



SELVITA S.A.  
CONSOLIDATED QUARTERLY  
REPORT (SUMMARY)

**Q1**  
**2019**

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May 22, 2019

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## BASIC INFORMATION ON THE CAPITAL GROUP

### Parent Entity

<b>Business name of the Company</b>	Selvita Spółka Akcyjna
<b>Registered office</b>	ul. Bobrzyńskiego 14, 30-348 Kraków
<b>Company ID (REGON)</b>	120515330
<b>Tax ID (NIP)</b>	679-29-42-955
<b>Legal form</b>	Joint-Stock Company
<b>Website</b>	<a href="http://www.selvita.com">www.selvita.com</a>

### Related Entities (Subsidiaries)

<b>Business name of the Company</b>	BioCentrum spółka z ograniczoną odpowiedzialnością
<b>Registered office</b>	ul. Bobrzyńskiego 14, 30-348 Kraków
<b>Company ID (REGON)</b>	356815670
<b>Tax ID (NIP)</b>	676-226-47-81
<b>Legal form</b>	Limited Liability Company
<b>Website</b>	<a href="http://www.biocentrum.com.pl">www.biocentrum.com.pl</a>
<b>Shareholders</b>	100% shares held by Selvita S.A.

<b>Business name of the Company</b>	Selvita Services spółka z ograniczoną odpowiedzialnością
<b>Registered office</b>	ul. Bobrzyńskiego 14, 30-348 Kraków
<b>Company ID (REGON)</b>	122456205
<b>Tax ID (NIP)</b>	676-245-16-49
<b>Legal form</b>	Limited Liability Company
<b>Shareholders</b>	100% shares held by Selvita S.A.

<b>Business name of the Company</b>	Selvita Inc.
<b>Registered office</b>	Cambridge, USA
<b>Company File No.</b>	5700516
<b>Legal form</b>	Corporation
<b>Shareholders</b>	100% shares held by Selvita S.A.

<b>Business name of the Company</b>	Selvita Ltd.
<b>Registered office</b>	Cambridge, Great Britain
<b>Company No.</b>	9553918
<b>Legal form</b>	Limited Liability Company
<b>Shareholders</b>	100% shares held by Selvita S.A.

<b>Business name of the Company</b>	Ardigen Spółka Akcyjna
<b>Registered office</b>	ul. Podole 76, 30-394 Kraków
<b>Company ID (REGON)</b>	362983380
<b>Legal form</b>	Joint-Stock Company
<b>Shareholders</b>	Selvita S.A. holds 49,26% of shares

<b>Business name of the Company</b>	Selvita CRO S.A.*
<b>Registered office</b>	ul. Bobrzyńskiego 14, 30-348 Kraków
<b>Company ID (REGON)</b>	383040072
<b>Tax ID (NIP)</b>	676-256-45-95
<b>Legal form</b>	Joint-Stock Company
<b>Website</b>	www.selvitacro.com.pl
<b>Shareholders</b>	100% shares held by Selvita S.A.

## Affiliated Entity

<b>Business name of the Company</b>	Nodthera Ltd
<b>Registered office</b>	Aberdeen, Scotland
<b>Company ID</b>	SC540381
<b>Share capital</b>	GBP 12,988.996
<b>Legal form</b>	Ltd
<b>Website</b>	<a href="https://nodthera.com/">https://nodthera.com/</a>
<b>Shareholders</b>	14,7%** shares held by Selvita S.A.

Parent entity and related entities (subsidiaries) within the Selvita Capital Group are consolidated. Nodthera's shares are valued to fair value.

*\*Selvita CRO S.A. was incorporated on March, 22 2019 as a wholly owned Affiliate of Selvita S.A., which owns 100% of Selvita CRO's shares. Formation of Selvita CRO S.A. is closely related to planned split of Selvita S.A. into two separate listed entities (subject to financial authorities and shareholders' approvals) which was announced on March, 28 2019. One company will focus on development of small molecule therapeutics in oncology and the other will provide contract research services. Each company will build upon capabilities that have been integral to the Company since the founding of Selvita in 2007. Both companies will be publicly listed on the Warsaw Stock Exchange.*

*\*\*As of the date of this report, with regard to the Nodthera's issue of shares following II tranche of share capital increase according to current report dated April, 3 2018 (No 15/2018) Selvita has decreased its interest in Nodthera by 3,65% comparing to the last periodic report.*

## The Core Business of the Capital Group

The activities of the Capital Group cover three main business segments:

- **Innovative segment** – research and development activities implemented through in-house research projects on innovative drugs,
- **Service segment** – R&D services provided to external clients, in particular to pharmaceutical and biotechnology industry,
- **Bioinformatics segment (Ardigen S.A.)** – bio-data science and complementary advanced software services to support data-driven Life Science and Healthcare organizations.

## FINANCIAL HIGHLIGHTS

Selvita Group	Consolidated data in PLN thousand		Consolidated data in EUR thousand	
	Item	From 01.01.2019 to 31.03.2019	From 01.01.2018 to 31.03.2018	From 01.01.2019 to 31.03.2019
Revenues from sales	20 664	17 878	4 808	4 279
Revenues from subsidies	9 136	5 300	2 126	1 268
Revenues from R&D projects	-	-	-	-
Other operating revenues	357	141	83	34
Revenues on operating activities	30 157	23 319	7 017	5 581
Operating expenses	(37 760)	(24 193)	(8 786)	(5 790)
Depreciation	(4 304)	(1 695)	(1 001)	(406)
Depreciation (excl. IFRS 16 impact)	(2 960)	(1 695)	(689)	(406)
Profit/loss on operating activities (EBIT)	(7 603)	(874)	(1 769)	(209)
Profit/loss before income tax	(7 135)	19 961	(1 660)	4 777
Net profit/loss	(7 353)	19 894	(1 711)	4 761
EBITDA	(3 299)	821	(768)	196
EBITDA (excl. IFRS 16 impact)	(4 643)	821	(1 080)	196
Net cash flow from operating activities	(17 166)	(4 330)	(3 994)	(1 036)
Net cash flows from investing activities	(7 884)	(4 516)	(1 834)	(1 081)
Net cash flows from financing activities	8 472	130 730	1 971	31 287
Total net cash flow	(16 578)	121 884	(3 857)	29 170
Number of shares	15 971 229	14 121 229	15 971 229	14 121 229
Profit (loss) per share (in PLN)	(0,47)	1,24	(0,11)	0,30
Diluted profit (loss) per share (in PLN)	(0,47)	1,24	(0,11)	0,30
Book value per share (in PLN)	11,54	13,27	2,68	3,15
Diluted book value per share (in PLN)	11,54	13,27	2,68	3,15
Declared or paid dividend per share (in PLN)	-	-	-	-

