

Selvita Group  
Annual Report

**2014**

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# 1 BASIC INFORMATION ON THE SELVITA GROUP

## 1.1. 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
KRS number	0000367359
Website	www.selvita.com

### Related 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
KRS number	0000206301
Website	www.biocentrum.com.pl
Shareholders	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
KRS number	0000403763
Shareholders	100% shares held by Selvita S.A.

All entities within the Selvita Group are consolidated.

## 1.2. Governing Bodies of the Parent Entity

### Management Board

As of November 2013 the Management Board of Selvita S.A. consists of:

- Paweł Przewięźlikowski – President of the Management Board,
- Bogusław Sieczkowski – Vice President of the Management Board,

- Krzysztof Brzózka, PhD – Vice President of the Management Board
- Sebastian Kwaśny – Member of the Management Board,
- Miłosz Gruca, PhD – Member of the Management Board,
- Mirosława Zydroń, PhD – Member of the Management Board.

The term of office expires after the General Meeting approving the financial statements for the financial year 2014.

### **Supervisory Board**

The Supervisory Board was established on 20 August 2010 for a common five-year term expiring after the General Meeting approving the financial statements for the financial year 2014.

Between 18 May 2011 and 26 May 2014 the Supervisory Board comprised of:

- 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
- Professor Adam Dubin – Member of the Supervisory Board
- Adam Przewięźlikowski – Member of the Supervisory Board

Following resignation of Mr Wojciech Chabasiewicz, as of 27 May 2014 the Supervisory Board comprises of:

- Piotr Romanowski, PhD – President of the Supervisory Board
- Tadeusz Wesołowski, PhD – Vice President of the Supervisory Board
- Rafał Chwast – Member of the Supervisory Board
- Professor Adam Dubin – Member of the Supervisory Board
- Adam Przewięźlikowski – Member of the Supervisory Board

## 2 ECONOMIC AND FINANCIAL HIGHLIGHTS

### 2.1 Financial Results Attained in the Reporting Period

Item	Consolidated data in PLN		Consolidated data in EUR	
	From 01.01.2014 to 31.12.2014	From 01.01.2013 to 31.12.2013	From 01.01.2014 to 31.12.2014	From 01.01.2013 to 31.12.2013
Currency	PLN	PLN	EUR	EUR
Net revenues from sales of products, goods and materials	28 865	13 053	6 890	3 100
Revenues from subsidies	12 430	8 688	2 967	2 063
Total revenues from sales and subsidies	41 295	21 741	9 857	5 163
Operating expenses	-36 285	-24 142	-8 661	-5 733
Depreciation	-2 354	-2 082	-562	-494
Profit/loss on investing activities	5 272	-2 228	1 258	-529
Net profit/loss	5 427	-2 427	1 295	-576
Net profit/loss	5 850	-2 445	1 396	-581
EBITDA	7 626	-146	1 820	-35
Net cash flow from operating activities	-4 902	-7 198	-1 170	-1 709
Net cash flows from investing activities	-3 592	-2 150	-857	-511
Net cash flows from financing activities	7 954	9 550	1 899	2 268
Total net cash flow	-540	202	-129	48
Total Assets	26 803	18 258	6 288	4 402
Short term receivables	9 822	5 161	2 304	1 244
Cash and other monetary assets	4 758	5 298	1 116	1 277
Liabilities and provisions for liabilities	17 550	14 855	4 117	3 582
Long term liabilities	2 278	3 454	534	833
Short term liabilities	15 271	11 401	3 583	2 749
Equity	9 254	3 403	2 171	821
Share capital	4 185	4 185	982	1 009
Number of shares	10 463 566	10 463 566	10 463 566	10 463 566
Profit (loss) per share (in PLN/EUR)	0.56	-0.23	0.13	-0.06
Diluted profit (loss) per share (in PLN/EUR)	0.56	-0.23	0.13	-0.06
Book value per share (PLN/EUR)	0.88	0.33	0.21	0.08
Diluted book value per share (PLN/EUR)	0.88	0.33	0.21	0.08
Declared or paid dividend per share (PLN/EUR)	-	-	-	-

The year 2014 marks the first year in which Selvita Group recorded an operating profit. This positive result is associated with achieving profitability in innovation as well as a continued profitability in service activities. The Group's net profit in 2014 was PLN 5,850k compared to a net loss of PLN 2,445k in 2013. This translates into a net margin of 14.2%, calculated as the net profit compared to revenues on sales and subsidies. The net financial result was positively influenced by the creation of a deferred income tax amounting to PLN 502k for tax benefits expected in 2015, as a result of the activities of Selvita Services Sp. z o.o. in the Special Economic Zone in the Krakow Technology Park. It is worth emphasizing that, except for the tax asset referred to above, there were no one-off events affecting the financial results which are derived solely from the organic business development. The Group reported profit in all quarters of 2014 which indicates a positive trend starting from the first profitable quarter (i.e. Q4 2013). In the reporting period, the Group consistently conducted intensive research and development activities under projects commenced in the previous years, which, according to the Group's accounting policy, are recognized as costs.

In 2014, Selvita Group achieved operating income of PLN 41,557k compared to PLN 21,914k in 2013 (a revenue growth of 89.6%). Net revenues from sales (excluding subsidiaries) reached PLN 28,865k, up by 121.1% compared to 2013 when the net sales totalled PLN 13,053k.

Of particular note are revenues generated by the innovative segment, i.e. Selvita in-house R&D projects, which totalled PLN 12,744k – a 293.3% increase compared to 2013 which saw revenues of PLN 3,241k. This significant revenue growth derives both from a low base (execution of contracts with H3 Biomedicine and Merck Serono commenced at the turn of Q3/Q4 2013) as well as extending the scope of collaboration based on previously concluded contracts.

In the area of services, throughout 2014 Selvita consistently pursued its strategy to focus on service projects with high added-value and hence greater profitability. As a result, the Group's order portfolio reflects a positive trend that has already translated into higher dynamics of commercial revenues in 2014 and which should continue in the coming quarters. The cost effective and rapidly growing service segment is a stable foundation for growth – revenues from services in 2014 reached PLN 16,121k, which marks a 64.3% growth compared to the previous year.

