EDISON

Selvita

Company update

Fruitful partnership with Merck KGaA

Pharma & biotech

2016 has started on a positive note for Selvita with FY15 results showing excellent organic growth and a second R&D development deal with Merck KGaA announced at the end of March. With solid service revenue growth expected to continue, the R&D pipeline is progressing and lead-product SEL24 should enter Phase I by mid-2016. Other potential catalysts during the next 18-24 months include possible partnership deals for SEL24 or SEL120 and new drug development deals from existing collaborations with H3 Biomedicine and Merck. We raise our valuation to PLN354m (vs PLN333m previously), or PLN27 per share (was PLN25.4).

Year end	Revenue (PLNm)	PBT* (PLNm)	EPS* (PLN)	DPS (PLN)	P/E (x)	Yield (%)
12/14	41.6	5.4	0.56	0.0	39.6	N/A
12/15	56.1	7.5	0.84	0.0	26.4	N/A
12/16e	66.8	5.8	0.44	0.0	50.4	N/A
12/17e	76.4	8.7	0.65	0.0	34.1	N/A

Note: *PBT and EPS are normalised, excluding exceptional items and share-based payments.

51% revenue CAGR 2012-2015

2015 was a second profitable year with total revenue reaching PLN56.1m, up 35% year-on-year. Three-year revenue growth corresponds to a CAGR of 51% and we expect double-digit total revenue growth to continue, specifically 19% and 12% in 2016 and 2017 respectively. Strong organic sales growth in FY15 translated into increasing profitability with core operating profit of PLN6.8m up 29% and profit after tax of PLN7.7m up 31% year-on-year (adjusted for employee stock options programme expense and the impact of deferred tax asset changes in 2015).

Sound progress of lead R&D projects

Selvita's own two lead R&D projects – SEL24 and SEL120 – made sound progress with SEL24 on track to enter Phase I by mid-2016. The company is able to finance the trial itself, which would enable it to retain more of the project's value when out-licensing after Phase I, but a deal at an earlier stage is also a possibility. SEL120 should be ready for Phase I in 2017 with further development depending on available resources and interest from partners. According to recent industry news, Merck & Co in-licensed a selective CDK8/CDK19 inhibitor from Harvard University with an upfront payment of $20m and tiered royalties, which is the largest fee for a technology licence developed at the university. In our view, this clearly shows that interest in selective CDK inhibitors is high. SEL120 is a selective CDK8 inhibitor.

Valuation: Increased to PLN354m or PLN27/share

With good organic growth in FY15 and positive developments in the backlog year to date, we have increased our revenue and profitability forecasts. The only change in our assumptions for R&D projects was the postponement of SEL24 development timelines by one year post Phase I to reflect our view that a potential partnership deal is less likely this year (but not impossible). After upgrading our forecasts and rolling our DCF and rNPV models forward by one quarter, our new valuation is PLN354m (PLN333 previously) or PLN27.0/share (PLN25.4 previously).

25 April 2016

Price	**PLN22.18**
Market cap	**PLN290m**

Net cash (PLNm) at end 2015	28.8
Shares in issue	13.1m
Free float	51%
Code	SLV
Primary exchange	WSE
Secondary exchange	N/A

Share price performance

%	1m	3m	12m
Abs	1.3	17.4	27.8
Rel (local)	2.3	4.3	65.8

52-week high/low	PLN25.25	PLN15.7

Business description

Selvita is a drug discovery services provider based in Poland. It employs c 300 staff (30% with PhDs) and operates two main business units: the Innovations Platform (internal NME pipeline) and Research Services (medicinal chemistry/biology, biochemistry).

Next events

Q116 results	12 May 2016
Start SEL24 Phase I	Mid-2016
Start SEL120 IND studies	H116

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Edison profile page

Collaborations: Maturing partnership with Merck

Selvita's partnership with Merck is gaining pace, with the most recent drug development agreement announced on 31 March. The two companies have signed a second deal, which involves an undisclosed protein target with potential therapeutic compounds initially developed by Selvita using its cancer metabolism platform. Financial details are same as in the previous deal with Merck, announced on 22 December 2015. According to that agreement, Selvita may receive up to €1.9m in payments during the first five years depending on undisclosed R&D milestones. Total payments may add up to €16.5m if the drug is successfully commercialized.

