



Selvita Group  
Annual Report  
(Summary)

**2018**

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## 1 LETTER TO THE SHAREHOLDERS

Dear Sir/Madam, Selvita Shareholders,

I have the pleasure of presenting you with a summary of Selvita Group's activity in 2018.

I shall begin the review of the Selvita Group's activities by discussing progress regarding the innovation segment projects.

In Selvita's most advanced project – SEL24, which is used for treating acute myeloid leukemia, the year 2018 can be summarized taking two significant stages of the project into consideration. The first focused on work to resume clinical trials after they had been temporarily held by the US Food and Drug Administration (FDA), including renewed recruitment of patients for the clinical centres. The second stage of the work, however, was focused on the clinical trials themselves which are now being carried out in five renowned centres in the USA. Please bear in mind that based on a licence agreement, our partner, the Menarini Group, is fully responsible for managing the trials. At the same time, we cooperate closely and also support the project with translational research. The progress of the research so far enables us to anticipate that in 2019 we will obtain the first clinical data in the Selvita Group's history.

With regard to the SEL120 project – CDK8 selective small-molecule kinase inhibitor, which can be used for treating haematological malignancies and solid tumours, as well as the most advanced R&D project, which is fully owned by Selvita, the year 2018 was full of important decisions and positive scientific results. In the third quarter of 2018, we commissioned Icon Clinical Research Limited, an entity with nearly thirty years' experience in running clinical trials, with the performance of phase I/II SEL 120. It should be noted that preliminary research allows us to assume that the molecule indicates it is effective both when used as a single agent of treatment, and also in combination with other drugs, and could therefore be a good alternative for drugs currently available on the market. The ongoing work schedule assumes the activation of clinical centres in the USA and administering SEL120 to the first patients in the Q3 of 2019 at latest.

It should also be noted that in 2018 we significantly reinforced the management staff of the teams responsible for R&D. Another change involved concentrating resources on the most advanced projects, which will contribute to achieving subsequent milestones much faster.

SEL120 and projects which are part of other R&D platforms will undoubtedly develop at a faster pace thanks to the funds (PLN 134 million) obtained from the secondary public offering which was successfully completed in February 2018.

It should be emphasized that from 2019, we will be able to work on developing new drugs using the Innovative Drug R&D Centre (*Centrum Badawczo-Rozwojowe Innowacyjnych Leków*) which is currently being constructed. This investment, worth PLN 55.9 million net, will contribute to reducing the demand for outsourcing part of the services which will have a positive impact on margins and accelerate the research processes in the Selvita Group.

With regard to the Selvita Group's service segment, it has recorded constant, dynamic growth, fulfilling the Company's and Management's expectations, and showing an increase in revenue of more than 34% and double-digit net profit margin. Also of importance is the fact that over the past few years Poland has been increasingly and ever more willingly selected by global biotechnological and

pharmaceutical firms seeking partners able to offer highly specialized services. As a result, the Selvita Group is counting on advanced integrated projects which not only meet the expectations of global concerns, but also ensure high profitability of the Group's activities. We are certain that our divisions in Kraków and Poznań, and also in the United States and the United Kingdom are appropriately prepared and ready to face new challenges so as to be able to provide the highest quality services.

The activities of affiliated companies are on an upward curve. NodThera has accelerated its R&D efforts, and is getting gradually closer to identifying a clinical candidate, thanks to funds of more than PLN 41 million, as the first out of three financing tranches, obtained in the second quarter of 2018 from a transatlantic consortium of venture capital funds. These funds are to reach a total of more than PLN 121 million by 2020.

In 2018, Ardigen recorded its first transaction of more than USD 1 million in the services area. It should be noted that this company's revenue went up by 24% compared with that obtained in the previous financial year. The company is also strengthening its R&D activities which contribute to supplementing its service offer significantly.

None of these achievements would have been possible but for an increase in the staff who are excellent specialists in their field. The number of Selvita Group's employees increased from 431 people at the end of 2017 to 553 at the end of 2018. At this point, it is worth noting that year on year, Selvita's staff are becoming increasingly international – already nearly 10% of employees are from outside Poland and of 10 different nationalities.

I would like to thank you for placing your trust in our project and your enthusiasm regarding the Selvita Group's bold plans, as well as your valuable advice and guidance which we use in our day-to-day activities. We also thank you for your confidence in us from the very outset of our presence on the Warsaw Securities Exchange. Our undertaking from the very start has been to build strong and sustained bonds of trust between the investor and Selvita, which we strive to strengthen each year. Thanks to you, we managed to accumulate funds used to develop our projects, and thereby support our battle against cancers in the field of oncology. The goals set for the coming years include intensive progress in developing new drugs and the constant growth of service activities.

We hope that 2019 and subsequent years will bring valuable and ground-breaking discoveries and success in all areas of the Group's activities.

With best regards,  
Pawel Przewieźlikowski  
Selvita CEO

## 2 BASIC INFORMATION ON THE SELVITA GROUP

### 2.1. Structure of the Capital Group

#### Parent Entity

Business name of the Company	Selvita Spółka Akcyjna
Registered office	ul. Bobrzyńskiego 14, 30-348 Kraków
Company ID (REGON)	120515330
Tax ID (NIP)	679-29-42-955
Legal form	Joint-Stock Company
Website	www.selvita.com

#### Affiliated Entities

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

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

Business name of the Company	Selvita Inc.
Registered office	100 Cambridge Street, Boston, USA
Company File No.	5700516
Legal form	Corporation
Shareholder	100% shares held by Selvita S.A.

Business name of the Company	Selvita Ltd.
Registered office	20 Station Rd, CB1 2JD Cambridge, Great Britain
Company No.	9553918
Legal form	Limited Liability Company
Shareholder	100% shares held by Selvita S.A.

Business name of the Company	Ardigen Spółka Akcyjna
Registered office	ul. Bobrzyńskiego 14, 30-348 Kraków
Company ID (REGON)	362983380
Tax ID (NIP)	676-249-58-65
Legal form	Joint-Stock Company
Shareholders	49,26% shares and 51,85 % of votes held by Selvita S.A.

## Related Entity

<b>Business name of the Company</b>	Nodthera Ltd.
<b>Registered office</b>	Aberdeen, Great Britain
<b>Company No.</b>	540381
<b>Legal form</b>	Limited Liability Company
<b>Shareholders</b>	18,35% shares held by Selvita S.A.

Parent Entity and Affiliated Entities which form Capital Group of Selvita S.A. (hereinafter “Selvita Group”, “Group”, “Selvita Capital Group”) are subject to consolidation. The management board of Selvita S.A. decided that all shares of Nodthera Ltd. will be valued to fair value, based on the price of shares issued on March 30, 2018.