## MANAGEMENT BOARD'S COMMENTS ON FACTORS AND EVENTS AFFECTING THE FINANCIAL RESULTS

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

1. Items relating to the profit and loss statement, and the cash flow statement were converted according to the exchange rate constituting the arithmetic mean, 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 01/01/2019 – 31/03/2019: PLN 4.2978;
  - for the period from 01/01/2018 – 31/03/2018: PLN 4.1784.
2. Balance sheet items were converted according to the average exchange rate announced by the NBP applicable as at the balance sheet date; this exchange rate amounted to:
  - as at 31 March 2019: PLN 4.3013;
  - as at 31 December 2018: PLN 4.3000;
  - as at 31 December 2017: PLN 4.1709.

### Increase and Dynamics of Revenues and Financial Results

In the reporting period, the Group continues the phase of very intense investments, started in the previous year, as part of the implementation of Selvita strategy for years 2017-2021. Over PLN 130 million obtained from the successful issue of shares in 2018 has enabled an increase of expenditures on the research and development projects which will be commercialized on later stages which in the assessment of Management Board will secure better financial conditions.

In the first quarter of 2019 Selvita Group recognised total operating revenue in the amount of PLN 30,157 thousand, which means 29% increase compared to Q1 2018 when total operating revenue amounted to PLN 23,319 thousand. Total commercial revenue for Q1 2019 amounted to PLN 20,664 thousand which means dynamics of 16% compared to corresponding period of 2018, in which total commercial revenue amounted to PLN 17,878 thousand.

On January 1, 2019, the Group for the first time applied IFRS 16 "Leasing" standard. The purpose of the new standard is to facilitate the comparison of financial statements, presenting both financial and operating lease in the lessee's financial statements and to provide information to users of the financial statements about the associated risks. The impact of this standard on total operating revenue was insignificant (PLN 49 thousand).

In Q1 2019 the Selvita Group reported a loss at the level of the entire activity (net profit) as well as on an operating level. This is a result of the implementation of Selvita strategy adopted in 2017, according to which the innovation segment focuses on increasing the value of ongoing projects, that will be commercialized on later stages.

Net loss of the Selvita Capital Group for the first quarter of 2019 amounted to PLN 7,353 thousand compared to the net profit achieved in the corresponding period of 2018 in the amount of PLN 19,894 thousand. In the first quarter of last year, the Group decided to value its shares in Nodthera at fair value (earlier, these shares were

accounted for using the equity method), which significantly affected the financial result. The net result of Q1 2019 excluding the change in valuation of Nodthera's shares would amount to PLN -893 thousand (loss).

The service segment in Q1 2019 achieved, similarly to previous years, very good profitability while keeping good growth's dynamics at the same time. The Q1 2019 revenue from sales of services to external customers totalled PLN 17,355 thousand compared to PLN 13,643 thousand in Q1 2018, which constitutes growth of over 27%. The operating profit (EBIT) of that segment in Q1 2019 amounted to PLN 1,925 thousand, which constitutes a decrease of around 11% compared to PLN 2,175 thousand in 2018, and profitability at the level of operating profit (calculated as the ratio of the operating profit of the segment to its total sales revenue) amounted to 10%. The drop in profitability is related to significant investments that have been made as part of the service segment, in particular those related to the purchase of new equipment in the last period of 2018, which resulted in a sharp increase (+59%) in depreciation in Q1 2019 compared to Q1 2018. Investments in laboratory modules as well as specialized equipment resulting in increase of the work efficiency and the quality of services will allow for a further dynamic growth in the revenues of the services segment and increase in profitability in subsequent periods.

Revenues of the innovation segment in Q1 2019 amounted to PLN 8,610 thousand, which means an increase of 23% in comparison to Q1 2018, when commercial revenues of the innovation segment amounted to PLN 6,978 thousand. Innovations segment's operating loss (EBIT) for Q1 2019 amounted to PLN 9,772 thousand which means an increase compared to Q1 2018, when innovations segment's operating loss (EBIT) amounted to PLN 3,071 thousand. The above, i.e. an increase in revenues (resulting from a significant increase in revenues from subsidies) and a greater loss (resulting from higher expenditures on research projects) confirms that the Group strongly focuses on the development of its own research projects and preparing them for commercialization at later stages of development.

In Q1 2019 bioinformatics segment's revenue amounted to PLN 2,943 thousand, which means an increase of 51% compared to Q1 2018 when revenues amounted to PLN 1,950 thousand. Bioinformatics segment generated in Q1 2019 operating profit in the amount of PLN 244 thousand, compared to Q1 2018 when operating profit amounted to PLN 22 thousand.

In the first quarter of 2019, revenues from grants increased by 72% compared to the previous year – from PLN 5,301 thousand to PLN 9,136 thousand. The increase in revenues from grants is primarily due to the growth of costs incurred for new innovative projects implemented under the new financial perspective 2017-2021.

The value of the 2019 contracts portfolio resulting from commercial contracts and grant agreements signed as of the publication date of this report (backlog) amounts to PLN 92,657 thousand, including:

- Services PLN 53,642 thousand,
- Innovation PLN 3,309 thousand,
- Bioinformatics PLN 7,275 thousand,
- Grants PLN 28,431 thousand

and it has increased compared to the 2018 backlog announced in May 2018 by 13%. It should be emphasized that the services segment backlog for 2019 has increased by 31%, bioinformatics backlog has increased by 60%. However the innovation segment backlog has decreased by 52% compared to the contracting in the same period last year.