In 2014 Selvita signed new contracts with large multinational pharmaceutical corporations under which the Group's companies commenced advanced research projects, i.e. services with high added-value and profit margin. Moreover, of particular importance for the service segment were contracts signed with Polish partners, contributing to diversification of revenues and lower exchange rate risk across the Group.

At the publication date of this report, revenues from the concluded commercial contracts and grant agreements for 2015 were PLN 31,814k of which:

- Service                      PLN 7,838k
- Innovation                  PLN 9,853k
- Subsidies                    PLN 14,123k

Revenues from subsidies were up by 43.1% (from PLN 8,688k in 2013, to PLN 12,430k in 2014. This was associated mostly with the planned increase in expenditures associated with the initiation of SEL300 and SEL128 projects, as well as successive writing-off as revenue the received infrastructural subsidies included in the deferred revenue.

Another important figure reflecting positive development of Selvita Group is a steady increase in employment which rose from 166 to 220 employees.

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

In 2014, the value of the Group's assets grew by 46.8% from PLN 18,258k in 2013, to PLN 26,803k. This was largely due to an increase in the current assets position, including a 90.3% (PLN 4,661k) increase in short-term trade receivables due to invoices of significant value issued in December 2014, and a PLN 1,913k increase in the value of tangible fixed assets.

At the end of 2014, the main items under the fixed assets position comprised tangible fixed assets amounting to PLN 6,844k, including mostly laboratory equipment and deferred income tax assets of PLN 2,128k. Compared to 2013, the value of fixed assets increased by PLN 2,426k. This is mostly due to investment in research infrastructure and an increase in deferred income tax assets

associated with recognition of assets due to tax relief on the activities of Selvita Services Sp. z o.o. in the Special Economic Zone.

In 2014 Selvita SA did not hold or make any significant capital investments within the Capital Group.

## **2.3 Current and Projected Financial Condition**

The Group's financial situation at the time of the report is very good.

As of December 31, 2014 the Group's cash value was PLN 4,758k and PLN 30,241k at the time of the report. The increase in cash and cash equivalents after the balance sheet date, is related to the proceeds from the issue of shares.

The Group's business activities are profitable both in the innovative and service sector. R&D activities are financed by revenues from the service customers, as well as co-financed through research grants and proceeds from the issue of shares. Further increase in revenue from service and commercialization of upcoming research projects as well as continuation of the positive trends in profitability are expected in the financial year 2015.

The Company fulfils its obligations on an on-going basis and keeps safe cash levels to maintain liquidity. With proceeds from the issue of shares and cash generated through operating activities, Selvita is able to complete the planned investments, particularly in innovative projects and laboratory infrastructure, as well as to set up foreign companies to support business development.

## **3 INFORMATION ON THE ACTIVITIES OF SELVITA GROUP**

### **3.1 Products and Services**

The activities of the Group cover two 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.

#### **Innovative Segment**

Selvita is engaged in the discovery and development of breakthrough medicines to treat cancer, CNS and autoimmune disorders. Selvita discovers and invests in the development of bioactive molecules with therapeutic potential, with the purpose of their further commercialisation in the global pharmaceutical market. It focuses on small-molecule chemical compounds discovered in-house or by researchers from Polish universities. Initial ideas are then evaluated, and drug discovery projects are launched. This way they acquire real commercial value. Further work on the project is conducted in cooperation with a strategic partner (a large pharmaceutical company), with milestone payments received for each completed project phase plus the right to royalties throughout the period of sale of the future drug product. Moreover, partnership agreements ensure access to the know-how of large organisations. Such model of cooperation is commonly employed by pharmaceutical and biotechnology companies worldwide and thanks to the synergy in the science and business areas it ensures a higher probability of success. Selvita's effectiveness in commercialisation of its research is

reflected by conclusion of four major partnering contracts including a contract for kinase inhibitor platform with H3 Biomedicine, cancer metabolism platform with Merck Serono and cancer quiescence platform with Felicitex Therapeutics. Selvita's portfolio also contains a number of promising internally developed projects, the most developed of which are SEL24 project (a potential drug against leukaemia and other tumours) and SEL120 project (a potential drug targeting colorectal carcinomas and other solid tumours).

#### Partnering model in biotechnology

The total direct cost of research necessary to develop and register an innovative drug currently exceeds 100 million USD. Considering the cost of unsuccessful projects and the cost of capital required to finance a usually several-year long investment cycle for a single research programme, average R&D expenditures necessary to register a single molecule exceed 1 billion USD. For this reason, only the largest global pharmaceutical companies can afford such expenses. In order to further develop their projects, the majority of biotech firms, including Selvita, must at some point secure a project partner. Such partner can be a biotechnology or pharmaceutical company,, as well as an investment fund interested in investing in a particular project (the so-called asset-based funding). The main tasks of a partner include:

- securing capital for further research,
- independent performance of clinical research or having it performed by a specialised clinical research organization (CRO),
- conducting the registration process,
- launching the manufacture of the finished drug,
- conducting additional clinical trials covering new therapeutic indications,
- marketing and distribution of the drug.

This kind of partnering model enables sharing the risks and benefits of innovation between the biotech company and its pharmaceutical partners. One of the financial benefits of such partnering model, is a fact that a large pharmaceutical firm maintains a larger and more diversified portfolio of innovative projects and markets already registered drugs. With high sales revenues, large pharmaceutical companies are highly profitable which, together with lower risk of innovative projects portfolio, ensures significantly lower cost of capital. Consequently, after establishing investment cooperation with a professional investor, the projects which would otherwise have a low internal risk-weighted rate of return if implemented solely by a biotech company, become much more attractive.