## 2.2. Governing Bodies of the Parent Entity

As of March 27, 2019, the Management Board and Supervisory Board of Selvita S.A. consist of:

### Management Board

- Paweł Przewięźlikowski – President of the Management Board
- Bogusław Sieczkowski – Vice President of the Management Board
- Krzysztof Brzózka, PhD – Vice President of the Management Board
- Miłosz Gruca, PhD – Member of the Management Board
- Mirosława Zydróż, PhD – Member of the Management Board
- Edyta Jaworska – Member of the Management Board

### Supervisory Board

- Piotr Romanowski, PhD – President of the Supervisory Board
- Tadeusz Wesołowski, PhD – Vice President of the Supervisory Board
- Wojciech Chabasiewicz – Member of the Supervisory Board
- Rafał Chwast – Member of the Supervisory Board
- Wojciech Sobieraj – Member of the Supervisory Board

## 3 ECONOMIC AND FINANCIAL HIGHLIGHTS

### 3.1 Financial Results Attained in the Reporting Period

Selvita Group	Consolidated data in PLN thousand		
	01.01.2018 - 31.12.2018	01.01.2017 - 31.12.2017	01.01.2017 - 31.12.2017 (excl. Incentive program)
Revenue from sales	77 206	67 536	67 536
Revenue from subsidies	32 014	17 591	17 591
Revenue from R&D projects	0	20 285	20 285
Other operating revenue	878	460	460
Revenue on operating activities	110 098	105 872	105 872

Operating expenses	(123 709)	(93 233)	(92 650)
Depreciation	(8 225)	(5 240)	(5 240)
Profit/loss on operating activities (EBIT)	(13 611)	12 639	13 222
Profit/loss before income tax	8 986	9 600	10 183
Net profit/loss	892	6 732	7 315
EBITDA	(5 386)	17 879	18 462
Net cash flow from operating activities	(36 417)	10 982	10 982
Net cash flows from investing activities	(37 199)	(21 509)	(21 509)
Net cash flows from financing activities	147 866	17 557	17 557
Total net cash flow	74 250	7 029	7 029
Number of shares	15 522 744	13 771 229	13 771 229
Profit (loss) per share (in PLN)	0,0	0,48	0,51
Diluted profit (loss) per share (in PLN)	0,0	0,48	0,51
Book value per share (in PLN)	12,4	4,52	4,57
Diluted book value per share (in PLN)	12,4	4,52	4,57
Declared or paid dividend per share (in PLN)	-	-	-

Selvita Group		Consolidated data in EUR thousand		
Item	01.01.2018 - 31.12.2018	01.01.2017 - 31.12.2017	01.01.2017 - 31.12.2017 (excl. Incentive program)	
Revenue from sales	18 094	15 911	15 911	
Revenue from subsidies	7 503	4 144	4 144	
Revenue from R&D projects	0	4 779	4 779	
Other operating revenue	206	108	108	
Revenue on operating activities	25 803	24 942	24 942	
Operating expenses	(28 993)	(21 965)	(21 827)	
Depreciation	(1 928)	(1 235)	(1 235)	
Profit/loss on operating activities (EBIT)	(3 190)	2 978	3 115	
Profit/loss before income tax	2 106	2 262	2 399	
Net profit/loss	209	1 586	1 723	
EBITDA	(1 262)	4 212	4 349	
Net cash flow from operating activities	(8 535)	2 587	2 587	
Net cash flows from investing activities	(8 718)	(5067)	(5 067)	
Net cash flows from financing activities	34 654	4 136	4 136	
Total net cash flow	17 401	1 656	1 656	
Number of shares	15 522 744	13 771 229	13 771 229	
Profit (loss) per share (in EUR)	0,0	0,11	0,12	
Diluted profit (loss) per share (in EUR)	0,0	0,11	0,12	
Book value per share (in EUR)	2,9	1,09	1,09	
Diluted book value per share (in EUR)	2,9	1,09	1,09	
Declared or paid dividend per share (in EUR)	-	-	-	

Selvita Group	Consolidated data in PLN thousand			Consolidated data in EUR thousand		
	31.12.2018	31.12.2017	31.12.2016	31.12.2018	31.12.2017	31.12.2016
Total assets	255 700	103 574	89 121	59 465	24 832	20 145

Short-term receivables	43 292	19 225	16 320	10 068	4 609	3 689
Cash and equivalents	110 374	36 124	29 095	25 668	8 661	6 577
Other short-term financial assets	15 075	93	60	3 506	21	14
Liabilities and provisions	60 840	39.578	33 410	14 149	9 489	7 552
Long-term liabilities	25 272	12.826	14 477	5 877	3 075	3 272
Short-term liabilities	35 568	26 752	18 933	8 272	6 414	4 280
Equity	194 860	63 996	55 711	45 316	15 343	12 593
Share capital	6 388	5 508	5 377	1 486	1 321	1 215

## 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:

- 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 01/01/2018 – 31/12/2018: PLN 4,2669;
  - for the period from 01/01/2017 – 31/12/2017: PLN 4,2447.
- 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 December 2018: PLN 4,3000;
  - as at 31 December 2017: PLN 4,1709;
  - as at 30 September 2016: PLN 4,4240.

*In order to maintain comparability financial data of Selvita Group for 2017 does not account PLN 583 thousand for the costs of the incentive program, which was carried out in 2015-2017.*

In the reporting period, and as part of the implementation of Selvita strategy for years 2017-2021, the Group has entered the phase of very intense investment. Over PLN 130 million obtained from the recent (February, 2018) successful issue of shares 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 result in securing better financial conditions in comparison with the ones obtained so far. In addition, the Group has changed and implemented its accounting policy over the years 2017 and 2018 which aimed at ensuring compliance with International Financial Reporting Standards. Pursuant to this change, all expenditures within conducted projects shall be recognized directly in the profit and loss account. Above factors resulted in a significant cost increase that is presented in the innovation segment.



In 2018 the Selvita Group reported a profit at the level of the entire activity (net profit). The Group reported a loss on an operating level. This is a result of the intensification of research & development projects in the Innovation Segment and lack of new commercialization deals in the reporting period. According to the Group's Strategy adopted in 2017, the Innovation Segment has focused on increasing the value of ongoing projects and preparation of their commercialization at later stages.

The Group's net result for the year 2018 amounted to PLN 892 thousand in comparison to PLN 7,315 thousand in the comparative period of 2017. The Group's net profitability for the year 2018 (calculated as the net profit divided by total operating activities that is revenue from sales and subsidies) amounted to 1% which means a decrease of 6 p.p. in comparison to the corresponding period of 2017. In this period of 2018 net profit significantly exceeded profit on operating activities as a result of positive valuation of Nodthera's shares held by Selvita and write off of previously recognized deferred income tax assets on Selvita operation in Special Economic Zone (SEZ). Both factors are described in detail below. In 2018 net profit, without accounting for the changes in the tax assets, related to operations in the SEZ amounted to PLN 4,372 thousand (in 2017: PLN 9,352 thousand) and net profitability (calculated as the ratio of the net profit to its total revenue, including revenue from sales and subsidies) amounted to 4%.

Throughout 2018, Selvita Group recognized revenue on operating activities in the amount of PLN 110,098 thousand which gives 4% increase compared to PLN 105,872 thousand in 2017. Revenue from sales in 2018 (including revenue from R&D programs' sales; excluding subsidies) amounted to PLN 77,206 thousand, reflecting 12% decrease compared to 2017 when sales revenue amounted to PLN 87.820 thousand (including PLN 20,285 thousand from commercialization of SEL24).

The Services Segment in 2018 reached very good profitability while keeping good growth's dynamics at the same time. The 2018 revenue from sales of services to external customers totalled PLN 59,084 thousand compared to PLN 44,208 thousand in 2017, which constitutes growth of over 34%. The operating profit (EBIT) of that segment in 2018 amounted to PLN 8,828 thousand, which constitutes growth of over 67% compared to PLN 5,277 thousand in 2017, 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 14%.

In 2018 the Innovation Segment did not sign any new agreement on commercialization of the scientific project, which resulted in a decrease of revenue from external customers generated by this segment (amounting to PLN 9,741 thousand) as compared to 2017 (amounting to PLN 36,727 thousand) when the commercialisation of SEL24 took place. In this period operating loss (EBIT) of the Innovation Segment in 2018 totalled PLN 24,625 thousand, reflecting a decrease as compared to 2017 when the operating profit equalled PLN 6,414 thousand.

In 2018 Bioinformatics Segment's revenue from sales of services to external customers amounted to PLN 8,557 thousand, which means an increase of 24% compared to 2017, when revenue amounted to PLN 6,885 thousand. Bioinformatics Segment generated in 2018 operating profit in the amount of PLN 2,186 thousand.