## The Group's Assets and the Structure of Assets and Liabilities

As of the end of Q1 2019, the value of the Group's assets was PLN 263,175 thousand and increased by PLN 7,475 thousand compared to the end of 2018 (PLN 255,700 thousand). As of the end of Q1 2019 the highest value of current assets is cash in the amount of PLN 108,769 thousand (as of the end of 2018 amounted to PLN 125,449 thousand), presented in consolidated statement of financial position as cash and cash equivalents amounting to PLN 93,796 thousand and as other short-term financial assets in the amount of PLN 14,973 thousand (including PLN 14,889 thousand in bonds with interests). Fixed assets are mainly laboratory equipment, deferred income tax asset in the amount of PLN 4,338 thousand and other long-term financial assets in the amount of PLN 22,826 thousand. The decrease in cash and other financial assets results from expenditures incurred on research projects and the construction of the Innovative Drug R&D Centre (Centrum Badawczo-Rozwojowe Innowacyjnych Leków). The value of non-current assets increased in comparison to December 31, 2018 by PLN 23,426 thousand. The increase consists mainly of the recognition, starting from 1 January 2019, of the right to use the assets (mainly lease of premises) in accordance with IFRS 16. As at 1 January 2019, the Group recognized assets of PLN 17,992 thousand. The same amount was included in other financial liabilities.

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

	31/03/2019	31/12/2018
<b>Liquidity indicator</b>		
current assets/current liabilities including short-term provisions and accruals (excl. deferred revenues)	5.02	5.56
<b>Increased liquidity indicator</b>		
(current assets-inventory)/current liabilities including short-term provisions and accruals (excl. deferred revenues)	4.96	5.49

Cash surpluses not used in the operating activities are invested in safe financial instruments that is: bank deposits, PKO Leasing S.A.'s bonds.

The main item in the Selvita Group's equity and liabilities is equity, which amounted to PLN 187,430 thousand as of March 31, 2019 and decreased by PLN 7,430 thousand compared to 31 December 2018. The decrease in equity is mainly a result of net loss for the year Q1 2019. The second largest source of funding is long-term liabilities which amounted to PLN 40,018 thousand at the end of Q1 2019. The highest value long-term liabilities item are deferred revenues (most of them grants, to be settled in the future) in the amount of PLN 11,225 thousand and other financial liabilities in the amount of PLN 21,019 thousand. The increase in other financial liabilities (both long and short term) results from the impact of IFRS 16, which was described above.

## Current and Foreseen Financial Situation

The Group's financial position as of the report date is very good. As of March 31, 2019 the value of the Group's cash amounted to PLN 108,769 thousand, including PLN 93,796 in cash and PLN 14,973 thousand in short-term financial assets (including PLN 14,889 thousand in bonds with interests). As of May 17, 2019, the value of the Group's cash amounted to PLN 103,889 thousand, including PLN 89,000 thousand in cash and PLN 14,889 thousand in bonds, and safe investment fund units.

Activity of Selvita Group in innovative segment in Q1 2019 recorded a loss, however activity in the service and bioinformatics segment was profitable. Activity of R&D is financed by customer revenue, supplemented by research grants and funds acquired through share issue in 2018. In the future periods, further revenue increase is



expected both in services and bioinformatics segment. On the other hand, revenues in the innovative segment depend on the commercialization of research projects.

The Group meets its obligations on time and maintains a sustainable cash flow ensuring its liquidity. Income from share issue from Q1 2018 and cash generated from operations allow the Company to execute its planned investments, in particular the development of ongoing and new innovative projects and expansion of laboratory infrastructure.

## INFORMATION ON THE GROUP'S ACTIVITY IN Q1 2019

### R&D Activities (Innovative Segment)

#### TARGETED THERAPEUTICS PLATFORM TTP

##### SEL24

SEL24/MEN1703 is a selective, dual inhibitor of PIM and FLT3 kinases, two enzymes that are strongly implicated in malignant transformation of hematopoietic cells. This compound is a novel small molecule discovered by Selvita and is currently in development as a therapeutic option for cancers including acute myeloid leukemia (AML). SEL24/MEN1703 is being evaluated in a Phase 1/2 clinical trial for the treatment of patients with AML at 5 sites in the U.S., with the main purpose of establishing the recommended dose for further development. The study is enrolling patients regardless of FLT3 mutational status and has the potential to address cancers that have developed resistance to FLT3 inhibitor treatment. Details of the study can be found at ClinicalTrials.gov: <https://clinicaltrials.gov/ct2/show/NCT03008187>.

A poster submitted by Menarini describing the design of the Phase 1/2 trial has been accepted and will be presented at the American Society of Clinical Oncology (ASCO) Annual Meeting taking place from May 31 to June 4, 2019, in Chicago. A poster relating to the Phase 1/2 study has also been accepted for presentation at the 24th Congress of the European Hematology Association taking place June 13-16, 2019 in Amsterdam.

The Company indicated, in accordance with information published in the abstracts to aforesaid posters, that 17 patients took part in the SEL24/MEN1703 trial until 8 January 2019, and the study is close to the completion of the phase of escalating the dose, and therefore determining the recommended dose, which marks the completion of phase I of the two-stage first in-human study. The second part of the study – expansion cohorts at the recommended dosage level is planned to confirm the safety profile of the compound and assess its activity as monotherapy. In phase II of the study, as indicated by the sponsor – Menarini Ricerche SpA – in the abstracts, it will be extended to involve approx. 40 centres in the USA and Europe (currently it is conducted in 5 centres located exclusively in the USA).

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In the first quarter of 2019, Selvita established a new Scientific Advisory Board (SAB) that aims to support all ongoing research projects and provide regular guidance regarding future directions for the company. The SAB includes Michael Savona, M.D., from the Vanderbilt University Medical Center; Greg Nowakowski, M.D., from the Mayo Clinic; Heinz-Josef Lenz, M.D., from the Keck School of Medicine of the University of Southern California; Alvin Kramer, M.D., from Heidelberg University; Przemysław Juszczynski, M.D., Ph.D., from the Institute of Hematology and Transfusion Medicine in Warsaw and Cezary Szczylik, M.D., Ph.D., from the Centre of Postgraduate Medical Education and European Health Centre in Otwock.