Implementation of a partnering contract covers one of the following forms of commercial transactions or, combination thereof, with one or more partners in different geographical locations and within different therapeutic indications:

- a biotech company retains full intellectual property rights (copyright and propriety rights) to a molecule and grants the partner (e.g. a pharmaceutical company) a license to further develop, register, manufacture and sell the drug (so called *out-licensing*). Such rights usually cover the right to sublicense to regional partners;



- a biotech company sells its intellectual property rights to the molecule to the partner. This allows the partner to continue the work on the molecule or to sell or license it in its sole discretion;
- a biotech company obtains funding from the partner to finance research in exchange for the exclusive right to purchase IP rights resulting from the project in the future. Such funds may be granted as payment for research and development work, or as the pharmaceutical firm's equity investment in the biotech company;
- a biotech company conducts part of the R&D work and covers its costs. A pharmaceutical company conducts parallel research and development on the same molecule and bears the costs. Both companies agree to share the economic benefits of the project. Collaboration established at the discovery stage is called *co-discovery*. Collaboration at pre-clinical or clinical stage is called *co-development*. Trade cooperation after the registration of the molecule is termed *co-promotion*;
- a pharmaceutical company acquires from a biotech company the right to execute one of the above-mentioned types of partnering transactions in the future, in return for advance payment (*option-deal*).

#### Selvita's partnering contracts

Until the publication of this report, Selvita signed the following four partnering agreements, the last three of which are currently being executed:

- agreement with Orion Pharma for development of SEL103 project covering symptomatic treatment of Alzheimer's disease,
- agreement with US based H3 Biomedicine – collaboration on development of new kinase inhibitors in oncology (kinase inhibitor platform),
- agreement with Germany based Merck Serono – collaboration on discovery of new drugs targeting the mechanisms of specific cancer metabolism pathways (cancer metabolism platform),
- agreement with US based FeliciteX Therapeutics – collaboration on development of new drugs targeting quiescent cancer cells (cancer chemoresistance platform).

Selvita is a Polish leader in securing partnering contracts. According to the publicly available data, as of the date of this report, no other Polish biotechnology company has ever signed a partnering contract for a research project with a Western based pharmaceutical or biotechnology company.

#### **Service 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, drug discovery and contract chemistry as well as in biochemistry, pharmacy, molecular biology and biotechnology, specialized in particular parts of the R&D process, and bioinformatics.
- services related to synthesis and analysis of small and large molecule chemical compounds,

- creation and implementation of innovative bioinformatic and computer systems, including laboratory information management systems (LIMS) for managing the laboratory data.

Selvita provides services through three main departments: Contract Chemistry Department, Biology Research Department and Bioinformatics Department.

### ***Contract Chemistry Department***

Contract Chemistry Department specializes in providing services in the field of medicinal and computational chemistry, as well as pharmaceutical, chemical, agrochemical and industrial synthesis. In terms of revenue, Contract Chemistry Department is the Company's largest organisational unit.

Selvita's main focus is the variety of synthesis processes. These processes involve combining two or more simple compounds into a more advanced product with complex structure and different properties. The most important services in this area include:

- design and synthesis of new compounds with potential pharmacological activity, based on biological assays, and with the use of computational tools,
- contract synthesis of chemical compounds, pharmaceutical substances and impurities on a milligram to kilogram scale (*custom synthesis*),
- development of alternative technologies for chemical substances production,
- optimization of synthesis processes, e.g. in order to develop more cost-effective manufacturing process or eliminate hazardous and toxic substances from the process,
- provision of comprehensive services in the field of chemical analysis consisting of studying the structure of compounds and mixtures and their qualitative and quantitative chemical composition according to the requirements of the pharmaceutical and chemical market.

Most projects implemented by the Contract Chemistry Department cover issues related to the areas of medicinal chemistry (approx. 53%) and generic pharmaceutical contracts (laboratory scale, optimization, process validation and synthesis of impurities), which account for approximately 32% of the contracts.

The Contract Chemistry Department is expecting further dynamic development of its activities. By 2013 the team secured a diversified client base (clients from different market segments, industries and geographical locations), as well as the necessary experience in working on various types of projects. This creates prospects for further dynamic growth in sales revenue.

### ***Biology Research Department***

The Biology Research Department provides biological, biochemical and analytical services. It specialises in conducting certified studies in accordance with GLP and GMP principles in the following areas: pharmacodynamic tests, cytotoxicity studies, development and validation of biochemical, bioanalytical and cellular assays and analytical methods (including ADME testing and DMPK analysis). The Department's Protein Chemistry Laboratory also offers a wide panel of research in protein biochemistry.

The Biology Research Department comprises of three laboratories offering a wide range of services: Protein Chemistry Laboratory, Analytical Laboratory and Molecular and Cell Biology Laboratory . The service portfolio has been designed in order to establish cooperation with both Polish and

international pharmaceutical and biotechnology companies. The comprehensive offer enables the Biology Department to conduct complex integrated research projects associated with the development of innovative drugs (two projects are currently underway in collaboration with Merck Serono and H3 Biomedicine).

In the nearest future, the Biology Research Department will focus on strengthening the presence of its offer in the markets of Western Europe and the United States, with special emphasis on the offer directed at pharmaceutical and biotechnology clients looking for integrated solutions for projects associated with the development of innovative drugs. Securing this type of projects will enable the department to implement its other long-term objective, i.e. a transition from the currently employed fixed-fee collaboration model to much more favourable full-time-equivalent (FTE) contracts. This model of collaboration has already been successfully employed in projects implemented by the Contract Chemistry Department and the Innovative Segment. Another key condition for further dynamic growth of the Biology Research Department in the coming years, is securing new projects and clients in the areas of studies on biological and biosimilar drugs. Currently Selvita is the leader on the Polish market in this type of research services provided to pharmaceutical and biotechnological companies. The experience and knowledge gained in projects implemented for Polish clients will help Selvita to secure new orders in foreign markets.

### ***Bioinformatics Department***

Bioinformatics Department specialises in the implementation of IT and bioinformatics systems for the broad market including production and service companies operating their own laboratories, as well as for companies and research bodies operating their own research and development laboratories. Such systems come as custom software, partner companies solutions and customized projects.

The most significant of them include:

- LIMS – comprehensive IT solutions for laboratory data management (STARLIMS solutions),
- SDMS – scientific data management systems (STARLIMS solutions),
- bioinformatics solution for analysis of nucleic acid sequence and proteins (CLC\*bio software),
- comprehensive hardware and software platform solutions for implementations of IT systems.

The company also provides software development services on foreign markets, particularly in USA and Great Britain, taking part as an international software production team to ensure appropriate quality of new product solutions implemented in Poland and abroad.