In 2018, revenue from subsidies increased by 82% compared to the previous year – from PLN 17,591 thousand to PLN 32,014 thousand. The increase in revenue from subsidies is primarily due to the

growth of costs incurred for new innovative projects implemented under the new financial perspective 2017-2021.

### Tax reliefs from operations in Special Economic Zone

Due to the application of tax reliefs available to companies operating on the basis of permits for operations in the Special Economic Zones (SEZ), the Selvita Group companies are obliged to record and regularly update deferred income tax assets. In 2018, as a result of the loss generated by Selvita S.A. on SEZ activity, the Group decided to write off deferred tax accrued in previous years from this activity in the amount of PLN 3,882 thousand. The Group also updated its deferred tax on Selvita Services Sp. z o.o. operations in SEZ in the amount of PLN 403 thousand. Both changes resulted in a total negative impact on gross income in the amount of PLN 3,479 thousand. Deferred tax assets ("DTA") and changes between the companies from the Group are presented below:

	31.12.2018	31.12.2017	change
DTA from SEZ in Selvita S.A.:	0	3 882	(3 882)
DTA from SEZ in Selvita Services sp. z o.o.:	3 793	3 390	<u>403</u>
			(3 479)

### Impact of SEL 120 asset release on profit and loss account.

In 2018 the Group continues its dynamic development of drug discovery, in particular, related to SEL 120.

In accordance with IAS 38 requirements, from January 1, 2018, the Selvita Group recognizes all of its expenditures on research and development activities directly in profit and loss account. At the end of 2018, Selvita wrote off all of its expenditures on SEL120 and related subsidies that were already capitalized until 2017. As a result, previously accrued revenue from cooperation with LLS (subsidy) were also recognized in profit and loss account. Impact of released assets on gross income of the Group (PLN 176 thousand) is presented in other operating revenue.

Capitalized costs (at the end of 2017)	(6 988)
Capitalized subsidies (at the end of 2017)	3 780
LLS accrued revenue from subsidy (in the period 2017-2018)	<u>3 384</u>
Impact on consolidated gross income 2018	176

### Valuation method of shares in Nodthera Ltd.

On March 30, 2018 the share capital in the related company Nodthera Ltd. (with its registered office in Aberdeen, Great Britain) was increased by 8,666,667 GBP (which amounts to 41.615.602 PLN according to the exchange ratio GBP/PLN published by the National Bank of Poland: 1 GBP = 4,8018 PLN) by issuing 3,482,270 new shares, which were subscribed by the majority shareholder Epidarex Capital II LP and new external investors F-Prime Capital, Sofinnova and 5AM Ventures. After the increase of share capital and the issue of shares directed at key employees, Selvita holds 18,35% in the fully diluted share capital of Nodthera Ltd. As a result of the loss of significant control over Nodthera Ltd. the management board of Selvita S.A. decided that all shares will be valued to fair value, based on

the price of shares issued on March 30, 2018 (till the end of March 2018, shares in Nodthera Ltd. were valued using the equity method).

#### Fair value method valuation of shares in Nodthera Ltd.

Price of new shares (in GBP)	2,4888
Average rate of exchange NBP (29.03.2018)	4,8018
Price of issue of new shares (in PLN)	11,95
Number of shares owned by Selvita S.A.	1 910 000
Share value	22 825 875
Share value in balance sheet (31.12.2017)	2 038 611
Deferred tax	4 207 923
Change in valuation – impact on financial results	<b>16 579 341</b>

The value of the backlog for 2019 resulting from commercial contracts and subsidy agreements signed as of the publication date of this report amounts to PLN 81.992 thousand, including:

- Services PLN 41,715 thousand,
- Innovation PLN 2,454 thousand,
- Bioinformatics PLN 6,730 thousand,
- Subsidies PLN 31,093 thousand

and it has increased compared to the 2018 backlog announced in April 2018 by 19%. It should be emphasized that the Services Segment backlog for 2019 has increased by 43%, bioinformatics backlog has increased by 42%. However the Innovation Segment backlog has decreased by 65% compared to the same period last year.

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

As of the end of 2018, the value of the Group's assets was PLN 255,700 thousand and increased by PLN 152,126 thousand compared to the end of 2017 (PLN 103,574 thousand). As of the end of 2018 the highest value of current assets is cash in the amount of PLN 125,449 thousand (as of the end of 2017 amounted to PLN 36,217 thousand), presented in consolidated statement of financial position as cash and cash equivalents amounting to PLN 110,374 thousand and as other short-term financial assets in the amount of PLN 15,075 thousand (including PLN 14,986 thousand in bonds with interests). Fixed assets are mainly laboratory equipment, deferred income tax asset in the amount of PLN 4,336 thousand and other long-term financial assets in the amount of PLN 22,826 thousand. Compared to the amounts as of 31 December 2017 the value of cash and cash equivalents and value of other short-term financial assets increased mainly as a result of the issue of series H shares. The value of fixed assets increased by PLN 38,781 thousand compared to 31 December 2017 as a result of investments in state-of-the-art scientific equipment and the increased valuation of shares in Nodthera Ltd.

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

	2018	2017
<b>Liquidity indicator</b>		
current assets/current liabilities including short-term provisions and accruals (excl. deferred revenue)	5,56	3,27

<b>Increased liquidity indicator</b> (current assets-inventory)/current liabilities including short-term provisions and accruals (excl. deferred revenue)	5,50	3,18
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Cash surpluses not used in the operating activities are invested in safe financial instruments that is: bank deposits, PKO Leasing bonds.

The main item in the Selvita Group's equity and liabilities is equity, which amounted to PLN 194,860 thousand as of December 31, 2018 and increased by PLN 130,865 thousand compared to 31 December 2017. Increase in equity is a result of recent successful issue of shares and net profit for the year 2018. Another important source of funding are long-term liabilities which amounted to PLN 25,272 thousand at the end of 2018. The highest value long-term liabilities item is deferred revenue (most of them subsidies to be settled in the future) in the amount of PLN 10,503 thousand.

### 3.3 Current and Projected Financial Condition

The Group's financial position as of the report date is very good. As of December 31, 2018 the value of the Group's cash amounted to PLN 125,449 thousand, including PLN 110,374 thousand in cash and PLN 15,075 thousand in short-term financial assets (including PLN 14,986 thousand in bonds with interests). As of March 22, 2019 the value of the Group's cash amounted to PLN 113,662 thousand, including PLN 98,773 thousand in cash and PLN 14,889 thousand in bonds, and safe investment fund units.

Activity of Selvita Group in Innovative Segment in 2018 recorded a loss, however activity in the Services and Bioinformatics Segment was profitable. Activity in Bioinformatics Segment achieved a slight positive financial result. Activity of R&D is financed by customer revenue, supplemented by research subsidies and funds acquired through share issue. In the future periods, further revenue increase is expected both in Services and Bioinformatics Segment as well as from commercialization of next research projects, following by sustaining of the profitability in aforementioned segments.

The Group meets its obligations on time and maintains a sustainable cash flow ensuring its liquidity. Income from share issue 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.

## 4 INFORMATION ON THE ACTIVITIES OF SELVITA GROUP

### 4.1 Products and Services

The activities of the Selvita Group cover three segments:

- Innovative Segment – research and development activities involving in-house research projects on innovative drugs,
- Services Segment – drug discovery services provided to external clients from the pharmaceutical and biotechnology industry,
- Bioinformatics Segment – bioinformatics and data science services as well as development of personalized and precise medicine products.

#### **4.1.1 Innovative Segment (Research and Development Activity)**

In 2018, the Selvita Group successfully continued all research projects, both these in which it invests own funds, as well as projects performed in cooperation with external partners e.g.: Cancer Cell Metabolism Platform in cooperation with Merck.