## **SEL120**

SEL120 is a highly selective, small molecule CDK8 kinase inhibitor discovered by Selvita in development for the treatment of diverse cancer indications. Preclinical studies have indicated a crucial role for CDK8 in the regulation of oncogenic gene expression and a particularly important role in the disease biology of AML. In preclinical studies, inhibition of CDK8 results in differential cytotoxicity for cancer cells over healthy cells and induces cell differentiation. By targeting the population of leukemic stem cells in AML, CDK8 inhibition offers the potential to improve upon treatments based on targeting a narrow population of differentiated cancer cells. Signs of activity for SEL120 have been also observed in preclinical studies of other hematological malignancies and solid tumors. In addition, SEL120 has demonstrated promise either as a single agent or in combination with immune checkpoint inhibitors.

In March 2019, Selvita received notice of acceptance of the Investigational New Drug (IND) application from the U.S. Food and Drug Administration (FDA) for the first-in-human, Phase 1 clinical trial of SEL120 in patients with AML or high-risk myelodysplastic syndromes (HR-MDS). The primary aim of this study, to be conducted at five sites in the U.S., will be to establish the recommended dose and treatment schedule of SEL120 for further development. Secondary endpoints include measurements of pharmacokinetic properties and an assessment of signs of clinical activity. Dosing of the first patient is expected in the third quarter of 2019.

In April 2019, Selvita presented results from preclinical studies of SEL120 with patient-derived xenografts at the American Association for Cancer Research (AACR) Annual Meeting. In these studies, treatment with SEL120 resulted in tumor growth inhibition, providing additional validation of SEL120 as a potential treatment for AML.

The SEL120 project has received scientific and financial support from the Leukemia and Lymphoma Society Therapy Acceleration Program.

## **TARGETED THERAPEUTICS PLATFORM (TTP)**

TTP platform develops novel targeted therapies in oncology. Lead projects are focused on solid tumors with defined molecular background and the concept of synthetic lethality. Other projects target hematological malignancies by inhibition of proteins responsible for epigenetic reprogramming of cancer cells. One of the revealed protein targets is BRM/SMARCA2. Inhibition of this protein is effective in the context of over 8% of lung cancers (NSCLC), with loss of function mutations in the SMARCA4 gene. Selvita develops innovative, first-in-class inhibitors of ATPase/helicase activity of BRM. Best compounds show satisfactory low nM activity, high specificity and selectivity in vitro. Cellular profiling indicated on-target mechanism of action and differential activity in cells bearing loss of function mutations of SMARCA4. Other proprietary protein targets and programs could not be revealed due to confidentiality constrains.

## **IMMUNO-ONCOLOGY PLATFORM (IO)**

Immuno-Oncology Platform aims to provide novel immunotherapies mobilizing and stimulating human immune system to recognize and sensitize tumors to immune attack.

The most advanced project within the platform are the small molecule, direct STING agonists. Next generation of Selvita STING agonists efficiently activated in vitro human and mouse immune cells responsible for neoantigen presentation (dendritic cells and macrophages) with superior efficacy to known cyclic dinucleotide STING agonists. The series has activity independent of STING mutations in biophysical tests and in blood samples of human donors, which holds promise for therapeutic intervention in a wide patient population.

In addition, formulated Selvita STING agonists effectively revived in vitro immunosuppressive human macrophages to an activated, antitumor state becoming an appealing candidates to reprogram tumor associated macrophages (TAM). These properties potentially empower checkpoints inhibitors in overcoming resistance, increasing response rate and durability. In vivo data from studies in mice revealed that systemically administered Selvita STING agonists mounted proinflammatory cytokine release promoting immunostimulatory and antitumor effects.

The Company has selected preliminary candidates for in vivo tests in solid tumor animal models. The current intensive optimization work aims to identify by the end of 2019 molecules with the highest therapeutic potential in animal models and to develop an optimal combination with other immunotherapeutics and chemotherapy.

The latest results not affecting Selvita's competitive position were presented in 2019 at the American Association for Cancer Research (AACR) Annual Meeting in USA and are available on the Selvita website at <https://selvita.com/research-and-development/download-a-poster/>.

Selvita's Immuno-Oncology Platform strategically focuses on identification of therapeutic targets that could simultaneously improve T cell function, tumor antigen presentation and combat the immunosuppressive tumor microenvironment. HPK1 (MAP4K1) is one of the major proteins involved in signalling cascade triggered by TCR activation and serves as a negative regulator in T cells and dendritic cells (DC). Inhibition of HPK1 kinase activity could address several key challenging factors in current immunotherapy (e.g. immune suppression and resistance in tumor microenvironment, impaired immune evasion with dysfunctional T effector cells) synergizing with immune checkpoints.

In Q1 2019 inactivation of HPK1 kinase activity by the low nanomolar inhibitors identified by Selvita efficiently modulated HPK1 downstream biomarkers, enhanced activation of T lymphocytes in vitro was proved. The chemical development of the series, the optimization of ADME parameters and selectivity are underway.

Other molecular targets and progress in the programs are confidential due to competitive environment.

#### **CANCER METABOLISM AND IMMUNOMETABOLISM PLATFORM (CMIM)**

Projects related to cancer metabolism and immunometabolism since 2017 have been grouped in the dedicated research platform. In the area of cancer metabolism, the company runs projects both internally and in cooperation with Merck KGaA.

The aim of projects in the field of immunometabolism is the development of innovative immunotherapeutics based on solutions that overcome the limitations of current therapies and give a chance for personalized, targeted treatment of patients with aggressive, refractory tumors. Work within the platform is focused on molecular targets with so-called adenosine pathway. Adenosine is one of the major microenvironmental immunosuppressive agents responsible for the tumor's immune escape.