Selvita offers a comprehensive range of IT services including pre-implementation consulting, professional implementation, hardware delivery and configuration, training, assistance with system validation and preparation of documents, maintenance and complete technical support. The company's specialists have many years' experience in managing IT projects and implementations for customers. This ensures effective and successful implementation of all LIMS projects in laboratories.

In the coming years the Company plans to expand its existing implementation and software development services and launch new services to ensure a stable year-to-year growth of revenue. It also aims to further diversify the revenue from different sources. It is estimated that the revenue will

mostly derive from: sales of new versions of LIMS software with mobile module, development services and new service contracts, projects for integration of laboratory systems (STARLIMS) with equipment, testing apparatus and ancillary systems, as well as development of software development services in markets where the company is already present and on new European markets it intends to explore.

## 3.2 Target Markets

Life science is one of the most globalised industries in the world. Innovative products (e.g. drugs) developed in one country are protected by international patents and commercialized globally. Their development is supported by numerous subcontractors providing the necessary copyright as well as research and development, production and marketing services. Due to the high value of end products, logistics and transportation costs are negligible, which encourages customers to cooperate with major companies from the USA, Europe and Asia. Polish accession to the European Union began the process of fundamental change in the strategy of Polish businesses. Selvita intends to seize these opportunities by: developing in-house innovative compounds, providing services within research projects conducted by pharmaceutical companies and continually tailoring its offer to the needs of the international market.

### Market value and perspectives

According to *IMS Health The Global Use of Medicines: Outlook through 2017*, the pharmaceutical market in 2012 was worth USD 965b. It is estimated that by 2017 this figure will increase to about USD 1.200b (ca. 5% growth per annum). This growth will be mostly driven by increased spending in the developing countries and the development of the biopharmaceuticals market. It is also likely to reflect historical trends – in the years 2007-2012 the market's average annual growth rate was approx. 5.5%.

Over the next five years, the difference in growth rate dynamics between the developed and the developing markets will continue to increase. The developed markets of North America, Europe and Japan will grow at single-digit rate, mainly due to the economic situation, health care savings and lower costs due to the increasing availability of low-cost generic drugs replacing products which patents have expired.

Factors likely to have a crucial influence on the development of the pharmaceutical market in subsequent years will include: higher drug spending in the developing countries, expiring patents on the original drug products (lower spending on original drugs at the expense of generics due to expiry of patent protection in 2013-2017), introduction of innovative medicines and dynamic development of the biopharmaceuticals market.

The primary focus of Selvita's activities is the research on novel original drugs – both directly (within its own portfolio of innovative projects) and indirectly (through laboratory services contracted by other entities).

The development work within Selvita's innovation segment is mainly focused on cancer research. According to the report prepared by *IMS Institute for Healthcare Informatics*, the total global spending on cancer drugs in 2013 amounted to USD 91b (approx. 5% average annual growth rate in 2008-2013). In the subsequent years oncology is expected to remain the fastest growing therapeutic area in the developed countries generating over USD 100b in drug sales by 2017.

Almost 65% of the global oncology market (approx. USD 68b in 2013) is concentrated in only 7 countries: USA, Great Britain, Italy, Spain, Germany, France and Japan. Mexican and Brazilian markets are the second largest oncology region, concentrating about 12% of the entire market (approx. USD 11b in 2013).

As part of the innovation segment Selvita develops targeted therapies (small molecule kinase inhibitors specifically targeting cancer cells). According to the *IMS Institute for Healthcare Informatics* report, the share of such therapies in the oncology drugs market increased from 11% in 2013 to 46% in 2013.

According to the *IMS Institute for Healthcare Informatics* report, a total of over 6200 drugs are currently at different stages of development worldwide. Over 2000 of them are oncology drugs (over 30%). A significant number of such drug candidates are currently in the pre-clinical phase and in phase 1 clinical studies (almost 1400 therapies). These projects indirectly create a market for Selvita's service segment.

### **Partnering market (market of licences for potential original drugs) – innovative segment market**

Selvita's most important market is the market of partnering agreements (licence agreements) concluded between biotechnological companies and pharmaceutical companies. Its growing importance is related to the current model of innovation in the pharmaceutical industry, in which there is a growing division into academic institutions – conducting basic research, biotechnological companies – conducting early stage of research and development, and pharmaceutical companies – conducting advanced clinical trials and global commercialization of drugs. Almost half of revenue of large pharmaceutical corporations comes from drugs developed outside their laboratories. This creates a vast market of projects that are bought by large corporations from biotechnological companies, not only at the stage of clinical trials (which was characteristic in former years), but also at the pre-clinical stage. According to the Bloomberg service, between 2008 and 2013 the value of partnering transactions rose from USD 63b in 2008 to nearly USD 91b in 2013 (annual average growth of 8%).

The largest partnering activity concerns areas in which competition from generic drugs is not strong, and the drugs that function on the market do not allow patients to stabilize their diseases or to be cured safely. Such areas include first and foremost oncology and central nervous system diseases. In oncology, particularly significant are targeted therapies (most of the molecules developed are so called kinase inhibitors) and, in terms of the central nervous system diseases - Alzheimer's disease. In both these therapeutic areas there is a deep partnering market – for example in oncology each year approximately 50 collaboration agreements are concluded concerning early phase projects (discovery phase, preclinical phase and first phase of clinical trials) which gives approximately a 20% market share.

### **Outsourcing market – service segment market**

#### ***Global pharmaceutical outsourcing market***

According to the report by JZMed, Inc., the value of the global pharmaceutical outsourcing market in 2011 was approx. USD 85b. The value of the global pharmaceutical outsourcing market in the

following years will continue to grow, and in 2015 it will be USD 150b (anticipated annual average growth of 15%)<sup>1</sup>.

At present, most outsourcing services contracted by Western pharmaceutical and biotechnological corporations with Asian companies concern wholesale manufacture of simple chemical ingredients, including custom synthesis and contract manufacture. Contracting the development of drugs at early stages of development with Asian companies is not particularly popular among Western pharmaceutical corporations. The main reasons include concerns about compliance with intellectual property regulations and a low level of development of the Asian biotechnological market. Given this, a large part of pharmaceutical outsourcing orders is directed to the European and Israeli markets, which are considered specialised biotechnological centres. These markets compete with respect to safety in the areas of property law, convenient location and more similar culture. Unlike Asian companies, European companies are suppliers of advanced solutions, processes and technologies, and not of mass production of simple chemical compounds.

