthorized - in the Contractor's

opinion - application of the performance bond and removal of the defects and faults (PLN 2.063.507,56). With the statutory interests, the Contractor demands from the Company a total amount of PLN 7.671.285.

The Company disputes the validity of the claims indicated in the Contractor's statement of claim both in principle and in amount. The Company will take appropriate legal steps in order to protect its interests in connection with the claims made by the Contractor.

#### Appointment of the new Chief Medical Officer

Effective February 1st, 2022 Mr. Hendrik Nogai, M.D. has been appointed to the role of Chief Medical Officer. Dr. Nogai will lead medical, clinical, and regulatory functions to support and guide the development of the company's pipeline. Dr. Nogai is a board-certified medical doctor in Hematology/Oncology as well as in Internal Medicine, with almost 10 years of experience in patient care and basic research in different academic settings, including Charité – University Medicine Berlin, University Hospital Grosshadern in Munich, and Zentralklinikum Augsburg. Besides his clinical expertise, Dr. Nogai brings 17 years of industry experience including business consulting at Mercer Management Consulting/ Oliver Wyman, Medical Advisor role at Nordic Biotech Capital ApS, and positions of increasing responsibility at Bayer AG, with his most recent role of Vice President, Global Development Leader NTRK program.

## B) EVENTS OCCURRED BETWEEN THE END OF REPORTING PERIOD UNTIL THE APPROVAL OF FINANCIAL STATEMENT

### AACR 2022 ANNUAL MEETING

During the American Association of Cancer Research (AACR) Annual Meeting 2022, April 8-13 2022, Company presented the latest data of its oncology projects: RVU120 (SEL120), a program developing a selective CDK8/19 kinase inhibitor as an effective therapy for the treatment of hematologic malignancies and solid tumors, as well as a project developing MTA - cooperative inhibitors of PRMT5 - as a synthetically lethal therapy for the treatment of tumors with MTAP gene deletion.

Poster details:

- **Title:** *RVU120, a selective CDK8/CDK19 inhibitor, demonstrates efficacy against hormone independent breast cancer cells in vitro and in vivo*

**Abstract number:** 2647

- **Title:** *Discovery of novel MTA-cooperative PRMT5 inhibitors as a targeted therapeutic for MTAP deleted cancers*

**Abstract number:** 1117

- **Title:** *Trials in Progress – RVU120 SOL-021: An open-label, single agent, Phase I/II trial of RVU120 (SEL120) in patients with relapsed/refractory metastatic or advanced solid tumors*

**Abstract number:** 8023

## ASCO 2022 Annual Meeting

On April 27th, 2022, the Company informed that during the upcoming American Association of Clinical Oncology Research (ASCO) Annual Meeting 2022, June 3-7 2022, Company will feature its oncology projects: RVU120 (SEL120), a program developing a selective CDK8/19 kinase inhibitor as an effective therapy for the treatment of hematologic malignancies and solid tumors (abstract book), as well as a selective PIM/FLT3 inhibitor SEL24 (MEN1703), currently under development by Menarini Group (poster presentation).

Details of abstracts accepted for publication:

- **Title:** *Phase 1/2 study of SEL24/MEN1703, a first-in-class dual PIM/FLT3 kinase inhibitor, in patients with IDH1/2-mutated acute myeloid leukemia: The DIAMOND-01 trial*

**Session Title:** Hematologic Malignancies—Leukemia, Myelodysplastic Syndromes, and Allotransplant

**Abstract number:** 7024

**Session date and time:** Saturday, June 4, 2022, 8:00 AM-11:00 AM CDT

- **Title:** *Phase I/II trial of RVU120 (SEL120), a CDK8/CDK19 inhibitor in patients with relapsed/refractory metastatic or advanced solid tumors*

**Abstract Number (online publication only):** e15091

## NodThera announces clinical progress for lead NLRP3 Inflammasome inhibitors and candidate selection of novel brain-penetrant compound

On May 10<sup>th</sup>, 2022, NodThera announced several key advancements across the portfolio. NodThera's lead candidate, NT-0796, demonstrated positive interim results from its Phase 1 single-ascending dose (SAD) study. Additionally, the company has commenced first-in-human dosing in the Phase 1 study of its second lead candidate, NT-0249, and announced the selection of its third pipeline candidate, NT-0527 – a brain-penetrant NLRP3 inflammasome inhibitor from a novel chemotype.