##### **TARGETED THERAPIES PLATFORM (TTP)**

###### **SEL24/MEN1703**

The aim of the project is to develop a novel therapy for treatment of cancer including Acute Myeloid Leukemia (AML), based on the SEL24 molecule. The mechanism of action of this molecule involves selective (dual) inhibition of PIM and FLT3 kinases, crucial in the neoplastic process. The project is currently at the stage of clinical trials. The first application of SEL24 to a patient with AML took place in a phase I/II clinical trial conducted in the United States, which was announced by the Company on March 17<sup>th</sup>, 2017.

In Q1 2018, following the issuing of consent by US Food and Drug Administration to resume the clinical trial in December 2017, Selvita focused on re-activation of sites and enrolment of patients to the CLI24-001 study. By the end of H1 2018 Selvita obtained favorable opinions of local Institutional Review Board (IRB) for the three existing sites and the study resumed with successful patient recruitment and administration of SEL24 in March 2018. In addition, two renowned clinical sites in the US were engaged in the study, namely Cleveland Clinic, Taussig Cancer Institute in Ohio and Fred Hutchinson Cancer Research Center in Seattle.

On 19 of June 2018 Selvita concluded a tripartite agreement between the Company, Menarini Ricerche S.p.A. and Theradex Europe Ltd, under which the Company assigned rights and obligations concluded under the agreement by the Company with Theradex for the conduct of Phase I/II clinical trial, for Menarini. Pursuant to the agreement, from 30<sup>th</sup> June 2018, Theradex continued its work under the aforementioned SEL24 clinical trial on behalf of and for the benefit of Menarini. The conclusion of the agreement is the fulfillment of the obligation resulting from the license agreement of the SEL24 concluded between the Company and Menarini Group in March 2017.

The details of the clinical trial are available at the website: <https://clinicaltrials.gov/ct2/show/NCT03008187>. Information about the status and progress of the phase I study is planned to be presented by Menarini at scientific and medical conferences in 2019. The Company will notify about the progress of project, the results and further plans based on the information received from Menarini.

###### **SEL120**

SEL120 project is focused on development of CDK8/19 kinase inhibitor as an effective treatment of cancer. Preclinical research studies indicated crucial role of CDK8 in regulation of oncogenic gene expression programs, particularly in AML. Inhibition of CDK8 results in differential cytotoxicity on cancer cells and induction of differentiation. Although AML remains the best validated indication for SEL120, promising signs of activity have been also observed in solid tumors as a single agent and in combination with immune checkpoint inhibitors.

In 2018 major focus in the project was completion of the studies and preparation of documentation required for IND (Investigational New Drug) application submission for first-in-man Phase I clinical trials to the FDA. SEL120 candidate molecule was tested in a series of regulatory safety and toxicology

experiments. Moreover, preclinical activities involved manufacture of preclinical and clinical scale drug product, analytical method development and bioanalytical support. Selvita was supervising these preclinical works which were performed by specialized CROs, in particular Aptuit (currently part of Evotec) and other partners. Experimental part has been successfully completed in Q4 2018.

In 2018, Selvita concluded a framework agreement (with the accompanying work order) with ICON. This specialized CRO will submit an IND application on behalf of the Company to the Food and Drug Agency in the USA and will perform phase I clinical trials for SEL120.

Pre-clinical and clinical development of SEL120 is supported within the collaboration established by the Company with the American foundation - Leukemia and Lymphoma Society (LLS). Based on the agreement signed in August 2017, until March 28, 2019, the Group received payments for successful achievement of milestones in SEL120 project for a total amount of USD 1,100,000. These payments are strictly related to the progress of preclinical development.

The current actions schedule assumes the finalization of the process of commencing clinical trials on SEL120 in Q3 of 2019 at the latest.

Selvita in collaboration with several leading academic institutions (renowned on national and international level) continued preclinical studies supporting current clinical strategy in AML (acute myeloid leukemia). Moreover, additional translational studies were aimed at expansion into novel oncology indications and identification of patients' selection markers. These studies confirmed high efficacy of the compound *in vivo*, as a single agent, and in combinations, including complete remissions. High efficacy in preclinical AML models correlated with complete inhibition of established CDK8 markers and was achieved at well tolerated doses in animals. Results from AML cells provided better insight into molecular mode of action, essential for the optimal position of the compound in the current treatment paradigms. Results of the collaboration with scientists from the Lund University validated SEL120 as a promising agent in the treatment of ribosomopathies, such as Diamond-Blackfan anemia. Results in that field have been presented during the ASH (American Society of Hematology) annual meeting in San Diego 2018.

The results of SEL120 program were also presented at other prestigious scientific and medical conferences, among the others AACR Annual Meeting 2018 (Apr 2018, Chicago, USA), EORTC-NCI-AACR Molecular Targets and Cancer Therapeutics Symposium (Nov 2018, Dublin, Ireland) and during the Leukemia and Lymphoma Conference - Europe and the USA Linking Knowledge and Practice (Dubrovnik, Croatia). Conference materials are available at: <https://selvita.com/pl/projekty-innowacyjne/pobierz-poster/>

#### ***Other TTP platform projects***

TTP platform develops novel drug candidates targeting major oncogenic pathways. Lead projects are focused on the concept of synthetic lethality and inhibition of proteins responsible for epigenetic reprogramming, characteristics of cancer cells. Bioinformatic tools are used for identification of cancer dependency maps. The aim is discovery of relationships between unique cancer features, predominantly genetic, and specific inhibition of protein targets, leading to synthetic lethal phenotype.

Primary indication for synthetic lethality projects are cancers bearing recurrent mutations in the SWI/SNF complex. 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. First identified molecules effectively bind and inhibit ATPase activity of BRM and show selective biological activity in cells with mutations of SMARCA4. Molecular profiling of active compounds indicated on-target modulation of genes under control of SWI/SNF complex in cancer cells, mimicking the phenotype of genetic silencing of SMARCA2. Development of compounds with improved properties is in progress. Other proprietary protein targets and programs could not be revealed due to confidentiality constraints. Our own studies also identified novel epigenetic modulators active in genetically defined subgroups of leukemia. Functional studies validated inhibition of these protein targets as a promising therapeutic strategy in hemato-oncology. First active molecules have been identified and development of compounds with improved properties is in progress.

#### Collaboration with H3 Biomedicine

Due to significant strategic changes which occurred within the reporting period in H3 Biomedicine (USA biotech company) research collaboration with this scientific partner was not prolonged. Currently, there are ongoing negotiations between the partners, as a result of which the Company is to be granted the right to further, independently develop a part of a jointly initiated project that best fits into the portfolio of the TTP platform.

#### Collaboration with FeliciteX Therapeutics

In December 2018, the Company signed a license agreement with the American company FeliciteX Therapeutics, under which FeliciteX was granted an exclusive license for further development and commercialization of the molecules with anti-cancer activity generated within the previous research collaboration (years 2014-2015). If FeliciteX reaches the planned goals in further project development, the Company will be entitled to receive milestone and royalty payments.

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

Immuno-Oncology Platform aims to provide novel immunotherapies mobilizing and stimulating human immune system to recognize and sensitize tumors to immune attack. This approach transforms “cold”, aggressive cancers which are resistant to current immunotherapy with checkpoint inhibitors into “hot”, treatment susceptible malignancies.

Currently Selvita focuses on a STING signalling pathway. STING agonists may serve as immune boosters to support natural body’s defense systems by enhancing neoantigen presentation and tumour-specific T cell proliferation. Such immune system activation facilitates a durable anti-tumor response and consequently leads to the regression of established tumors and generation of a long-term immunological memory. They may also unlock the potential of other immunotherapies in resistant malignancies.