### ***Global market of drug development outsourcing***

In recent years, the global pharmaceutical industry has faced serious challenges. A significant increase in the costs of research and development, a shrinking portfolio of development projects, and an implementation of new technologies made quality, costs and speed of trials extremely important. For most pharmaceutical companies, the main aim is to maintain a stable flow of drugs in their portfolios. To achieve this, they must focus on improving effectiveness by accelerating the process of development of new drugs. This will be possible thanks to a collaboration with specialised biotechnological companies providing research and development services.

Although at present the pharmaceutical industry is capable of generating stable cash flows, if the research projects under development fail, the industry may be under a lot of financial pressure resulting from the risk related to the expiry of a large number of patents between 2014 and 2018.

In recent years, despite a significant increase in outlays on research and development, there has also been a strong decrease in the effectiveness of their use. Many pharmaceutical companies have been forced to limit or discontinue own development projects, especially at an early stage of research. Therefore, the biggest challenge for the pharmaceutical industry is finding new ways of creating value. One of such ways is outsourcing, as it allows to decrease costs and to increase effectiveness. Outsourcing allows to change fixed costs to variable costs and gives access to expert knowledge in selected areas. For this reason, outsourcing will become more and more important.

### **Major suppliers and recipients**

Information on leading customers with turnover exceeding 10% of revenue from total sales is given in note 6.5 of the Additional Information to the Consolidated Financial Statements of Selvita Group.

## **3.3 Employment data**

Given the dynamic growth in the period covered by the report, the Group has significantly increased employment, especially in the research and development department as well as the contract

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<sup>1</sup> ALMAC, Special Report – Outsourcing Formulation Development and Manufacturing: An Early Approach Saves Time and Money, Drug Development & Delivery, 31 March 2013

synthesis department. Employment increased from 166 employees at the end of 2013 to 220 employees at the end of 2014.

### **3.4 Report from the series F issue and use of the receipts by the company**

As a result of approval on 25 November 2014 by the Polish Financial Supervision Authority (KNF) of the Company's Prospectus, in December Selvita carried out an Initial Public Offering and transferred its listings from NewConnect to the regulated market of the Warsaw Stock Exchange (GPW). The offering was a success – Selvita obtained PLN 27.3m, selling shares at the maximum price of PLN 10.3. The reduction rate in the tranche for individual investors was 88 %.

The Company offered 2.651.891 new series F shares and all were acquired. Selvita added new assets to the main market of the Warsaw Stock Exchange together with previously available in business trading on the NewConnect market 6.413.566 series B, C, D and E shares. As a result of the issue of shares, Selvita's capital is divided into 13.115.457 shares.

The company plans to allocate the acquired funds (after a deduction of the costs of the issue of shares) to the financing of an investment programme, worth approx. PLN 60m, covering the development of innovative projects – mainly in oncology – and the extension of laboratory space as well as the purchase of laboratory equipment. The Company has secured approximately half of the value of the programme in the form of non-returnable subsidies.

#### **The Innovative Segment**

The aim of the Innovative Segment is to create new therapies and to increase the value of projects during their development at subsequent stages of the process of discovering drugs, until sale of the project and capitalisation of the profits from the intellectual value gained. Acquisition of capital as part of the issue of shares is another step designed to extend and develop further a diversified array of projects at different stages of development, from early stages to projects at clinical stage. From the perspective of further development of the Innovation Segment, the following aims were the main messages of the issue of shares:

1. Carrying out of comprehensive preclinical trials for clinical candidates under projects SEL24 and SEL120 and carrying out the first stage of the clinical trials for one of these projects (KIND-P1); The total value of the project is approx. PLN 20.9 m, of which in June 2014 the Issuer received a subsidy from the National Centre for Research and Development (NCBiR) of approx. PLN 9.4 m.
2. Continuation of the work carried out by the company as part of the already created and operating platforms for the discovery of new drugs in the field of kinase inhibitors (kinase platform) and cancer cell metabolism (metabolic platform) which are at the stage of optimization of leading particles, as well as commencing further research on new particles under these platforms. The total value of the above work is approx. PLN 15 m, of which approx. PLN 7 m was to be financed from own funds and approx. PLN 8 m from funds obtained from the issue of shares.
3. Creation of another research platform under the Innovation Segment – an epigenetic platform based on the grant which was included in the list of projects recommended for financing under the strategic programme Prevention and Treatment of Diseases Associated with the Progress of Civilization Strategmed financed by NCBiR (the EPTHERON project). The total value of the project is approx. PLN 12.5 m, of which approx. PLN 7.5 m was to be



financed from the subsidy of NCBiR and from own funds and approx. PLN 5 m from funds acquired from the issue of shares.

In total, approx. 80% of the funds acquired from the issue of shares will be allocated on financing projects under the Innovation Segment.

### **Aims of the Services Segment**

The Services Segment is growing dynamically. Selvita has an extensive base of customers in Europe, Asia and the Americas. The relations built with customers will be the base for further growth, by increasing the share in the expenditures of large strategic recipients of services. The company will also win further customers thanks to an increased reputation in key centres of concentration of the biotechnological and pharmaceutical industry in the world, such as Boston, Basel or San Francisco. From the perspective of further development of the Services Segment, the following aims were the main messages of the issue:

1. Extension of laboratory space by renting additional rooms – necessary access to a well equipped laboratory infrastructure. All Selvita laboratories are currently rented from Jagiellonian Center of Innovation in Cracow, and therefore the Company did not incur any expenses on the construction of any buildings. Extension of the scale of operations, continuation of intense growth of the Services Segment in the coming years, as well as the commitment associated with the entering of the Company subsidiary to the Special Economic Zone (creation of approx. 150 new jobs by 2023), make it necessary to extend the laboratory space. The planned cost of such extension is in total approx. PLN 8m, of which approx. PLN 4m will be financed from own funds and approx. PLN 4m from funds obtained from the issue of shares.
2. Purchase of additional laboratory equipment – Selvita intends to continue the extension of another laboratory modules and, therefore, it will be necessary to increase the costs of equipping laboratory rooms with the necessary research equipment. Also, the equipping of the Company's laboratories with additional research and analytical equipment, allowing a higher level of automation of work and more precise biological and chemical analyses, which will allow to provide new types of services and to increase productivity of the existing teams and, as a consequence, of the revenue generated by their work. Purchase of additional equipment is a cost of approx. PLN 4m, of which approx. PLN 2m is to be financed from own funds and approx. PLN 2m from funds coming from the issue of shares.