The positive interim results from the SAD portion of the Phase 1 trial with NT-0796 represent early clinical proof-of-mechanism for NT-0796 as a potent NLRP3 inflammasome inhibitor. Across all dosing cohorts, NT-0796 was safe and well tolerated and shown to be orally bioavailable with a dose-proportional pharmacokinetic (PK) profile. This portion of the study also showed a dose-dependent pharmacodynamic (PD) effect through the ability to lower IL-1 $\beta$  and IL-18 levels in an ex vivo NLRP3-stimulation assay. These results confirm the criteria to advance NT-0796 further in development and continue the ongoing multiple-ascending dose (MAD) portion of the Phase 1 study to assess brain exposure through cerebrospinal fluid (CSF) sampling.

### **New data from RVU120 and SEL24(MEN1703) programs to be presented at the EHA Hybrid Congress 2022**

On May 12th, 2022 the Company informed that three abstracts demonstrating data from the Phase 1b dose-escalation study of RVU120 (SEL120) in patients with AML or high-risk myelodysplastic syndromes (HR-MDS) and the Phase 1/2 study of SEL24(MEN1703) in Patients with IDH1/2-Mutated AML will be presented at the Annual European Hematology Association (EHA) 2022 Hybrid Congress, June 9-17 2022 in Vienna, Austria and on-line.



### **RVU120: orally available CDK8/19 inhibitor**

- Abstract Title: *Preclinical and Clinical Signs of RVU120 Efficacy, a Specific CDK8/19 Inhibitor in DNMT3A Mutation Positive AML and HR-MDS*

Abstract number: #P450

Session date and time: Friday, June 10, 2022, 16:30 – 17:45 CEST

- Abstract Title: *CLI120-001 Phase1b Dose Escalation Study of RVU120 in Patients with AML or High-Risk MDS Safety and Efficacy Data Update*

Abstract Number: #P501

Session date and time: Friday, June 10, 2022, 16:30 – 17:45 CEST

### **SEL24 (MEN1703): orally available dual PIM/FLT3 inhibitor**

- Abstract Title: *Phase 1/2 Study of SEL24/MEN1703, a First-In-Class Dual PIM/FLT3 Kinase Inhibitor, in Patients with IDH1/2-Mutated Acute Myeloid Leukemia: The DIAMOND-01 Trial*

Abstract Number: #P520

Session date and time: Friday, June 10, 2022, 16:30 – 17:45 CEST

## **2.3 Unusual events occurring in the reporting period**

### **COVID-19**

Covid-19 pandemic continued during the whole reported period. Because of that, the Issuer implemented recommendations given by the Chief Sanitary Inspectorate and other government institutions in connection with the epidemiological threat, including implementation of remote work and ensuring safe working conditions for stationary employees. Moreover, most business trips were still suspended. The Issuer used remote communication in its business contacts. Furthermore, the Issuer appointed a working team consisting of the representatives of various organizational units, whose task is to respond to the situation on an on-going basis and mitigate any adverse effects of the spread of the pandemic on the Issuer. The Company has also developed its internal policy for preventing spread of the coronavirus and has been taking actions aimed at ensuring appropriate health and safety conditions at work, including access for Company's employees to routine antigen testing. Internal policies are constantly updated and adapted to the latest guidelines and changing conditions.