Works on new dual A2A / A2B receptor antagonists in Q1 2019 resulted in obtaining one of the most active labeled substances with this activity profile (picomolar activity range, in vitro efficacy at a very high adenosine levels). Their therapeutic potential has been confirmed in in vivo efficacy studies, where inhibition of tumor growth was shown. In CT26 syngeneic model >90% tumor growth inhibition (TGI) was demonstrated in combination with anti-CTLA4 antibody, including the significant number of complete tumor regression. In the immunotherapy resistant

B16F10 model we have demonstrated the significant TGI in combination with anti-PD1 antibody, with complete resistance of this model to the antibody administered as a monotherapy. Additionally, in Q1 2019 the advanced research was underway to select the clinical candidate. The beginning of preclinical studies for the selected one molecule with the best profile is planned for Q4 2019. In parallel the translational research will be conducted, mainly in murine cancer models, in order to come up with an optimal therapeutic indications and clinical trials strategy.

The most recent results of the project, have been presented in April 2019 at AACR conference in Atlanta and are available at <https://selvita.com/research-and-development/download-a-poster/>.

The aim of long-term collaboration with Merck Serono, which has been ongoing since 2013, is the development of new oncology drugs for molecular targets related to disturbed metabolic pathways in cancer cells (cancer metabolism). The research continues according to the schedule, further details of the project are covered by trade secrets.

By virtue of the contract extension by Sep 2019, signed in Q4 2018, Merck continues to cover the research costs borne by Selvita, and the Company maintains the right to future milestone payments and royalties if the project achieves its intended scientific and commercial goals.

An internal cancer metabolism project aims at a crucial metabolic pathway related to tumorigenesis, both for solid tumors and hematological tumors. Nanomolar SHMT2 inhibitors have been obtained, the specificity and efficacy of inhibition has been confirmed in cellular models. In Q1 2019, the characterization of molecules in in vitro and in vivo models of alternative therapeutic indications was continued.

## **OTHER PROJECTS**

Apart from the aforementioned projects, within the platforms presented above Selvita Group also carried out other research and development projects, however their details and the current progress of work is confidential.

## **Service Segment**

### **BIOLOGY DIVISION**

Contract Biology Division provides biological, biochemical and analytical services. It specializes in certified testing conducted in GLP and GMP standards in areas such as pharmacodynamic testing, cytotoxicity testing, developing and validating biophysical, biochemical and cell-based assays as well as analytical methods (including ADME and DMPK analysis). Division's Biochemistry Laboratory also offers a broad range of protein biochemistry testing.

Contract Biology Division consists of three laboratories i.e. Biochemistry Laboratory, Analytical Laboratory and Cell and Molecular Biology Laboratory offering a wide spectrum of services. The production, purification and characterization of recombinant proteins were the core activities of the Biochemistry Laboratory and the main source of revenue in 2018. These projects were accomplished based on both bacteria- and insect-based expression systems. It should be noted that the share of projects using insect cell lines is growing systematically, this is related to the increased demand of existing and new clients for high quality recombinant proteins which require specific modifications that are unavailable in bacteria systems. An important part of the research and revenue corresponds to work on the crystallographic analysis of proteins (so-called "gene to structure" research) for global pharmaceutical clients. These projects are more sophisticated and usually have higher commercial value than projects related to recombinant proteins. The share of crystallographic projects in the laboratory's revenue has

been growing systematically which translated into an increase in revenue. It should be emphasised that the Biochemistry Department has the necessary resources to perform crystallographic projects, namely a team of highly experienced researchers as well as the required advanced equipment. The aforesaid groups of research projects were performed mainly for European and US clients representing global pharmaceutical and biotechnological companies, as well as smaller companies engaged in the development of new drugs. The high and still growing number of orders in the Biochemistry Department is connected with increasing recognition of the service offer and constantly growing standard (very high quality products and research data) of the provided services.

In Q1 2019, Selvita Analytical Laboratory performed services to pharmaceutical and agrochemical clients as well as clients in the chemical industry. The established division of the research into projects based on the FTE approach, and projects on analyses in accordance with the GMP and GLP quality assurance systems was continued. The majority of the projects were the continuation of the stability study begun in previous years, also as part of the cooperation initiated in 2018 – among other things, the CMC project for a global pharmaceutical company which comprised comprehensive analytical support for a project focusing on the process of compound synthesis and quality control, a project pursued in accordance with the Q3D guidelines, which comprised ICP-MS analysis of more than 40 products and formulations. Moreover, the Analytical Laboratory was engaged in integrated projects connected with the development of drugs, under which it carried out research in the field of ADME analysis.

In the area of release testing for one of the largest global pharmaceutical companies, routine research was continued for several small-molecule products. Work on biological products, which had been commissioned earlier, was continued for another pharmaceutical client.

The analytical laboratory continued to provide services to agrochemical companies in respect of the development and optimization of methods, validations, 5Batch and 1Batch research, stability studies, and physical-chemical tests. Customers in this industry were also provided with testing of dioxins and furans using the GC-MS technique. The first quarter of this year also saw work connected with the preparation of a comprehensive offer in respect of the implementation of the CIPAC method in the stability studies.

In the field of bioanalytical studies, the first quarter saw the completion of development work for a large client in the chemical industry, and the start of a subsequent phase of the project related to the validation of analytical methods, and routine research with the use of LCMS' equipment.

In the first quarter of 2019, the Analytical Laboratory made subsequent investments and increased its equipment base by more HPLC, LCMS apparatus, and an apparatus for capillary electrophoresis. The investments in the ADME team were related to the purchase of a multi-function device which increased its capacity for testing physical and chemical properties – pKa, logD, logP and solubility. Also negotiations regarding the purchase of a high-resolution mass spectrometer dedicated to the examination of biological products are at their final stage.

In the first quarter of 2019, the Molecular and Cell Biology Division continued its drug discovery projects based on the SAR analyses. The laboratory researchers develop biochemical and cell-based tests to characterize the activity and mechanism of the action of new compounds with potential therapeutic relevance. In the first quarter of 2019, one-third of the researchers in the department carried out FTE studies which involved the development of new therapeutic substances for European pharmaceutical concerns.