In total, approx. 20% of the funds acquired from the issue of shares will be allocated on financing projects under the Services Segment.

At the beginning of March 2015, the Company informed that a subsidiary was registered in the United States, which will be responsible for supporting on-going projects carried out for American customers, acquiring further partners for research and development projects in oncology, and sale of services. This event is part of the goals of the strategy of development of the Company presented during the public offering.

Since the funds from the issue of shares were received by the Issuer in January 2015, in the financial year 2014Selvit Group did not use any funds from the issue of shares.



## 3.5 Planned growth of Selvita Group

### The Innovative Segment

In 2015, Selvita Group plans to continue dynamic growth in the area of research and development of new drugs, using for this purpose the funds acquired from the issue of shares in December 2014, supported by the subsidies obtained in the previous years and the subsidies obtained systematically as part of the new financial perspective 2014-2020.

First it is planned to complete the preclinical phase in projects SEL24 and SEL120 and to prepare them for the commencement of the first phase of clinical trials in 2016. Selvita will continue discussions with prospective buyers of the proprietary R&D projects and anticipates that a large partnering contract will be signed in 2015.

Under the projects carried out together with Merck Serono and H3 Biomedicine, a selection of clinical candidates is planned.

### The Services Segment

In this area, the Group anticipates a organic growth due to a further increase in the share of FTE contracts in the sales volume, an increase of revenue, and a matching growth of employment and extension of the laboratory space.

### New initiatives

Since 2015, Selvita Group has been carrying out a plan of creation of foreign branches. First, a subsidiary (Selvita Inc.) was created in the United States. It will be located in the biggest centre of concentration of biotechnological companies in the world – the Greater Boston Area – and it will be responsible for supporting on-going projects carried out for American customers and for acquiring further partners for research and development projects in oncology and sale of services.

In the coming months, it is planned that a similar entity will be created in the United Kingdom.

## 3.6 Key achievements in research and development

The Company's research and development work is carried out as part of the Innovative Segment. The work consists in the development of own biologically active compounds, mainly in the field of oncology. This work is related mainly to the development of innovative chemical compounds showing pharmacological effect, which then, at a further stage of their development, are intended for clinical trials and commercialisation by leading international pharmaceutical companies.

In 2014, three significant achievements under the Innovation Segment must be mentioned:

1. Achievement of the first milestone in the strategic project carried out together with H3 Biomedicine, as reported by the Company on May 23rd. This achievement confirmed the high potential of the jointly developed project and involved the payment of PLN 0.79 m of additional remuneration for Selvita for the achievement of the milestone set forth in the contract. This is the first financial and the second scientific milestone achieved to date by Selvita in collaboration with its partners.
2. Establishing collaboration with FeliciteX Therapeutics in the development of the cancer quiescence platform, as reported by the Company on November 7th. Its aim is to develop new drugs targeting quiescent cancer cells. The signed contract guarantees to Selvita PLN

1.98 m of financing in the first 15 months of collaboration and many opportunities to increase remuneration as the work on the project progresses. The collaboration allows to combine FeliciteX Therapeutics' experience in research on quiescent cancer cells and Selvita's extensive knowledge on kinases, leading to a potentially ground-breaking collaboration and a development of effective anti-cancer drugs with a high commercial potential. Establishment of the third partnering collaboration over the last 14 months confirms the commercial potential of the innovative projects carried out by the Company.

3. Signing a contract with the National Centre for Research and Development (NCBiR) for the execution and financing of the research project KIND-P1, as reported by the Company on June 9th. The aim of the project is to perform comprehensive preclinical studies and to introduce to clinical trials the selected kinase inhibitor from SEL24 and SEL120 projects with the highest therapeutic potential as a new, innovative anti-cancer drug. The total net value of the project is PLN 20.91 m, of which PLN 9.44 m is the support from NCBiR. The project will be carried out between 2014 and 2017 and it is one of the key elements of the Company's investment plans for the coming years which might be carried out by Selvita on its own or in collaboration with its pharmaceutical partners under the partnering model.

At present, Selvita is engaged mainly in the development of research and development projects in oncology. The company implements in total several projects at different stages of development:

#### **SEL24**

The aim of the SEL24 project is to create an innovative anti-cancer drug based on the properties to selectively destroy cancer cells. This specific action was achieved by selective inhibition of the PIM and FLT3 kinases, which are key players in the signalling pathways responsible for the development of cancer, especially acute myeloid leukemia. The main achievement in the project was the identification of SEL24-B489 compound which was further selected as a drug candidate for first in man clinical trials.

In 2014, SEL24 project focused on the detailed characterization of the selected clinical candidate SEL24-B489 for the introduction into phase I clinical trials. For this purpose, an initial non-GLP toxicity studies were conducted and did not reveal any toxicity preventing the administration of the SEL24-B489 compound at doses necessary to obtain a therapeutic effect. Some of the research on the mechanism of action and therapeutic efficacy carried out at Selvita was repeated also in independent laboratories, confirming previously obtained results and thus further supporting a strong therapeutic potential of SEL24-B489 as the clinical candidate. Independently of the laboratory work, preparations were made for the selection of Contract Research Organization (CRO) which will perform a large-scale synthesis of the SEL24-B489 compound in the GMP standard and a preclinical regulatory toxicity studies in the GLP standard. Both GMP synthesis and GLP toxicity studies are necessary steps for commencing clinical trials in patients. The final selection of the CRO preparing the preclinical data package is planned for the end of Q1 2015. These activities will be carried out as a part of the KIND-P1 project.