During the reported period, the pandemic affected progress of the two Issuer's fully owned clinical trials: (i) CLI120-001 study and (ii) RVU120-SOL-021 study, due to the fact that generally and globally, phase I, dose escalation cancer clinical trials, got impacted. Due to the onset of COVID-19 pandemic, US and Polish clinical sites in both RVU120 studies have introduced additional safety measures and risk management processes which have impacted the possibilities for patients to participate in the clinical studies. This have applied primarily to relapsed, refractory AML patients who are frequently immunocompromised and very ill. Some patients themselves decided to limit their contacts with various healthcare facilities to minimize the possibility of COVID-19 exposure, while some were unable to enter the study due to an on-going coronavirus infection. As a result of that, enrollment in the study could have been impacted.

The Issuer's research and development laboratories worked in Q1 2022 with close to normal capacity. Any decrease in their capacity was associated with employees absence due to quarantine, the fact that

some foreigners could not enter Poland in time and the fact that some employees had to stay home with their children. A significant proportion of the Issuer's office staff however still worked remotely, which could also have had an adverse effect on the speed of carrying out the projects.

As of May 2022, thanks to the improving pandemic situation globally, and specifically in Poland, the residual impact of Covid-19 on Ryvu operations is very limited.

### **Conflict in Ukraine**

Due to the outbreak of the conflict in Ukraine, the Issuer's Management Board has analyzed the potential impact of the ongoing war on the Issuer's operations. In the opinion of the Management Board, apart from the currency risk, the Management Board did not identify any other significant risks that could affect the Issuer's operations.

In particular, it should be noted that the Issuer does not have any assets and does not conduct business and operations in Ukraine and Russia. The share of entities from Ukraine or Russia as suppliers in the Issuer's structure remains insignificant and is mostly limited to the provision of compound libraries for discovery stage projects at their early stage.

The Issuer also identifies foreign exchange risk. 90% of the Issuer's cash is kept in PLN. The grants obtained are also denominated in PLN, whereas the costs of clinical trials and external research and development services are mostly denominated in foreign currencies. This risk is partly mitigated by guaranteed and expected revenues from the commercialization of projects, which are denominated in foreign currencies. The Issuer also identified risks associated with delays in administrative processes relating to granting and settling grants or VAT reimbursement and regulatory processes concerning clinical trials.

The Company's Management Board is analyzing the Issuer's situation on an on-going basis. New circumstances, if any, having a significant effect on the Issuer's financial results and business position, will be communicated promptly in the individual current reports.

### 3. THE ISSUER'S CORPORATE BODIES

#### Issuer's Management Board:

- 1) Paweł Przewięźlikowski – President of the Management Board
- 2) Krzysztof Brzózka – Vice President of the Management Board
- 3) Kamil Sitarz – Member of the Management Board

#### Issuer's Supervisory Board :

- 1) Piotr Romanowski – Chairman of the Supervisory Board
- 2) Tadeusz Wesółowski – Vice Chairman of the Supervisory Board
- 3) Rafał Chwast – Supervisory Board Member
- 4) Axel Glasmacher – Supervisory Board Member
- 5) Colin Goddard – Supervisory Board Member
- 6) Jarl Ulf Jungnelius – Supervisory Board Member
- 7) Thomas Turalski – Supervisory Board Member

#### Issuer's Audit Committee:

- 1) Rafał Chwast – Chairman of the Audit Committee
- 2) Piotr Romanowski – Member of the Audit Committee
- 3) Tadeusz Wesółowski – Member of the Audit Committee
- 4) Jarl Ulf Jungnelius – Member of the Audit Committee

#### The Company's Remuneration Committee:

- 1) Piotr Romanowski – Chairman of the Remuneration Committee
- 2) Colin Goddard – Member of the Remuneration Committee
- 3) Axel Glasmacher – Member of the Remuneration Committee
- 4) Thomas Turalski – Member of the Remuneration Committee