Selvita possesses the most potent publicly disclosed known small molecule, direct STING agonists. They have immunomodulatory efficacy *in vitro* at low nanomolar concentration ranges outperforming activity of STING agonists currently being evaluated in clinical trials. Selvita STING agonists have the potential for systemic routes of administration due to their non-nucleotide structure and more beneficial ADME parameters. This is a more optimal approach compared to competitive STING agonists



(cyclic dinucleotides) at the stage of clinical development with intratumoral route of administration, constituting the competitive advantage.

In 2018 Selvita continued optimization of ADME parameters and cellular activity of a STING agonists lead series. The substances efficiently activate *in vitro* human and mouse immune cells responsible for neoantigen presentation (dendritic cells and macrophages) with superior efficacy to known cyclic dinucleotide STING agonists. Selvita STING agonists have activity independent of STING mutations in biophysical tests and in blood samples of human donors, which hold promise for therapeutic effectiveness of STING agonists in a wide patient population.

As a result of the work, the Company selected candidates for *in vivo* tests in animal models. Pilot studies confirmed therapeutic efficacy demonstrating a dose-dependent tumor growth inhibition and abscopal effect allowing for anti-cancer control of distant metastases. The current intensive optimization work aims to identify by the end of 2019 the molecule with the greatest therapeutic potential and to develop an optimal combination with other immunotherapeutics and chemotherapy.

The latest results not affecting Selvita's competitive position were presented in 2018 at the Immuno-Oncology Summit in Boston and SITC in Washington, DC and are available on the Selvita website at <https://selvita.com/research-and-development/download-a-poster/>.

Selvita's immuno-oncology platform consistently follows a clear strategy that comprises projects aiming at regulation of the T cell-dependent immune response. HPK1 (MAP4K1) is one of the major proteins involved in signalling cascade triggered by TCR activation. Inhibition of HPK1 kinase activity stimulates dendritic cells to antigen presentation and enhances activation and proliferation of T cells, which leads to mounting an immune response directed against the cancerous cells. The low nanomolar HPK1 inhibitors identified by Selvita efficiently inhibit protein enzymatic activity, modulate HPK1 downstream biomarkers and activate T lymphocytes *in vitro*. Chemical expansion of the series leading to improvement of ADME parameters and selectivity is ongoing.

Additionally, Selvita focuses on other innovative projects aiming at regulation of the immune response dependent on the STING and TCR/TLR signalling. The programs are at early drug discovery stage and details are confidential due to competitive environment.

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

Research projects in the field of cancer cell metabolism and immunometabolism have been grouped in a dedicated research platform since 2017. 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 to develop 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. Immunotherapy allows for mobilization of the immune system and using its potential to specifically destroy cancer cells, while lacking toxicity against healthy tissues. In 2018, work within the field of immunometabolism was 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. The inhibition of both, the production of adenosine by tumor cells (CD39 / CD73 enzymes) and its effects on the immune cells (A2A / B receptors) is a new therapeutic strategy validated in many models.



In 2018, very intense work on new dual A2A/A2B receptor antagonists resulted in obtaining the most active substances known to date with this activity profile (picomolar activity range). Their therapeutic potential has been confirmed in pilot *in vivo* studies, where inhibition of tumor growth and dose-dependent effects of increased infiltration of immune cells (eg. CD8 + T lymphocytes or natural killer cells) to the tumor were observed. In 2018 the advanced research was underway to identify the compound with the highest *in vivo* efficacy and to develop the optimal combination for clinical trials (approved inhibitors of immune checkpoints, chemotherapy). Selvita compounds demonstrate multifold improvement of potency in functional *in vitro* models. The short list of preclinical development pre-candidates has been limited to just few most advanced molecules and final nomination for pre-clinical development candidate is planned for 2019.

The most recent project results (but not affecting Selvita's competitive position) were presented in 2018 at Immuno-Oncology Summit conferences in Boston and SITC in Washington and are available on Selvita website at <https://selvita.com/pl/projekty-innowacyjne/download-poster/>.

The aim of long-term collaboration with Merck KGaA, which has been ongoing since 2013, is a development of new oncology drugs for molecular targets related to disturbed metabolic pathways in cancer cells (cancer metabolism). Dependence on specific metabolic pathways (such as glutaminolysis or glycolysis) is a feature of many types of cancer, therefore this kind of pharmacotherapy has potentially very wide application in oncology. Several molecular targets (undisclosed) have been selected in cooperation with the partner, and research works are at various levels (from target validation to lead optimization). Apart from financing, the project has scientific and infrastructural support from the partner, which is a R&D division of one of the 25 largest global pharmaceutical companies. The research continues according to the schedule, further details of the project are covered by trade secrets.

In Q4 2018, Merck and Selvita signed an annex to the expiring collaboration agreement, extending the contract for another year (until the end of September 2019). By virtue of the signed extension, Merck covers the costs of research conducted by Selvita, and the Company maintains the right to future milestone and royalty payments if the project achieves intended scientific and marketing goals.

An internal cancer metabolism project aiming at a crucial metabolic pathway related to tumorigenesis, both for solid and hematological tumors, nanomolar SHMT2 inhibitors is also an element in CMIMP portfolio. The specificity and efficacy of inhibition has been confirmed in cellular models. In 2018 there were research works performed with a goal to validate the selected therapeutic strategy in animal cancer models. Simultaneously, inspired by recent scientific publications, Selvita has initiated characterization of selected compounds in other *in vitro* models for therapeutic indications with a high level of unmet medical need.

#### **OTHER PROJECTS**

Apart from the aforementioned projects, in 2018 within the platforms presented above, Selvita Group also carried out other research and development projects, however the details and the current status thereof is confidential. In 2019, the Company plans to continue research on innovative molecular targets in the field of oncology in order to supply Selvita's portfolio with additional "first in its class" or "best-in-class" R&D compounds.

#### 4.1.2 Services Segment

Selvita is an integrated drug discovery partner for the pharmaceutical and biotechnology industries. The company offers drug discovery support at every stage of the early discovery phase up to the preclinical research phase, including:

- unique combination of experienced team of managers and top researchers in computational, medicinal and contract chemistry, as well as in biochemistry, pharmacology, molecular biology and biotechnology, specialized in particular parts of the R&D process,
- services related to synthesis and analysis of small and large molecule chemical compounds,

Selvita provides services through two main departments: Contract Chemistry Department and Contract Biology Department.

##### ***Contract Chemistry Division***

The Contract Chemistry Division specializes in providing research and development services in the area of chemistry, which lead to developing new therapies, innovative processes and technologies, and cost-effective products. This Division specializes in support of the projects aiming at discovery of new therapeutic compounds medicinal and computational chemistry, as well as organic synthesis for the pharmaceutical, biotechnology, chemical and agrochemical industry.

With regard to 2018, particular attention should be drawn to the increase in the share of Contract Chemistry revenue from the Contract Chemistry Division deriving from integrated research projects that aim at the discovery of new therapeutic molecules. Experts in the fields of chemistry, biology, analytics and computational chemistry were involved in such projects.

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.

In 2018 as a result of the intensification of activities performed in the integrated drug discovery projects, the Division invested in specialized apparatus supporting work on research and development

projects, including mainly, parallel synthesis, automatic purification and analyses of organic compounds, thus increasing the effectiveness of processes and their quality, which enabled to extend the range of services offered, what in turn was appreciated by customers.

As a result of constantly increasing standards (technical, quality and infrastructural), interest in the services of the Contract Chemistry Division grew significantly, which in turn had an impact on the increase in the number of employees and revenue.

The customer base of the Chemical 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 as well as the agrochemical and chemical industry.

In 2018 portion of revenue earned from FTE projects has increased by over 90 %. The Chemical Division also continued to acquire fixed-price contracts from new and regular customers. throughout the period.