Going further back, the first partnership agreement with Merck was signed in October 2013 with the goal of collaborating on discovery and development of multiple new compounds. This two-year agreement has clearly been successful, with the two new drug development programmes now ongoing. To capture the potential value of the drug discovery collaboration with Merck, we included two projects in the valuation of our last report. The new drug development deals in December and March confirm our expectations that Selvita is able to deliver services and innovation to attract large pharma attention.

Furthermore in November 2015 a second drug discovery collaboration was agreed with Merck to identify first-in-class small molecules as lead candidate drugs for multiple oncology indications. This indicates that we could see more development deals in the near term. We summarise the collaboration and drug development agreements with Merck below.

Exhibit 1: Selvita's partnerships with Merck KGaA

Deal signed	Drug discovery collaboration October 2013	Drug discovery collaboration November 2015	Preclinical drug development deal 22 December 2015	Preclinical drug development deal 31 March 2016
Contract period	2013-15	2015-18	N/A	N/A
Details	Discovery and development of multiple NCEs against selected protein targets (two projects on two targets) involved in cancer cell metabolism.	Discovery of first-in-class NMEs as lead candidates for multiple oncology indications. Separate collaboration to 2013-15.	Development and commercialization of therapeutic molecules developed by Selvita using its cancer metabolism platform for a specific target. Result of the 2013-15 collaboration with Merck.	Development and commercialization of therapeutic molecules developed by Selvita using its cancer metabolism platform for a second specific target. Result of the 2013-15 collaboration with Merck.
Funding	PLN18.8m in research funding over 2015-18, with PLN10m funding guaranteed over 2013-15.	Milestone payments and royalties on successful development and commercialisation of products by Merck.	Signing fee €0.2m; max payments of €1.9m over the next five years; total milestone payments may add up to €16.5m.	Same terms as the 22 December 2015 deal
Outcome	Selection of clinical candidates (2016-17).			

Source: Edison Investment Research, Selvita

Good progress with other collaborations as well

Other drug discovery collaboration partnerships are also progressing according to plan. The collaboration on a kinase platform with H3 Biomedicine was renewed for an additional year to September 2016 to further validate two kinase targets. While the details about the potential projects remain undisclosed, the companies plan to initiate IND-enabling studies in 2016.

The cancer quiescence platform is run in collaboration with Felicitex Therapeutics (US) with the aim of developing DYRK kinases, which is a novel approach with expected efficacy against quiescent cancer cells that are not actively proliferating and thus less susceptible to classical chemotherapy drugs. These more resistant malignant cells may cause tumour relapse once the treatment ends. The partnership was established in November 2014 and two series of compounds were developed with a high likelihood of naming clinical candidates, as reported in the FY15 results.

R&D: SEL24 in Phase I by mid-2016, SEL120 in 2017

SEL24 to enter Phase I by mid-2016

SEL24 is Selvita's most advanced oncology programme and is well on track to enter a Phase I study around mid-2016, which will be managed by US-based CRO Theradex. The study will run for nearly two years. While the company is able to finance the study itself, Selvita's goal is to secure a partner for the SEL24 programme, and the company has previously indicated that it is in advanced partnering negotiations with several potential pharma and biotech companies.

The project is focused on developing a first-in-class compound with a potential dual mechanism of action to target two kinases, namely PIM (1, 2 and 3 isoforms) and FLT3 mutants, which have been shown to be important in the development of acute myeloid leukaemia (AML) and other haematological malignancies.