In the same period, the Contract Biology Division performed three separate projects relating to the *in vitro* comparative trials of biosimilar insulin and insulin analogues. In each of them the researchers were responsible for optimization, validation and comparative analysis of biosimilar drugs with their references in the tests of insulin receptor affinity, mitogenic activity and regulation of cell metabolism.

Moreover during the reported period scientific research within the project, co-financed by the Małopolskie Centrum Przedsiębiorczości: “Development of a platform for *in vitro* testing of therapeutic biosimilar antibodies” (“Opracowanie platformy badań *in vitro* dla biopodobnych przeciwciał o działaniu terapeutycznym”) was continued. Within this project the research team develops several biophysical, biochemical and cell-based *in vitro* tests aimed at comparative analysis of the affinity and activity of monoclonal antibodies from the group of TNF $\alpha$  and VEGF inhibitors. The nature of this platform will be similar to the platform for the comparative analysis of biosimilar insulin and insulin analogues, which was developed by the team in prior years.

In the foreseeable future, the main goal of the Contract Biology Division will be to further increase Western European and U.S. market penetration, with special emphasis on the offer addressed to pharmaceutical/biotech customers who are looking for integrated solutions for projects related to the development of innovative drugs.

#### **CHEMISTRY DIVISION**

In the first quarter of 2019, the Contract Chemistry Division continued its work on integrated drug discovery projects (among other things, with Italian pharmaceutical companies and with a company from the European biotechnological sector) as well as chemical projects based on the FTE model, which had been started in prior years. Moreover, FTE contracts were signed with new clients, and cooperation with the existing clients was extended. The majority of the projects consisted of research and development work which led to the development of new pharmacologically active molecules, new synthetic processes, and technologies.

Other services offered by the Contract Chemistry Division in 2018 (similarly to previous years) included in particular the following services:

- designing new pharmacologically active molecules based on biological tests and with use of computational tools;
- synthetic support for research projects aimed at development of new therapies;
- developing new, effective and cost-efficient as well as environmentally safe synthesis processes and alternative technologies for obtaining chemical substances;
- scaling chemical processes for industrial purposes, optimization and parametrization of technologies for the registration purposes;
- custom synthesis of pharmaceutical and chemical compounds (aromatic, agrochemical, compounds for a specialized use) in a scale from mg to kg;
- synthesis of impurities, degradation products and analytical benchmarks for registration purposes;

- chemical analysis, structure testing, and qualitative and quantitative testing of the chemical composition of compounds and mixtures in accordance with the requirements of the pharmaceutical, chemical and agrochemical market;
- technical business consulting for the chemical industry.

The customer base of the Chemistry Division is well diversified in terms of market segments, industries and geographical locations. The main customers of the Contract Chemistry Division are both global pharmaceutical concerns as well as medium pharmaceutical companies, biotechnology companies, the agrochemical and chemical industry as well as academic society and CRO/CMO companies.

In order to maintain upward trends and with a perspective to make new contacts which are interesting in terms of trade and scientific cooperation, in the first quarter of 2019, the Company's employees actively participated in sales activities in Europe, Asia and the USA, in industry conferences, fairs, visits to clients, and visits of potential business partners in the Company's office.

From the perspective of the Contract Chemistry Division activities, the most interesting industry conferences / fairs in the first half of 2019 were:

- 3rd Annual Drug Discovery Chemistry; London, 18–19/03/2019;
- Computationally Driven Drug Discovery: tackling Kinetics and Residence time; Rome, 28–29/03/2019;
- Bio Europe Spring 2019; Vienna, 25–27/03/2019.

In order to further reinforce the Selvita brand on the research and development market, the Company (in cooperation with its researchers and clients) is preparing scientific publications, presentations and patent applications based on commercial projects, thus confirming their reliability in the area of scientific research.

In the upcoming months, the Contract Chemistry Division will continue its strategy by focusing on its development in the area of service activities on the pharmaceutical, biotechnological, agrochemical and chemical market.

It is also planning to extend the team by including highly-qualified research staff, constantly increasing the Company's operating standards (technical, quality-related, infrastructural, sales-related) and by focusing on operating activities which lead to increased operational efficiency and increased interest in the Division's high-margin services.

As the demand for services increases, the Company will continue investing in specialist research equipment, including laboratories adapted to provide research and development services.

#### **BIOINFORMATICS SEGMENT (ARDIGEN S.A.)**

The introduction of immunotherapy into medical practice has been an indisputable breakthrough in oncological treatment. Unfortunately, although this treatment is highly efficient for some patients, a significant percentage do not respond to immunotherapy but report serious side effects. This is one of the key challenges of contemporary oncology.

The aim of Ardigen's technologies is to support the development of modern immunotherapy and to increase the positive response of patients to existing oncological immunotherapies. In this context, the company has a unique holistic approach which combines immunomics (digital analysis of the immune system) and metagenomics (digital analysis of the microbiome).

In the first quarter of 2019, after three years of research conducted by Ardigen, three technological in silico platforms based on advanced artificial intelligence algorithms were launched.

The Microbiome Analysis Platform is an innovative approach to functional microbiome analysis based on full available metagenomic information. These analyses introduce a new quality in the LBP (Live Biotherapeutic Product) development process. In the light of the latest scientific findings indicating the impact of the microbiome on patients' response to immunotherapy, the platform will be used for research in this field. As a result of such work, new LBPs or biomarkers based on bacterial composition analysis may be developed. This class of technology will be at the heart of future companies developing personalised microbiome therapies.

The Neoepitope Prediction Platform predicts the peptide composition on the surface of cancer cells recognised as foreign antigens and eliciting the immune system response, resulting in the elimination of cancer cells. The ability to accurately predict neoepitopes is crucial in the development of anti-cancer vaccines and adoptive cell therapies. These vaccines are a promising method to increase patients' response to immune checkpoint inhibitors. A technology capable of accurately predicting immunogenic neoepitopes will be the key to the success of personalised cancer vaccines and adoptive cell therapies.

The Biomarker Discovery Platform enables stratification of patients who either respond or do not respond to given immunotherapy. It is based on a holistic approach to the analysis of many types of data (e.g. WES, WGS, RNAseq, immunohistochemistry, microbiome, clinical data). The ability to construct highly predictive mathematical models while being aware of prognostic parameters is of key importance in ongoing immunotherapy clinical trials as well as in subsequent clinical practice. This class of technology will be essential for selecting the most effective immunotherapy for a given patient.