In 2018, similarly to the previous years, intense sales activities continued in the US, Europe, Israel and Japan, aimed at acquisition of new customers on those markets. Apart from standard sales activities, representatives of the Division participated in prestigious industry conferences which was not only a good occasion to meet with current business partners, but also led to making new, commercial contacts potentially interesting from sales perspective.

Currently contracted services and ongoing business negotiations enable to anticipate a further growth trend in 2019. Planned operating activities (increasing the level of technical, quality and infrastructural standards) and sales activities (Europe, Israel, further increasing activity on the US and Japanese markets) are planned in 2019, therefore constant and intense development of the Contract Chemistry Division is anticipated.

### ***Contract 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 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 2018, the surface area of laboratories in the Biochemistry Department increased (to 350 sq. m.), which was connected with opening a laboratory for eukaryotic cell culture. This was a necessary step for extending the Department's offer to include products (recombinant proteins) and services based on mammalian expression systems as well as a possibility of producing monoclonal antibodies and other proteins which require specific modifications unavailable in other expression systems.

In 2018, Selvita Analytic 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 number of projects in both areas increased, which translated in obtaining additional equipment for the laboratory, where the largest investments included UHPLC and GC chromatographs with detectors. Talks relating to the purchase of two new mass spectrometers, including one dedicated to the examination of biological products were initiated. In several cases the specific technical solutions of the equipment purchased was due to specific client requirements. Selvita's flexibility in this respect is appreciated by clients and certainly increases the chances of obtaining subsequent projects and extending cooperation. In 2018, research teams performed projects dedicated mainly to foreign clients, using comprehensive laboratory equipment. Many cooperation engagements started previously are being continued in the current year. First and foremost one should note a contract concluded with a global pharmaceutical company for which a CMC project which was being performed from September. Selvita has been listed as the Client's regular supplier for the coming years. At the end of the fourth quarter of 2018, talks were also held with companies interested in analysing metallic impurities in accordance with the ICH Q3D Guideline. In one of them, from the beginning of the fourth quarter, a long-term project is being carried out under which over 40 products and formulations will be subject to ICP-MS analysis. Many research projects were continued in 2018 in the field of quality control and as validations and verifications of methods, stability studies and exemption analyses. Method transfers were completed and routine research was commenced for one of the largest global pharmaceutical companies. With regard to testing biological drugs, the method transfer process was completed for three products, and exemption analyses are planned in the current year. The laboratory offered comprehensive services for the development and optimization of methods, validations, 5Batch and 1Batch research, stability studies, physical-chemical tests, certification of compounds and testing of dioxins and furans to agrochemical firm. In 2018, contracts were concluded with a large agrochemical company with which the analytical laboratory has been working for nearly three years, based on which the analytical laboratory became one of the main contract laboratories of this client. The contracts provide for the performance of several dozen projects a year. At the end of 2018, talks with clients in this industry were also commenced in respect of the implementation of CIPAC methods in stability studies. In 2018, cooperation with pharmaceutical and agrochemical clients interested in bioanalytic research and ADME support was also continued. The FTE cooperation initiated in respect of integrated projects is also being continued successfully in the

current year. After the completion of projects conducted in an ADME team and related to the development of methods for determining metabolites, a large chemical company decided to extend its cooperation in 2018 to identify impurities using high-resolution mass spectrometry. This cooperation resulted in subsequent orders at the end of the year, and the planned extension of their scope at the beginning of 2019.

Similarly to previous year, in 2018, the operations of the Molecular and Cellular Biology Laboratory were focused on carrying out projects from two main groups. The first comprised comprehensive research projects from the Drug Discovery Area, based on a SAR (Structure-Activity Relationship) analyses, where the lab professionals were responsible for developing a series of biochemical, biophysical and cell tests aimed at determination of the *in vitro* activity of new candidates for drugs. Within this project group several tests were also performed relating to analysis of the mechanism of action of tested compounds in various therapeutic indications. These tests were performed to support biotechnological companies from Europe, Asia and the U.S.

Comprehensive analyses of various classes of biosimilar drugs for pharmaceutical companies from Europe and Asia constituted the second group of projects. These tests were performed according to the GLP and GMP standards and their results will be used for clients of laboratory to release further batches of biosimilar medicines on the European market. A series of *in vitro* genotoxicity and mutagenicity analyses were also performed, according to the validated methods and OECD guidelines.

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 project will be performed till the first half of 2020.

It should be emphasized that comparing to the recent years, in 2017 and 2018 a significant increase was noted in projects performed on an FTE basis. This proves that Customer confidence in the quality and timeliness of services offered by the Molecular and Cellular Biology Laboratory is growing. It is also essential that as result of growth related to projects conducted within the abovementioned groups and performed by Molecular and Cellular Biology Laboratory in 2018, the number of employed scientists has doubled.

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.

#### **4.1.3. Bioinformatics Segment**

##### **Ardigen S.A.**

In 2018, three years had passed since the Company was established which should be considered unusually dynamic. In this time, the Ardigen team has performed more than 120 bioinformatic projects in the largest biotechnological centres worldwide. The *in silico* experiments being conducted by the Company are having an increasing impact on the development of innovative therapies and new

diagnostic methods. Scientific teams in biotechnological and pharmaceutical companies have started to appreciate the potential of bioinformatic and artificial intelligence technologies. This experience confirms the conviction of Ardigen's Management Board that combining bioinformatics and artificial intelligence allows breakthrough discoveries to be made in the process of developing innovative drugs, in particular personalized therapies. The Company has the necessary competencies at global level, at a time in which universal access to significant computing power, low cost of genome sequencing (access to data) and growing spending on treatment are converging. Market analysts, upon noticing the approaching revolution, have introduced a new concept – Biotechnology 2.0. In this context, Ardigen is becoming a valuable partner providing opportunities to enter a new dimension of biotechnology.

At the end of 2018, the Company's Management Board decided to focus the development of its own technologies on solving one of the key problems in modern oncology. The introduction of immunotherapy into medical practice was an undisputed breakthrough in oncological treatment. Nevertheless, despite being very effective for some patients, a significant percentage of patients do not respond to immunotherapy and simultaneously suffering from serious adverse effects. The purpose of the technologies developed by Ardigen is to increase the positive response of patients to oncological immunotherapies. In this context, the Company presents a unique, holistic approach which combines immunomics (computational analysis of the immune system) with metagenomics (computational analysis of the microbiome).

In the fourth quarter of 2018, based on existing research, three technological *in silico* platforms based on sophisticated AI algorithms were prepared for launch on the market.

The *Microbiome Analysis Platform* is an innovative approach to microbiome analysis based on the complete metagenomic information available. These analyses will introduce a new quality in the process of creating LBP-class (*Live Biotherapeutic Product*) drugs. In the light of the most recent scientific discoveries which indicate the impact of the microbiome on the patient's response to immunotherapy the platform will be used in the related research. As a result of such work, new LBP drugs or biomarkers can be developed based on an analysis of the bacterial composition. In the future, this class of technology will constitute the core of personalized microbiome therapies.

*Neopeptide Prediction Platform* is a tool which allows to predict the composition of peptides presented on the surface of cancer cells which are recognized as foreign antigens and trigger the response of the immune system, as a result of which the cancer cells are eliminated. The ability to precisely predict neopeptides is of key importance in the process of developing anti-cancer vaccines. Such vaccines are a promising tool which enhances patient response to immunotherapy related to the immune checkpoint inhibitor. In the future, technology allowing the precise prediction of immunogenic neopeptides will constitute the heart of the therapy with personalized oncological vaccines.

The *Biomarker Discovery Platform* is a tool for stratifying patients into those who respond and do not respond to a given immunotherapy. It is based on a holistic approach to an analysis of many types of data (WES, WGS, RNAseq, immunohistochemistry, microbiome, clinical data). The ability to build models with high prognostic and predictive parameters is of key importance in the clinical trials of immunotherapy as well as in subsequent clinical practice. In the future, this class of technology will become the core tool for selecting the most effective immunotherapy for a given patient.