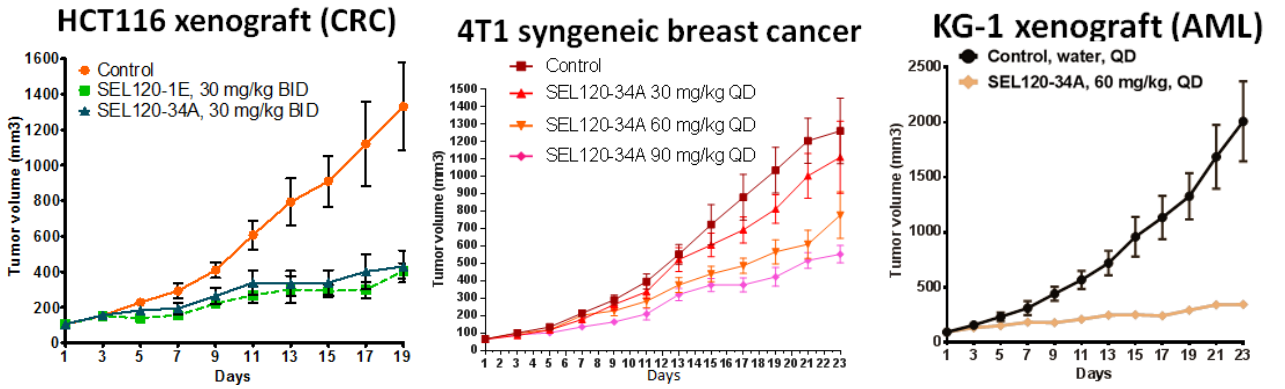
SEL120 in the spotlight after record Merck & Co deal with Harvard University

SEL120, Selvita's second lead product, is a first-in-class selective cyclin-dependent kinase 8 (CDK8) inhibitor, which differs from other less selective or pan-CDK inhibitors in late stage development or on the market. The main issues with the first generation of CDK inhibitors were not only the lack of selectivity within the CDK family, but they also inhibited numerous other kinases leading to a variety of side effects in clinical trials, most often bone marrow suppression, anaemia and leukopenia.

SEL120 is uniquely differentiated selective CDK8 inhibitor shown to have a favourable safety/efficacy profile in non-GLP studies in two species and now the company is preparing for IND enabling studies. Although the main concepts of CDK inhibition were discovered more than two decades ago, selective CDK8 inhibition is a fresh approach. It recently gained attention after Merck & Co in-licensed a selective CDK8/CDK19 inhibitor from Harvard University in a deal with an upfront payment of $20m and tiered royalties, which is the largest licence fee for technology developed at the university. In our view, this clearly shows interest in selective CDK inhibitors is high. The agreement involves a natural compound, cortistatin A, and recently published articles show anti-leukaemic in vitro and in vivo efficacy, which adds to Selvita's pre-clinical data.

Selvita plans further preclinical development of SEL120 in 2016 with the goal of entering Phase I in H217. So far, preclinical studies from the company (Exhibit 2) and from third parties point to potential efficacy in haematological malignancies, colorectal cancer or triple-negative breast cancer.

Exhibit 2: SEL120 inhibits tumour survival in multiple *in vivo* cancer models

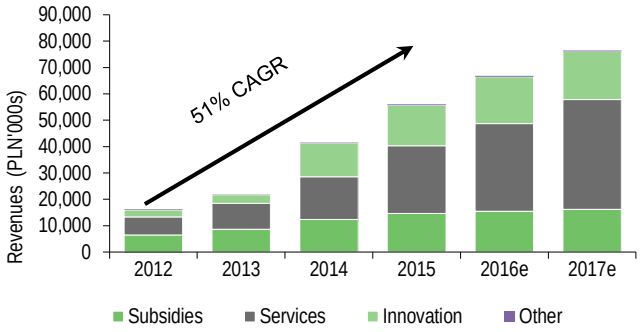


Source: Selvita. Note: HCT116=CRC, KG-1=AML (xenograft models – human tumour tissue transplanted in animals); 4T1=breast cancer (syngeneic model – tumour derived from same strain animals).

Financials

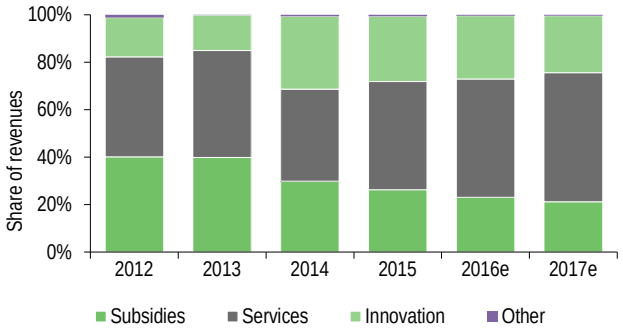
Selvita has demonstrated excellent growth, with 2015 being a second profitable year and total sales reaching PLN56.1m, up 35% year-on-year. Total sales growth corresponded to a CAGR of 51% since 2012 and we expect double-digit total revenue growth to continue (19% and 12% in 2016 and 2017 respectively). Exhibits 2 and 3 below demonstrate the revenue growth projections and change in revenue mix; notably, other operating revenues are immaterial. Strong organic sales growth in FY15 translated into increasing profitability with core operating profit of PLN6.8m up 29% and profit after tax of PLN7.7m up 31% year-on-year (adjusted for employee stock options programme expense and impact of deferred tax asset changes in 2015, Exhibit 5).