#### **SEL120**

The aim of the SEL120 project is to develop a new innovative oncology drug, based on specific properties to inhibit the CDK8 kinase, as a part of targeted therapy for colorectal cancer and beyond that other solid tumours. The ultimate result of the SEL120 project was a successful development of the best compound and further a clinical candidate, namely SEL120-34. The aim of further

development work is to precisely position the program in selected clinical indications, especially in colorectal and breast cancer. This work contains the comparison of the clinical effectiveness of SEL120-34 with selected conventional therapies, both as stand-alone or combinational treatment, with respect to the assumed mechanism of action. The planned actions will lead to the selection of an optimal scenario for clinical development, which assumes the selection of patients based on molecular markers of sensitivity to CDK8 inhibitors. As part of preclinical development, SEL120-34A safety will be assessed in initial non-GLP toxicity studies. The CRO commencing this work package was selected in Q1 2015. These activities will be carried out as a part of the KIND-P1 project.

### **Kinase platform**

The aim of the projects conducted under the kinase platform is to develop an innovative anti-cancer therapy with the use of small-molecule compounds aiming at new protein targets related with signalling pathways in cancer diseases. Despite a significant progress in the treatment of some types of cancer and a wide array of available therapies, cancer remains the main cause of death worldwide. At present, the used cancer treatment methods do not ensure full efficacy and safety, and the response to them is often difficult to predict. The project is conducted under the strategic collaboration with H3 Biomedicine Inc., Two separate targets were selected from the group of protein kinases, which expression and activity is significantly increased in specific types of cancers. The main effort was directed at confirming the biological role and the therapeutic capabilities of target proteins activity modification in cancer cell lines with various genetic origin and on the development of chemical compounds capable to inhibit their enzymatic activity. A series of separate groups of chemical compounds of a desired activity were identified, and selected representative compounds were tested in the largest available kinase panel, containing more than 440 different protein kinases. The obtained results indicate that the tested compounds show exceptional selectivity against our target protein kinases. Moreover, inhibitors of both protein kinases exert strong inhibitory effect on proliferation of cancer cells. All research work is conducted as scheduled, however the details of the project are confidential.

### **Cancer metabolism platform**

The aim of the metabolic platform, created in collaboration with Merck Serono, is to develop new oncology drugs acting on biological targets related to abnormal cancer metabolism. High dependence on specific metabolic pathways (e.g. glutaminolysis or glycolysis) is a known hallmark of many sorts of cancer, therefore pharmacotherapy which targets cancer metabolism has potentially a very broad application. In a collaboration with the partner, there were three biological targets selected (non-revealed) with the research on these targets being currently at various stages of development. In total, there were almost 1000 new compounds synthesized, and several thousand compounds were tested for the activity on the explored therapeutic targets. All the research work is performed in accordance with the project plan, however the details of the project are confidential.

### **Cancer cell chemoresistance platform**

The project was commenced in Q4 2014 and it is carried out in collaboration with FeliciteX Therapeutics. The aim of the project is to develop innovative anti-cancer drugs. Work is focused on research on a therapy, which target the protein kinase. The expected effect of kinase inhibiting consists of affecting quiescent cancer cells, being practically insensitive to currently used drugs. Quiescent cancer cells are largely responsible for cancer recurrence after a completed treatment cycle, and also for resistance to chemotherapy. The main therapeutic area of this project are

pancreatic and lung cancers. To date, work under the project concentrated on obtaining kinase inhibitors with confirmed *in vitro* activity . Some of the already developed inhibitors are very potent inhibitors, showing activity towards selected cancer cell lines. Further work will focus on demonstrating the ability to affect quiescent cells. In the longer perspective, *in vivo* experiments will be conducted to confirm the mechanism of action and efficacy of the developed kinase inhibitors. . Simultaneously, physicochemical properties and selectivity of those inhibitors will be optimized. The project details remain confidential. All the research work is performed as scheduled, however the details of the project are confidential.

### **Other projects**

In addition to the above projects, Selvita Group implements other research and development projects, which progress details remain confidential .

## 4 FINANCIAL INFORMATION

### 4.1 CONSOLIDATED INCOME STATEMENT

FOR THE PERIOD FROM 1 JANUARY 2014 TO 31 DECEMBER 2014

	01/01/2014 - 31/12/2014	01/01.2013 - 31/12/2013
	PLN	PLN
<b>Continued operations</b>		
Revenues from sales	28 864 758	13 053 068
Revenues from subsidies	12 429 909	8 688 258
Other operating revenues	262 091	172 818
<b>Revenues on operating activities</b>	<b>41 556 758</b>	<b>21 914 145</b>
Change in stock of goods	(143 884)	82 451
Amortisation and depreciation	(2 354 413)	(2 082 463)
Consumption of materials and energy	(7 479 464)	(4 985 672)
External services	(6 157 084)	(4 210 420)
Payroll	(17 755 059)	(11 625 899)
Taxes and charges	(262 673)	(186 265)
Other costs by type	(1 733 403)	(843 073)
Value of goods and materials sold	(345 421)	(258 584)
Other	(53 465)	(32 426)
<b>Operating expenses</b>	<b>(36 284 866)</b>	<b>(24 142 353)</b>
<b>Profit (loss) on operating activities</b>	<b>5 271 892</b>	<b>(2 228 208)</b>
Financial revenues	376 424	35 821
Financial expenses	(221 229)	(234 273)
Other	-	-
<b>Net profit (loss) before income tax</b>	<b>5 427 087</b>	<b>(2 426 660)</b>
Income tax expense	423 039	(18 584)
<b>Profit (loss) on operating activities</b>	<b>5 850 126</b>	<b>(2 445 244)</b>
<b>Discontinued operations</b>		
Profit (loss) on discontinued operations	-	-
<b>Net profit (loss)</b>	<b>5 850 126</b>	<b>(2 445 244)</b>
Net profit loss attributed to	-	-
Majority shareholders	5 850 126	(2 445 244)
Minority shareholders	-	-
	<b>5 850 126</b>	<b>(2 445 244)</b>
<b>Earnings per share</b> <b>(expressed in gr per share)</b>		
With continued and abandoned operations:	55,9	-23,37
Basic	55,9	-23,37
Diluted	55,9	-23,37
With continued operations:	55,9	-23,37
Basic	55,9	-23,37
Diluted	55,9	-23,37
<b>Total income</b>	<b>5 850 126</b>	<b>(2 445 244)</b>
Total comprehensive income attributed to:	5 850 126	(2 445 244)
Majority shareholders	5 850 126	(2 445 244)
Minority shareholders	-	-
	<b>5 850 126</b>	<b>(2 445 244)</b>