## 4. INFORMATION ON THE SHAREHOLDERS HOLDING (DIRECTLY OR INDIRECTLY) AT LEAST 5% OF THE TOTAL NUMBER OF VOTES AT THE GENERAL SHAREHOLDERS' MEETING OF THE COMPANY AND ON SHARES HELD BY MEMBERS OF THE ISSUER'S MANAGEMENT BOARD AND SUPERVISORY BOARD

### Shares held by members of the Management and Supervisory Board of Ryvu Therapeutics S.A. as of the date of Report publication

Shareholder	Series A*	Ordinary shares	Number of shares	% of Share Capital	Number of Votes	% of Votes at SM
<b>The Management Board</b>						
Paweł Przewięźlikowski	3 500 000	400 544	<b>3 900 544</b>	21.25%	<b>7 400 544</b>	33.03%
Krzysztof Brzózka		267 321	<b>267 321</b>	1.46%	<b>267 321</b>	1.19%
Kamil Sitarz		17 865	<b>17 865</b>	0.10%	<b>17 865</b>	0.08%
<b>The Supervisory Board</b>						
Tadeusz Wesołowski (directly)		92 975	<b>92 975</b>	0.51%	<b>92 975</b>	0.41%
Tadeusz Wesołowski (indirectly through Augebit FIZ**)		1 039 738	<b>1 039 738</b>	5.66%	<b>1 039 738</b>	4.64%
Piotr Romanowski		331 000	<b>331 000</b>	1.80%	<b>331 000</b>	1.48%
Rafał Chwast		121 115	<b>121 115</b>	0.66%	<b>121 115</b>	0.54%
Thomas Turalski		20 100	<b>20 100</b>	0.11%	<b>20 100</b>	0.09%

\*A single Series A share entitles to two votes at the Shareholder Meeting.

\*\*The beneficiary of Augebit FIZ is Tadeusz Wesołowski - Vice-Chairman of the Issuer's Supervisory Board.

After the reporting period, there was a change resulting from the transfer of 27 497 series B shares in the implementation of the Stock Grant Program for the years 2021-2024 in the Company. On April 1<sup>st</sup>, 2022, the Company informed that Mr. Paweł Przewięźlikowski donated 27 497 series B shares. Before the transaction, Mr. Paweł Przewięźlikowski owned 3 928 041 shares, entitling to 7 428 041 votes at the Issuer's general meeting, which constituted 21,40% of shares in the share capital and 33,15% of votes. After the transaction, Mr. Paweł Przewięźlikowski holds 3 900 544 shares, entitling to 7 400 544 votes at the Issuer's general meeting, which constitutes 21,25% of shares in the share capital and 33,03% of votes.

## Shares held by members of the Management and Supervisory Board of Ryvu Therapeutics S.A. as of 31.03.2022

Shareholder	Series A*	Ordinary shares	Number of shares	% of Share Capital	Number of Votes	% of Votes at SM
<b>The Management Board</b>						
<b>Paweł Przewięźlikowski</b>	3 500 000	428 041	<b>3 928 041</b>	21.40%	<b>7 428 041</b>	33.15%
<b>Krzysztof Brzózka</b>		267 321	<b>267 321</b>	1.46%	<b>267 321</b>	1.19%
<b>Kamil Sitarz</b>		17 865	<b>17 865</b>	0.10%	<b>17 865</b>	0.08%
<b>The Supervisory Board</b>						
<b>Tadeusz Wesołowski (directly)</b>		92 975	<b>92 975</b>	0.51%	<b>92 975</b>	0.41%
<b>Tadeusz Wesołowski (indirectly through Augebit FIZ**)</b>		1 039 738	<b>1 039 738</b>	5.66%	<b>1 039 738</b>	4.64%
<b>Piotr Romanowski</b>		331 000	<b>331 000</b>	1.80%	<b>331 000</b>	1.48%
<b>Rafał Chwast</b>		121 115	<b>121 115</b>	0.66%	<b>121 115</b>	0.54%
<b>Thomas Turalski</b>		20 100	<b>20 100</b>	0.11%	<b>20 100</b>	0.09%

\*A single Series A share entitles to two votes at the Shareholder Meeting.