Exhibit 3: Annual revenue performance



Source: Edison Investment Research

Exhibit 4: Share of revenue across business units



Source: Edison Investment Research

Selvita's operations are divided into two business segments – Services and Innovation, while revenues from subsidies are allocated to each of these segments.

- In 2015 revenues of PLN25.6m from **Services** to external customers (ie Services segment excluding subsidies) again recorded the strong growth of 59% vs 64% a year ago. This growth was supported by expanding the scope of activities and penetrating new markets.
- Revenues of PLN15.4m from the **Innovation** division (excluding subsidies) were up 21% year-on-year, supported by advanced research agreements with large international pharmaceutical corporations.
- Revenues from **grants and subsidies** totalled to PLN14.7m, up 18% compared to 2014. The growth is primarily related to an expected increase in R&D projects (namely SEL300) and infrastructure grants.

We note positive comparable growth in the backlog as well. Commercial backlog of PLN27.9m in Q116 (excluding grants and subsidies, per Selvita's corporate presentation, March 2016) increased 57% year-on-year. For comparison, the commercial backlog in Q115 was PLN17.7m and 2015 sales to external customers (ie excluding subsidies) came in at PLN41.0m, which translates to 2.3x the backlog at the beginning of the year. Our 2016 commercial sales estimate is PLN51.1m, which is 1.8x the current backlog so represents a conservative estimate, which nevertheless implies double-digit growth expectations for sales to external customers.

Exhibit 5: Changes to estimates

PLNm	2015 Estimate	2015 Actual	% Change	2016e Old	2016e New	% Change	2017e Old	2017e New	% Change
Revenue	55.4	56.1	+1%	64.0	66.8	+5%	72.2	76.4	+6%
EBITDA	10.4	10.2	-2%	9.3	9.2	-1%	11.8	12.8	+8%
EBITDA%	*19%*	*18%*	*-0.6pp*	*14.5%*	*13.8%*	*-0.7pp*	*16.3%*	*16.7%*	*0.4pp*
Operating Profit*	6.8	6.8	+0%	6.0	5.8	-3%	8.5	8.7	+3%
Operating Profit%	*12.2%*	*12.1%*	*-0.1pp*	*9.4%*	*8.7%*	*-0.7pp*	*11.7%*	*11.4%*	*-0.3pp*
Profit Before Tax*	6.8	7.5	+11%	6.0	5.8	-3%	8.5	8.7	+3%
Profit After Tax*	6.7	7.7	+14%	5.9	5.8	-1%	8.2	8.5	+3%
EPS (PLN)*	0.51	0.58	+14%	0.45	0.44	-1%	0.63	0.65	+3%
EPS reported	0.51	0.48	-5%	0.45	0.00	N/A	0.63	0.70	+11%

Source: Edison Investment Research. *Adjusted for employee incentive program expenses in 2015, 2016 and 2017 and positive impact of PLN3.4m for deferred tax asset changes in 2015.

As Exhibit 4 shows 2015 revenues and operating profit were in line with our expectations. We have included a milestone payment of €0.2m from Merck in Q116. Seeing the increase in backlog we have also adjusted our sales expectations upwards in FY16 and FY17, while revising the EBITDA margin slightly downwards in FY16 to reflect the expected expansion of research capacity and hiring of new personnel. However, we expect a partial recovery of EBITDA margin in FY17 to allow for economies of scale. We have also increased our bottom line estimates starting from 2017. Our organic growth expectations are supported by a rapid expansion of Selvita's sales capability. In 2015 the company opened three international sales offices based in Cambridge, UK, San Bruno in San Francisco Bay, US and Boston, US. This will allow for sales activities to be based closer to customers. Selvita will also open a new research facility in Poznan, which will potentially expand its research capacity by 30-100 employees in addition to the existing c 300 at end of December 2015.