The scientific level of work on the Ardigen technological platforms was positively assessed during specialized conferences which took place in the second half of the year in the United States. These were ASCO 2018 in Chicago, Biomarkers & Immuno-oncology World Congress 2018 in Boston, SITC 2018 in Washington, and Translational Microbiome Conference in Boston. After analysing competitors operating in similar scientific areas, we can confirm that Ardigen is currently the only company in the world which combines *in silico* analysis of human cells (both healthy and diseased) with an analysis of the microbiome in the context of immuno-oncology. Using AI technology in research is another strong factor which distinguishes the Company on the international arena. The R&D work in the coming year will focus on reinforcing this advantage.

In 2018, the service unit of the Company recorded a fast pace of growth. The year 2018 was closed with record-breaking sales and a record-breaking volume of contracts for the following year. In 2018, the service offer was extended to include AI technologies to search and optimize chemical compounds created in the process of developing drugs. The power of this technology was positively verified in two drug discovery projects.

At the end of 2018, Ardigen had a broad offer of supporting measures for pharmaceutical and biotechnological companies at each stage of the drug discovery process. After three years of intensive development of the competencies combining bioinformatics and data science in the era of artificial intelligence Ardigen has become a mature partner for companies developing drugs.

## **4.2 Company Responsibility**

Selvita S.A. within Corporate Social Responsibility plans to establish long-term relations with Krakow organizations which take active part in the life of both local and national communities.

Since June 2016, Selvita has been supporting the activity of Krakow UNICORN Charity Foundation (<http://unicorn.org.pl/>) as part of its Corporate Social Responsibility activities.

The UNICORN Foundation has been helping patients suffering from cancer and their families since 1999. UNICORN is currently running an on-site Psycho-Oncology Center, the first of this kind in Poland.

The intention of the founders of the on-site UNICORN Psycho-Oncology Center in Krakow is to create a place where patients diagnosed with cancer will receive comprehensive and professional support in an attempt to tame the disease and overcome the shock of the troublesome diagnosis.

Selvita is supporting the UNICORN Foundation both financially and through employee volunteering events. In 2018, Selvita donated 20.000 PLN for statutory goals of the UNICORN Foundation and sponsored the organization of the 4<sup>th</sup> Oncology Forum held on February 4, 2018, in the ICE Krakow Congress Center.

Moreover, Selvita yet again participated in the annual Kraków Business Run organized by the Polish Business Run Foundation. Selvita's representation participated in the Kraków Business Run for the first time in September 2015. Since then it has become Selvita's tradition that each year in September its employees participate in the run in support the people under the custody of the Foundation. It was no different in 2018, when as many as 11 teams participated in Poland Business Run in Krakow and for the first time one team in Poznan, where Company's laboratories are located.

The Poland Business Run Foundation helps people with locomotor disabilities, assists in their activation and removing social barriers. The organization propagates knowledge of locomotor disabilities and strives to change the popular perception of people who cope with such problems.

In 2018, Selvita also began cooperating with the “Piękne Anioły” Foundation in Kraków, which helps children and youth living in dysfunctional families or who are socially disadvantaged.

As part of its cooperation with the Foundation, Selvita financed the renovation of a hospital room for children, participating in the “Słoneczne pokoje” programme. Moreover, a charity Christmas fundraising event was carried out for the benefit of the Foundation among Selvita’s employees. The money collected enabled the purchase of bed linen, and educational and strategic games which were provided for the use of small and larger patients in the Stefan Żeromski Hospital in Kraków.

Anna Dymna’s “Mimo Wszystko” Foundation is yet another organization in Kraków which Selvita supported in 2018. The Company donated funds for the purchase of 12 works of art made by the Foundation’s wards; they were subsequently awarded to the staff of Selvita as prizes for Employee of the Month. Moreover, when selecting Christmas cards, Selvita chose gift vouchers with part of the income being earmarked for Anna Dymna’s “Mimo Wszystko” Foundation.

The Management Board of Selvita S.A. also donated 11 professional thermometers certified for hospital use for the nurses.

In 2018 Selvita S.A. donated altogether PLN 36.000 for various charity purposes. In subsequent years Selvita S.A. intends to increase financial sources dedicated to Corporate Social Responsibility activities and continue to support Krakow organizations.

### **4.3 Employment data**

Given the dynamic growth in the period covered by the report, the Group has significantly increased employment. Employment increased from 431 employees at the end of 2017 to 533 employees at the end of 2018.

### **4.4 Planned growth of Selvita Group**

#### **The Innovative Segment**

In 2019 Selvita Group is planning to continue its dynamic development in the area of research and development of new drugs by using new funds raised through the secondary public offering in February 2018, which is in line with the Selvita Group’s Development Strategy for 2017-2021 published in August 2017.

#### **Services Segment**

In this area the Group is expecting intense growth through continuous increase in the share of full time equivalent (FTE) contracts and integrated projects in the sales volume which shall result in, increase in revenue and the employee base accordingly, as well as extending the laboratory space.

#### **New Initiatives**

The Company pursues its Development Strategy for the years 2017–2021 published in August 2017. The pursuit of the Strategy should allow the Company to achieve the following business goals:

- sign a partnership contract for further development and commercialization of the SEL120 molecule in the phase II of clinical trials, on significantly better terms than in case of SEL24;
- independently develop and sell one R&D project a year;
- further dynamically increase revenue and profitability in the services segment;



- increase the Company's capitalization to over PLN 2 billion.

Another significant initiative of the Group is construction of the Innovative Drug R&D Centre (Centrum Badawczo-Rozwojowe Innowacyjnych Leków) realized within the boundaries of the Kraków Special Economic Zone, at Podole Str., close to the current laboratories of the Jagiellonian Centre of Innovation. In 2018 the Company executed an agreement on the construction of the Innovative R&D with Mota Engile Central Europe S.A. Completion of the construction of the Innovative Drug R&D Centre is planned at the end of 2019.

## 5 Financial Information

### 5.1 Consolidated Profit and Loss Statement

FOR THE PERIOD FROM 1 JANUARY 2018 TO 31 DECEMBER 2018	01/01/2018 - 31/12/2018	01/01/2017 - 31/12/2017
	PLN	PLN
<b>Continued operations</b>		
Revenue from sales	77 205 571	67 535 921
Revenue from subsidiaries	32 014 269	17 591 459
Other operating revenue	878 059	459 752
Revenue from sales of R&D projects	-	20 284 538
<b>Total operating revenue</b>	<b>110 097 899</b>	<b>105 871 670</b>
Change in stock of goods	-	-
Amortization and depreciation	(8 225 070)	(5 240 097)
Consumption of materials and energy	(25 362 083)	(18 554 614)
External services	(32 352 309)	(17 939 041)
Employee benefit expense	(52 290 326)	(39 843 129)
Taxes and charges	(862 681)	(619 666)
Other costs by type	(4 288 926)	(2 986 921)
Cost of goods and materials sold	-	(42 619)
Cost of R&D projects sold	-	(7 328 770)
Other	(327 644)	(95 180)
<b>Total operating expenses excluding impact of share-based incentive program</b>	<b>(123 709 039)</b>	<b>(92 650 037)</b>
<b>Profit (loss) on operating activities excluding impact of share-based incentive program</b>	<b>(13 611 140)</b>	<b>13 221 633</b>
Share-based incentive program	-	(583 000)
<b>Profit (loss) on operating activities</b>	<b>(13 611 140)</b>	<b>12 638 633</b>
Financial revenue	2 131 712	93 269
Financial expenses	(322 098)	(2 049 437)
Other	-	-
<b>Profit (loss) on business activities</b>	<b>(11 801 526)</b>	<b>10 682 465</b>
Equity method valuation of investments in associates	(651 843)	(1 082 161)
Fair value method valuation of investments in associates	21 439 106	-
<b>Profit (loss) before income tax</b>	<b>8 985 737</b>	<b>9 600 304</b>
Income tax expense	(8 093 253)	(2 868 379)
<b>Net profit (loss) on continued operations</b>	<b>892 484</b>	<b>6 731 925</b>
<b>Discontinued operations</b>		
Profit (loss) on discontinued operations	-	-
<b>Net profit (loss)</b>	<b>892 484</b>	<b>6 731 925</b>
Net profit loss attributed to:		
Majority shareholders	(106 320)	6 406 932
Non-controlling shareholders	998 804	324 993
Other comprehensive income:		
Foreign subsidiaries results translation differences	101 668	152 697
<b>Total other comprehensive income (loss)</b>	<b>101 668</b>	<b>152 697</b>
<b>Total comprehensive income (loss)</b>	<b>994 152</b>	<b>6 884 622</b>
Total comprehensive income (loss) attributed to:		
Majority shareholders	(4 652)	6 559 629
Non-controlling shareholders	998 804	324 993
<b>Earnings per share (expressed in gr per share)</b>		
With continued and discontinued operations:		
Basic	0,0	47,6
Diluted	0,0	47,6
With continued operations:		
Basic	0,0	47,6
Diluted	0,0	47,6