In the first quarter of 2019, the new technology platforms were presented at the following conferences:

- Personalized Medicine World Conference in Santa Clara, California,
- The 3rd Microbiome Movement - Drug Development Europe in Paris,
- Bio-IT West in San Francisco, California,
- Immuno-Oncology Summit Europe in the UK.

The subsequent promotion campaigns have been planned for the second quarter. The intensity of marketing and sales activities in the first half of 2019 is the highest in the company's history.

In the first quarter, the Ardigen 2019 service offer was also presented. Ardigen was shown as a mature partner for companies developing drugs in the era of Artificial Intelligence. In relation to the previous year, the service offer has been enriched with new, dynamically developing areas, namely bioinformatics in projects using the CRISPR/Cas9 gene editing technology and the scRNA-seq (single cell) technology.



It is also worth mentioning that Ardigen competences in applying Artificial Intelligence in the search for therapeutic targets and in finding and optimising chemical molecules in the process of drug discovery are attracting more and more interest. The White Paper developed by the team of Ardigen AI Labs describing the results of the use of Ardigen’s Artificial Intelligence algorithms validated in the laboratory met with great interest from large and medium-sized pharmaceutical companies. This has resulted in numerous talks with potential clients.

On 20 March 2019, mSphere (ASM Journal), published the first paper by the Ardigen team entitled “Identification of Differentiating Metabolic Pathways between Infant Gut Microbiome Populations Reveals Depletion of Function-Level Adaptation to Human Milk in the Finnish Population” [Majta et al., 2019]. The results presented in the publication were obtained using the Ardigen microbiome analysis platform. This publication is an important element in building Ardigen credibility in the biotechnology environment as a provider of technology platforms using Artificial Intelligence.

### Employment details

Further to a dynamic development the Group significantly increased its staffing. The staffing level grew from 553 employees as of the end of 2018 to 587 employees in May 2019.

### Information on Selvita S.A. Shareholding Structure

As at the date of publication of the Report, the shareholder structure of Selvita S.A. including shareholders holding at least 5 % of votes at the Meeting of Shareholders, is as follows:

Shareholder	Shares	% of shares	Votes	% of votes
Paweł Przewięźlikowski	4 990 880	31,25%	8 490 880	42,41%
Bogusław Siczkowski	924 384	5,79%	1 474 384	7,36%
Augebit FIZ*	1 039 738	7,55%	1 039 738	5,83%
Nationale Nederlanden PTE S.A.**	1 316 969	8,25%	1 316 969	6,58%
Remaining shareholders	7,699, 258	47,16%	7,699, 258	37,82%
<b>Total</b>	<b>15,971, 229</b>	<b>100,00%</b>	<b>20,021, 229</b>	<b>100,00%</b>

\*The beneficiary of Augebit FIZ is Tadeusz Wesołowski – Vice Chairman of Selvita Supervisory Board; information based on the number of shares from the last notification provided by the shareholder to the Company

\*\*Number of shares represented at the Annual Shareholders' Meeting on May, 14 2018

## FINANCIAL INFORMATION

### Consolidated Profit and Loss Statement

FOR THE PERIOD FROM 1 JANUARY 2019 TO 31 MARCH 2019	01/01/2019 - 31/03/2019 PLN	01/01/2018 - 31/03/2018 PLN
<b>Continued operations</b>		
Revenue from sales	20 663 927	17 878 095
Revenue from subsidiaries	9 135 898	5 300 526
Other operating revenues	357 121	140 712
<b>Total operating revenue</b>	<b>30 156 946</b>	<b>23 319 333</b>
Change in stock of goods	-	-
Amortization and depreciation	(4 303 562)	(1 694 839)
Consumption of materials and energy	(7 561 315)	(5 483 380)
External services	(7 724 173)	(4 518 416)
Employee benefit expense	(16 539 317)	(11 575 868)
Taxes and charges	(249 266)	(183 876)
Other costs by type	(1 309 618)	(698 146)
Other	(72 839)	(38 838)
<b>Total operating expenses</b>	<b>(37 760 090)</b>	<b>(24 193 363)</b>
<b>Profit (loss) on operating activities</b>	<b>(7 603 144)</b>	<b>(874 030)</b>
Financial income	648 027	538 368
Financial expenses	(179 892)	(490 170)
Other	-	-
<b>Profit (loss) on business activities</b>	<b>(7 135 009)</b>	<b>(825 832)</b>
Equity method valuation of investments in associates	-	(651 843)
Fair value method valuation of investments in associates	-	21 439 106
<b>Profit (loss) before income tax</b>	<b>(7 135 009)</b>	<b>19 961 431</b>
Income tax expense	(218 328)	(67 873)
<b>Net profit (loss) on continued operations</b>	<b>(7 353 337)</b>	<b>19 893 558</b>
<b>Discontinued operations</b>		
Profit (loss) on discontinued operations	-	-
<b>Net profit (loss)</b>	<b>(7 353 337)</b>	<b>19 893 558</b>
Net profit loss attributed to:		
Majority shareholders	(7 547 855)	19 962 813
Non-controlling shareholders	194 518	(69 254)
Other comprehensive income:		
Foreign subsidiaries results translation differences	(90 396)	(129 446)
<b>Total other comprehensive income (loss)</b>	<b>(90 396)</b>	<b>(129 446)</b>
<b>Total comprehensive income (loss)</b>	<b>(7 443 733)</b>	<b>19 764 113</b>
Total comprehensive income (loss) attributed to:		
Majority shareholders	(7 638 251)	19 833 367
Non-controlling shareholders	194 518	(69 254)
<b>Earnings per share (expressed in gr per share)</b>		
With continued and discontinued operations:		
Basic	-47,8	123,7
Diluted	-47,8	123,7
With continued operations:		
Basic	-47,8	123,7
Diluted	-47,8	123,7