\*\*The beneficiary of Augebit FIZ is Tadeusz Wesołowski - Vice-Chairman of the Issuer's Supervisory Board.

## Shares held by significant shareholders of the Company

### Shares held by significant shareholders of the Company as of the date of Report publication

Shareholder	Shares	% [Shares]	Votes	% [Votes]
Paweł Przewięźlikowski	3 900 544	21.25%	7 400 544	33.03%
Bogusław Siczkowski	924 384	5.04%	1 474 384	6.58%
Nationale Nederlanden OFE	1 771 000	9.65%	1 771 000	7.90%
Aviva OFE Aviva Santander	1 430 521	7.79%	1 430 521	6.38%

### Shares held by significant shareholders of the Company as of 31.03.2022

Shareholder	Shares	% [Shares]	Votes	% [Votes]
Paweł Przewięźlikowski	3 928 041	21.40%	7 428 041	33.15%
Bogusław Siczkowski	924 384	5.04%	1 474 384	6.58%
Nationale Nederlanden OFE	1 771 000	9.65%	1 771 000	7.90%
Aviva OFE Aviva Santander	1 430 521	7.79%	1 430 521	6.38%

The above information on the state of possession of the Issuer's shares by shareholders (including those being members of the Company's bodies) holding directly and indirectly at least 5% of the total number of votes at the Company's General Meeting has been prepared on the basis of information obtained from shareholders through their performance of duties imposed on shareholders of public companies by virtue of relevant legal regulations, including on the basis of the provisions of the Act of 29. July 2005 on public offering and the conditions for introducing financial instruments to the organized trading system and on public companies (art. 69 and art. 69a) and on the basis of the provisions of the Regulation (EU) No 596/2014 of the European Parliament and of the Council of 16 April 2014 on market abuse and repealing Directive 2003/6/EC of the European Parliament and of the Council and Commission Directive 2003/124/EC, 2003/125/EC and 2004/72/EC (MAR Regulation, art. 19). In addition, information on the ownership of the Company's shares is provided on the basis of publicly available data on the portfolio exposure and asset structure of investment funds or pension funds, including information on the number of shares registered at the Company's General Meeting (data available periodically, inter alia, based on information from the financial statements of investment funds and pension funds - data may be subject to change since the date of publication of the last information).

## 5. ADDITIONAL INFORMATION

### **Proceedings pending at court, before an arbitration institution or a public administration authority**

Company has filed a lawsuit against Mota-Engil Central Europe S.A. in connection with construction of the Research and Development Center for the payment of PLN 13.756.717,07. With this lawsuit, the Company seeks claims related to the agreement for "Construction of the Research and Development Center of Innovative Drugs Selvita S.A.", the conclusion of which was announced by the Company in the current report No. 27/2018 of August 13, 2018. The total value of the Contract was PLN 68,783,585.34 including VAT.

Mota-Engil has filed a lawsuit for payment against to the Regional Court in Kraków in connection with the performance of the general contractor agreement for the project entitled: "Construction of the Research and Development Center for Innovative Drugs Selvita S.A.". In the lawsuit the Contractor is claiming damages for the costs incurred in connection with prolonged performance of the Contract, the unpaid portion of the lumpsum fee as well as supplementary remuneration for additional, replacement and omitted works (PLN 5,391,425.63) as well as damages resulting from the Company's unauthorized - in the Contractor's opinion - application of the performance bond and removal of the defects and faults (PLN 2,063,507.56). With the statutory interests, the Contractor demands from the Company a total amount of PLN 7,671,285.

### **Significant non-arm's length transactions with related entities**

Not applicable.

### **Information on organizational or capital relations of the Issuer with other entities**

As at the publication date of the report, the Issuer does not form a Capital Group. As at the date of this Report, the Issuer holds 4,19% of shares in NodThera Inc.

### **Warranties for loans and borrowings and guarantees granted**

Not applicable.