## 5.2 Consolidated Balance Sheet

AS OF 31 DECEMBER 2018	31/12/2018	31/12/2017
	PLN	PLN
<b>ASSETS</b>		
<b>Fixed assets</b>		
Tangible fixed assets	52 439 692	31 377 112
Investment property	-	-
Goodwill	280 740	280 740
Other intangible assets	2 403 174	126 011
Unfinished development works	-	2 231 330
Investments in associates	-	2 038 611
Deferred tax assets	4 336 109	7 451 082
Other financial assets	22 825 875	-
Other assets	196 038	196 038
<b>Total fixed assets</b>	<b>82 481 628</b>	<b>43 700 924</b>
<b>Current assets</b>		
Inventory	1 989 469	1 591 108
Trade and other receivables	42 500 309	18 592 306
Construction contracts receivables	791 604	633 207
Other financial assets	15 075 299	92 694
Current tax related assets	-	446 374
Other assets	2 487 459	2 392 763
Cash and other monetary assets	110 373 895	36 124 149
	<b>173 218 035</b>	<b>59 872 601</b>
Non-current assets held for sale and discontinued operations	-	-
<b>Total current assets</b>	<b>173 218 035</b>	<b>59 872 601</b>
<b>Total assets</b>	<b>255 699 663</b>	<b>103 573 525</b>

### 5.3 Consolidated Balance Sheet (cont.)

AS OF 31 DECEMBER 2018	31/12/2018	31/12/2017
	PLN	PLN
<b>EQUITY AND LIABILITIES</b>		
<b>Equity</b>		
Share capital	6 388 492	5 508 492
Surplus from sale of shares above par value	154 702 441	25 480 803
Own shares	-	-
Supplementary capital	25 955 714	18 647 783
Other reserve capitals	11 172 000	11 172 000
Foreign subsidiaries results translation differences	211 734	110 066
Previous years' profit (loss)	(6 411 401)	(5 028 156)
Net profit (loss)	(106 320)	6 406 932
Provisions related to non-current assets held for sale and discontinued operations presented directly in equity	-	-
<b>Equity attributed to majority shareholders</b>	<b>191 912 660</b>	<b>62 297 920</b>
Equity attributed to minority shareholders	2 947 424	1 697 642
<b>Total equity</b>	<b>194 860 084</b>	<b>63 995 562</b>
<b>Long-term liabilities</b>		
Long-term credits and loans	3 171 878	3 981 697
Other financial liabilities	6 864 769	2 188 096
Retirement provision	156 674	156 674
Deferred income tax provision	4 574 992	525 516
Long-term provisions	-	1 740 650
Deferred income	10 503 421	4 233 055
Other liabilities	-	-
<b>Total long-term liabilities</b>	<b>25 271 734</b>	<b>12 825 688</b>
<b>Short-term liabilities</b>		
Trade and other liabilities	18 998 849	10 873 295
Construction contracts liabilities	1 156 678	379 582
Short-term credits and loans	894 571	912 416
Other financial liabilities	2 540 280	911 438
Current tax liabilities	378 958	74 491
Short-term provisions	7 179 084	5 149 870
Deferred income	4 419 425	8 451 183
Other liabilities	-	-
<b>Total short-term liabilities</b>	<b>35 567 845</b>	<b>26 752 275</b>
<b>Total liabilities</b>	<b>60 839 579</b>	<b>39 577 963</b>
<b>Total equity and liabilities</b>	<b>255 699 663</b>	<b>103 573 525</b>

## 5.4 Consolidated Cash Flow

	01/01/2018- 31/12/2018	01/01/2017- 31/12/2017
	PLN	PLN
<b>Cash flows from operating activities</b>		
<b>Net profit (loss)</b>	<b>892 484</b>	<b>6 731 925</b>
<b>Adjustments</b>		
Equity method valuation of investments in associates and joint ventures	(20 787 264)	1 082 161
Fair value method valuation of other financial assets	-	-
Amortization and depreciation	8 225 070	5 240 097
Exchange gains (losses)	101 668	-
Interest and profit-sharing (dividends)	(984 008)	166 291
Profit (loss) on investing activities	-	-
Change in receivables	(24 066 400)	(1 802 194)
Change in inventory	(398 361)	(187 845)
Change in short-term liabilities and provision excluding credits and loans	8 902 650	3 193 621
Change in grants	(17 725 471)	(15 814 466)
Change in deferred revenue	(696 942)	(435 934)
Change in provisions	288 564	3 290 552
Change in other assets	1 916 134	8 217 429
Income tax paid	(177 963)	717 143
Change in deferred income tax	-	-
Income tax cost in P&L	8 093 253	-
Contribution in kind of non-controlling shareholders	-	-
Share-based incentive program	-	583 000
Other	-	-
<b>Cash flows from operating activities</b>	<b>(36 416 586)</b>	<b>10 981 780</b>
<b>Cash flows from investing activities</b>		
Proceeds from sale of tangible and intangible fixed assets	-	10 000
Purchase of tangible and intangible fixed assets	(10 623 578)	(11 388 846)
Purchase of tangible and intangible fixed assets partially financed with grant	(12 823 121)	(10 169 405)
Purchase of other financial assets	(14 928 600)	-
Purchase of shares of a subsidiary	(40 180)	-
Interest received	1 215 772	71 693
Repayment of loans	30 000	47 306
Loans granted	(30 000)	(80 000)
Other inflows from financial assets	-	-
Other	-	-
<b>Cash flows from investing activities</b>	<b>(37 199 707)</b>	<b>(21 509 252)</b>
<b>Cash flow from financing activities</b>		
Proceeds from shares issue	134 200 000	935 888
Payment of liabilities from finance lease agreements	(1 806 956)	(1 214 612)
Proceeds from credits and loans	92 990	34 471
Grants	20 661 021	19 134 925
Repayment of credits and loans	(920 654)	(875 236)
Dividends paid	-	-
Interest paid	(285 769)	(237 984)
Other	(4 074 593)	(220 500)
<b>Net cash flows from financing activities</b>	<b>147 866 039</b>	<b>17 556 952</b>
Increase of net cash	74 249 746	7 029 480
Cash opening balance	36 124 149	29 094 669
<b>Cash and cash equivalents - end of the period</b>	<b>110 373 895</b>	<b>36 124 149</b>

## 5.5 CONTACT DETAILS

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