As of March 2016 the cash position was PLN32.4m with virtually no debt. Based on this and combined with cash generated from profitable research services business, we believe there is sufficient cash for the internal drug candidates SEL24 and SEL120 to complete Phase I and pre-Phase I studies respectively. For these programmes to progress further, we anticipate additional financing and/or a partnership deal is needed.

Valuation

Applying a standard DCF model for the research services business and a risk-adjusted NPV model for the SEL24 and SEL120 programmes, our valuation of Selvita is now increased to PLN354m (€83m) vs PLN333m (€70m) previously, or PLN27.0/share vs PLN25.4/share. The change is driven by rolling our model forwards, raising our forecasts and adjusting for the net cash position of PLN28.8m at end of December 2015. Note that Selvita had cash of PLN32.4m at end of March 2016 (per the FY15 results announcement) and the company was virtually debt free at end FY15.

We have made some minor adjustments to our rNPV model to reflect our view that a partnership deal for SEL24 in 2016 is less likely (but not impossible). We have postponed our assumed partnership deal to 2017, which implies a delay in development timelines by one year after Phase I (we note that Selvita is on track with its R&D plan for Phase I trial to start in mid-2016). This however, had rather minor impact on the project's rNPV, which now is PLN51m vs PLN54m previously. We have not changed our SEL120 assumptions or those related to collaboration projects (see our last outlook for more details).

For collaboration deals, we have already included two projects to capture the value of the partnership with Merck. As detailed in Exhibit 5, each project has similar characteristics with the total milestone value of €28m each and royalty rates up to 2%. This compares to a €16.5m total milestone value and no royalties in each of the two deals with Merck. Although the value of the announced deals is less than what we currently model, we maintain our assumptions as we take

the two new development agreements as a positive confirmation of Selvita's ability to deliver to large pharma standards. We see further potential for the partnership with Merck to expand especially given the fresh drug discovery collaboration signed in November.

Although we see our combined DCF and risk-adjusted NPV valuation at PLN354m, we note that due to the early stage of the lead R&D projects, success probabilities typically range from 5% to 7.5%. In other words, if all programmes (in Exhibit 6) achieve success, as per our model, the valuation will be PLN911m.

Exhibit 6: Selvita valuation model

Division	Metric	Non risk adj. value (PLNm)	Probability (%)	Risk-adj. value (PLNm)	Value per share (PLN)	Notes
Services/ research collaborations	DCF (2016-21)	77	100%	77	5.90	Services: sliding scale pa growth 25-15% between 2015-2021; research collaborations: +7.0% pa growth; subsidies: +5.0% pa growth; tax = 2%-11% sliding scale (2016-2021); 10% WACC.
	Terminal value	155	100%	155	11.85	0.75% growth on 2021 FCF
	Subtotal	233		233	17.76	
Internal pipeline	SEL24	310	7.5%	51	3.89	$750m indicative peak sales (2029); launch in 2023; 5% royalty (pre-clinical); 7.5% probability of success (pre-clinical). Includes deal milestone estimates: $15m up-front in 2017 (60%); $10m on start of Phase II in 2018 (60%); $20m on start Phase III in 2020 (15%); $40m on NDA filing/approval in 2022 (7.5%). 12.5% WACC. Internal R&D Phase I costs of $5m over 2016/2017.
	SEL120	284	5%	34	2.56	$750m indicative peak sales (2029); launch in 2023; 5% royalty (pre-clinical); 5% probability of success (pre-clinical). Includes deal milestone estimates: $3m upfront in 2017 (60% probability); $5m on IND/Phase I start in 2017 (50%); $15m on start Phase II in 2018 (25%); $20m on start Phase III in 2020 (10%); $40m on NDA filing/approval in 2022 (5%). 12.5% WACC. Internal R&D pre-Phase I costs of $1m in 2016.
	Collaboration	85	5%	8	0.61	Indicative oncology projects to reflect the value of the partnership with Merck KGaA. Assume two projects in Phase I in 2020. Milestones of up to US$31.5m each relate to candidate selection, commencement of phase I, initiation of pivotal trials, launch in major regions and sales thresholds. Royalties on annual sales of 0.5% up to $500m, 1% on $500m-1bn and 2% on sales greater than $1bn+. Probability of 5% to market.
	Subtotal	679		93	7.06	
Net cash				29	2.19	
Selvita total		911		354	27.0	Based on 13.1m shares outstanding.