## 4.2 CONSOLIDATED BALANCE SHEET

AS AT 31 DECEMBER 2014

	31/12/2014	31/12/2013
	PLN	PLN
<b>ASSETS</b>		
<b>Fixed assets</b>		
Tangible fixed assets	6 844 817	4 931 570
Investment in real-estate		
Goodwill	280 740	280 740
Other intangible assets	50 452	1 054
Investments in related parties		
Deferred tax assets	2 128 090	1 691 952
Other financial assets	-	-
Other assets	189 645	162 043
<b>Total fixed assets</b>	<b>9 493 744</b>	<b>7 067 359</b>
<b>Current assets</b>		
Inventory	706 336	391 211
Short-term receivables	9 821 900	5 160 613
Receivables on long-term contracts	492 320	-
Other financial assets	120 000	120 000
Current tax related assets	-	0,00
Other assets	1 411 136	220 575
Cash and other monetary assets	4 757 817	5 298 287
	17 309 509	11 190 686
Non-current assets held for sale and discontinued operations	-	0,00
<b>Total current assets</b>	<b>17 309 509</b>	<b>11 190 686</b>
<b>Total assets</b>	<b>26 803 253</b>	<b>18 258 045</b>

## CONSOLIDATED BALANCE SHEET

	31/12/2014	31/12/2013
	PLN	PLN
<b>EQUITY AND LIABILITIES</b>		
<b>Equity</b>		
Share capital	4 185 426	4 185 426
Revaluation reserve	-	-
Own shares	-	-
Supplementary capital	2 521 789	2 521 789
Other reserve capitals	1 883 442	1 883 442
Previous years profit (loss)	-5 187 170	-2 741 926
Net profit (loss)	5 850 126	-2 445 244
	<u>9 253 614</u>	<u>3 403 488</u>
Provisions related to non-current assets held for sale and discontinued operations presented directly in equity	-	-
Equity attributed to majority shareholders	9 253 614	3 403 488
Equity attributed to minority shareholders		
<b>Total equity</b>	<b><u>9 253 614</u></b>	<b><u>3 403 488</u></b>
<b>Long-term liabilities</b>		
Long-term credits and loans	-	-
Other financial liabilities	176 893	109 355
Liabilities for retirement	27 074	27 074
Provision for deferred income tax	64 126	95 525
Provisions for liabilities-long-term	0,00	0,00
Deferred income	2 010 246	3 221 675
Other liabilities		
<b>Total long-term liabilities</b>	<b><u>2 278 339</u></b>	<b><u>3 453 629</u></b>
<b>Short-term liabilities</b>		
Trade liabilities	6 055 224	3 480 752
Long-term liabilities	1 340 554	39 805
Short-term credits and loans	90 921	161 480
Other financial liabilities	367 131	159 760
Current tax liabilities	-	-
Provisions-short-term	2 800 593	2 103 946
Deferred income	4 616 877	5 455 186
Other liabilities		
	<u>15 271 300</u>	<u>11 400 929</u>
Liabilities related to non-current assets held for sale and discontinued operations	-	-
<b>Total short-term liabilities</b>	<b><u>15 271 300</u></b>	<b><u>11 400 929</u></b>
<b>Total long-term liabilities</b>	<b><u>17 549 639</u></b>	<b><u>14 854 558</u></b>
<b>Total liabilities</b>	<b><u>26 803 253</u></b>	<b><u>18 258 045</u></b>

## 4.3 CONSOLIDATED CASH FLOW

FOR THE PERIOD FROM 1 JANUARY 2014 TO 31 DECEMBER 2014

	01/01/2014 - 31/12/2014	01/01.2013 - 31/12/2013
	PLN	PLN
<b>Cash flows from operating activities</b>		
<b>Net profit (loss)</b>	<b>5 850 126</b>	<b>(2 445 244)</b>
<b>Adjustments</b>		
Amortisation and depreciation	2 354 414	2 082 463
Exchange gains (losses)	-	37 500
Interest and profit-sharing (dividends)	20 824	20 168
Profit (loss) on investing activities		
Change in receivables	(5 153 607)	-2 687 562
Change in inventory	(315 125)	27 182
Change in short-term liabilities and provision excluding credits and loans	3 828 880	989 838
Change in grants	(4 125 223)	-2 106 442
Change in other assets	(8 113 676)	-4 162 455
Change in provisions	696 647	1 158 264
Income tax paid	46 341	0
Other	8 322	-112 196
<b>Cash flows from operating activities</b>	<b>(4 902 078)</b>	<b>(7 198 482)</b>
<b>Cash flows from investing activities</b>		
Proceeds from sale of property, plant and equipment	-	-
Purchase of tangible and intangible fixed assets	(3 524 117)	(1 470 552)
Purchase of tangible and intangible fixed assets partially financed with grant	(86 318)	(696 490)
Interest	18 227	17 236
Loans granted	-	-
Other inflows from financial assets		
Other	-	-
<b>Cash flows from investing activities</b>	<b>(3 592 208)</b>	<b>(2 149 805)</b>
<b>Cash flow from financing activities</b>		
Payment of liabilities from finance lease agreements	(485 043)	(198 471)
Proceeds from credits and loans	840 921	391 480
Subsidies	8 548 469	9 641 897
Repayment of credits and loans	(911 480)	(230 000)
Dividends	-	-
Interest paid	(39 051)	(54 736)
Other	-	-
<b>Net cash flows from financing activities</b>	<b>7 953 815</b>	<b>9 550 170</b>
Increase of net cash	(540 470)	201 882
Cash opening balance	5 298 287	5 096 404
<b>Cash and cash equivalents - end of the period</b>	<b>4 757 817</b>	<b>5 298 287</b>