## Consolidated Balance Sheet

AS OF 31 MARCH 2019	31/03/2019	31/12/2018
	PLN	PLN
<b>ASSETS</b>		
<b>Fixed assets</b>		
Tangible fixed assets	57 478 548	52 439 692
Right of use assets	17 991 684	-
Investment property	-	-
Goodwill	280 740	280 740
Other intangible assets	2 500 709	2 403 174
Unfinished development works	-	-
Deferred tax assets	4 337 867	4 336 109
Investments in Nodthera Ltd.	22 825 875	22 825 875
Other assets	492 254	196 038
<b>Total fixed assets</b>	<b>105 907 677</b>	<b>82 481 628</b>
<b>Current assets</b>		
Inventory	1 989 469	1 989 469
Trade and other receivables	40 247 119	42 500 309
Construction contracts receivables	3 028 360	791 604
Other financial assets	14 972 512	15 075 299
Current tax related assets	-	-
Other assets	3 234 553	2 487 459
Cash and other monetary assets	93 795 610	110 373 895
	<b>157 267 623</b>	<b>173 218 035</b>
Non-current assets held for sale and discontinued operations	-	-
<b>Total current assets</b>	<b>157 267 623</b>	<b>173 218 035</b>
<b>Total assets</b>	<b>263 175 300</b>	<b>255 699 663</b>

## Consolidated Balance Sheet (cont.)

AS OF 31 MARCH 2019	31/03/2019	31/12/2018
	PLN	PLN
<b>EQUITY AND LIABILITIES</b>		
<b>Equity</b>		
Share capital	6 388 492	6 388 492
Surplus from sale of shares above par value	154 702 441	154 702 441
Own shares	-	-
Supplementary capital	25 955 714	25 955 714
Other reserve capitals	11 172 000	11 172 000
Foreign subsidiaries results translation differences	121 338	211 734
Previous years' profit (loss)	(6 415 421)	(6 411 401)
Net profit (loss)	(7 547 855)	(106 320)
Provisions related to non-current assets held for sale and discontinued operations presented directly in equity	-	-
<b>Equity attributed to majority shareholders</b>	<b>184 376 709</b>	<b>191 912 660</b>
Equity attributed to minority shareholders	3 953 044	2 947 424
<b>Total equity</b>	<b>187 429 753</b>	<b>194 860 084</b>
<b>Long-term liabilities</b>		
Long-term credits and loans	2 969 423	3 171 878
Other financial liabilities	21 018 891	6 864 769
Retirement provision	156 674	156 674
Deferred income tax provision	4 647 821	4 574 992
Long-term provisions	-	-
Deferred income	11 224 965	10 503 421
Other liabilities	-	-
<b>Total long-term liabilities</b>	<b>40 017 774</b>	<b>25 271 734</b>
<b>Short-term liabilities</b>		
Trade and other liabilities	14 505 199	18 998 849
Construction contracts liabilities	2 682 820	1 156 678
Short-term credits and loans	999 703	894 571
Other financial liabilities	7 147 177	2 540 280
Current tax liabilities	-	378 958
Short-term provisions	5 978 504	7 179 084
Deferred income	4 414 370	4 419 425
Other liabilities	-	-
<b>Total short-term liabilities</b>	<b>35 727 773</b>	<b>35 567 845</b>
<b>Total liabilities</b>	<b>75 745 547</b>	<b>60 839 579</b>
<b>Total equity and liabilities</b>	<b>263 175 300</b>	<b>255 699 663</b>

## Consolidated Cash Flow

	01/01/2019- 31/03/2019	01/01/2018- 31/03/2018
	PLN	PLN
<b>Cash flows from operating activities</b>		
<b>Net profit (loss)</b>	<b>(7 353 337)</b>	<b>19 893 559</b>
<b>Adjustments</b>		
Fair value method valuation of investments in Nodthera Ltd.	-	(20 787 264)
Amortization and depreciation	4 303 562	1 694 839
Exchange gains (losses)	(90 396)	-
Interest and profit-sharing (dividends)	(349 801)	31 134
Profit (loss) on investing activities	-	-
Change in receivables	16 434	(2 900 965)
Change in inventory	-	-
Change in short-term liabilities and provision excluding credits and loans	(3 114 765)	(2 602 057)
Change in grants	(8 288 799)	(3 557 775)
Change in deferred revenue	(263 820)	10 111
Change in other short-term assets	(1 043 310)	3 763 763
Change in provisions	(1 200 580)	124 348
Income tax paid	-	-
Income tax cost in P&L	218 328	-
Share-based incentive program	-	-
Other	-	-
<b>Cash flows from operating activities</b>	<b>(17 166 484)</b>	<b>(4 330 306)</b>
<b>Cash flows from investing activities</b>		
Proceeds from sale of tangible and intangible fixed assets	-	-
Purchase of tangible and intangible fixed assets	(6 669 366)	(3 884 620)
Purchase of tangible and intangible fixed assets partially financed with grant	(1 755 391)	(632 956)
Proceeds from sale of other financial assets	15 075 299	-
Purchase of other financial assets	(14 886 510)	-
Purchase of shares of a subsidiary	-	-
Interest received	351 717	31 819
Repayment of loans	-	-
Loans granted	-	(30 000)
Other inflows from financial assets	-	-
Other	-	-
<b>Cash flows from investing activities</b>	<b>(7 884 251)</b>	<b>(4 515 757)</b>
<b>Cash flow from financing activities</b>		
Proceeds from shares issue	13 402	134 200 000
Payment of liabilities from finance lease agreements	(624 819)	(293 694)
Proceeds from credits and loans	84 751	89 615
Grants	9 269 108	1 328 870
Repayment of credits and loans	(182 074)	(236 926)
Dividends paid	-	-
Interest paid	(87 918)	(62 954)
Payments connected with shares issue	-	(4 295 094)
<b>Net cash flows from financing activities</b>	<b>8 472 450</b>	<b>130 729 818</b>
Increase of net cash	(16 578 285)	121 883 755
Cash opening balance	110 373 895	36 124 149
<b>Cash and cash equivalents - end of the period</b>	<b>93 795 610</b>	<b>158 007 904</b>

## CONTACT DETAILS

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