Source: Edison Investment Research

Exhibit 7: Financial summary

PLN'000s	2013	2014	2015	2016e	2017e
Year end 31 December	IFRS	IFRS	IFRS	IFRS	IFRS
PROFIT & LOSS					
Revenue	21,914	41,557	56,077	66,842	76,441
of which: Services (research outsourcing)	9,812	16,121	25,612	33,296	41,620
Innovation pipeline funding	3,241	12,744	15,416	17,811	18,314
Subsidies	8,688	12,430	14,700	15,435	16,206
Cost of Sales (External services; value of goods sold)	(4,469)	(6,503)	(9,214)	(11,654)	(14,567)
Gross Profit	17,445	35,054	46,862	55,188	61,874
EBITDA	(146)	7,626	10,235	9,236	12,769
Operating Profit (before GW and except.)	(2,228)	5,272	6,802	5,798	8,706
Intangible Amortisation	0	0	0	0	0
Exceptionals/Other	0	0	(4,729)	(5,860)	(583)
Operating Profit	(2,228)	5,272	2,073	(62)	8,123
Net Interest	(198)	155	748	14	10
Exceptionals/Other	0	0	0	0	0
Profit Before Tax (norm)	(2,427)	5,427	7,550	5,812	8,716
Profit Before Tax (reported)	(2,427)	5,427	2,821	(48)	8,134
Tax	0	(45)	(5)	1	(244)
Deferred tax	0	468	3,417	0	0
Profit After Tax (norm)	(2,427)	5,850	10,962	5,813	8,472
Profit After Tax (reported)	(2,427)	5,850	6,233	(47)	7,890
Average Number of Shares Outstanding (m)	10.5	10.5	13.1	13.1	13.1
EPS - normalised (PLN)	(0.23)	0.56	0.84	0.44	0.65
EPS – reported (PLN)	(0.23)	0.56	0.48	(0.00)	0.60
Dividend per share (PLN)	0.0	0.0	0.0	0.0	0.0
BALANCE SHEET					
Fixed Assets	7,067	9,494	16,718	18,279	17,716
Intangible Assets	282	331	2,274	2,274	2,274
Tangible Assets	4,932	6,845	8,597	10,158	9,595
Other	1,854	2,318	5,847	5,847	5,847
Current Assets	11,191	17,310	48,524	40,614	48,284
Stocks	391	706	1,174	1,158	1,142
Debtors	5,161	10,314	17,961	17,961	17,961
Cash	5,418	4,878	28,807	20,912	28,597
Other	221	1,411	582	583	583
Current Liabilities	(11,401)	(15,271)	(16,319)	(16,315)	(16,559)
Creditors	(11,239)	(15,180)	(16,286)	(16,281)	(16,525)
Short term borrowings	(161)	(91)	(33)	(33)	(33)
Long Term Liabilities	(3,454)	(2,278)	(2,043)	(2,043)	(2,043)
Long term borrowings	0	0	0	0	0
Other long term liabilities	(3,454)	(2,278)	(2,043)	(2,043)	(2,043)
Net Assets	3,403	9,254	46,880	40,535	47,398
CASH FLOW					
Operating Cash Flow	(7,198)	(4,902)	(16,430)	(18,324)	(5,021)
Net Interest	0	0	0	0	0
Tax	0	0	0	(4)	0
Capex	(2,167)	(3,610)	(5,190)	(5,000)	(3,500)
Acquisitions/disposals	0	0	0	0	0
Financing	0	0	27,314	0	0
Dividends	0	0	0	0	0
Other (incl. subsidies)	9,567	7,972	18,354	15,435	16,206
Net Cash Flow	202	(540)	24,049	(7,894)	7,686
Opening net debt/(cash)	(5,192)	(5,257)	(4,787)	(28,773)	(20,878)
HP finance leases initiated	0	0	0	0	0
Exchange rate movements	0	0	0	0	0
Other	(137)	71	(63)	(1)	0
Closing net debt/(cash)	(5,257)	(4,787)	(28,773)	(20,878)	(28,564)

Source: Edison Investment Research, Selvita

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