### **Other information significant for the assessment of the Issuer's position in the area of human resources, assets, cash flows, financial results and changes thereof and information significant for the assessment of the Issuer's ability to settle its liabilities**

Not applicable.

### **Factors which, in the Issuer's opinion, will affect the results over at least the following quarter**

The results of the subsequent quarters will depend primarily on the execution of the Company's strategy, which assumes in particular that the following business objectives will be met:

- Complete Phase I/II clinical development of our fully-owned lead asset RVU120 in AML/MDS;
- Expand therapeutic potential for RVU120 in solid tumors in the ongoing Phase I/II study;
- Support Phase II development by Menarini for lead partnered candidate, SEL24/MEN1703 in IDH-mutated AML and potentially other indications;

- Strengthen position in novel target discovery and in developing novel, proprietary drug candidates in synthetic lethality;
- Complete preclinical programs for STING candidate
- Partner selected early pipeline programs with biotech and pharma companies providing synergistic competences and resources.

**Description of factors and events, in particular of an unusual nature, having a significant effect on the financial performance**

In the reported period, the Covid-19 pandemic occurred. The Issuer described its effect on the Company's operations under Significant events that occurred in the reporting period.

**Explanations regarding the seasonal or cyclical nature of the Issuer's operations in the reported period**

Not applicable.

**Information on inventory write-downs to the net realizable amount and reversal of such write-downs**

Not applicable.

**Information on impairment write-downs in respect of financial assets, tangible fixed assets, intangible assets or other assets and the reversal of such write-downs**

Not applicable.

**Information on the set-up, increase, utilization and reversal of provisions**

Information on the changes in provisions for holidays and bonuses is provided in note 30 to the financial statements.

**Information on deferred income tax provisions and assets**

Information on deferred income tax provisions and assets is provided in note 10 to the financial statements.

**Information on significant purchases or disposals of tangible fixed assets**

Information on tangible fixed assets is provided in note 13 to the consolidated financial statements.

**Information on significant liabilities in respect of purchases of tangible fixed assets**

Information on the liabilities in respect of purchases of tangible fixed assets is provided in note 37 to the consolidated financial statements.

**Information on significant settlements resulting from court cases**

Not applicable.

**Error corrections relating to previous periods**

Not applicable.

**Information on changes in the economic situation and business conditions, which have a significant effect on the fair value of the entity's financial assets and financial liabilities**

Not applicable.

**Information on the failure to repay a loan or borrowing or a breach of significant terms and conditions of a loan agreement, with respect to which no corrective action had been taken by the end of the reporting period**

Not applicable.

**Information on changes in the method of valuation of financial instruments measured at the fair value**

Not applicable.

**Information on changes in the classification of financial assets due to a change in their purpose**

Not applicable.

**Information on the issue, redemption and repayment of non-equity and equity securities**

Not applicable.

**Information on dividends paid (or declared) in the total amount and per share, divided into ordinary and preference shares**

Not applicable.

**Events that occurred after the date for which the quarterly financial statements were prepared, not disclosed in these financial statements although they may have a significant effect on the Issuer's future financial results**

Information on events that occurred after the date for which the financial statements were prepared is provided in note 46 to the financial statements.

**Information on changes in contingent liabilities or contingent assets that occurred after the end of the last financial year**

Information on changes in contingent liabilities or contingent assets is provided in note 38 to the financial statements.

**Other disclosures which may have a material impact on the assessment of the Issuer's financial position and results of operations**

Not applicable.

**Amounts and types of items affecting the assets, liabilities, equity, net profit/ (loss) or cash flows, which are unusual in terms of type, amount or frequency**

Not applicable.



Krakow, May 17, 2022

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Paweł Przewięźlikowski  
President of the Management Board

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Krzysztof Brzózka  
Vice-President of the Management Board

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Kamil Sitarz  
Management Board Member

# CONTACT



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## **GENERAL INQUIRIES**

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