EDISON

Selvita

Q216 results/R&D update

Continuous growth fuels capacity expansion

Pharma & biotech

Selvita delivered strong overall organic growth in Q216, while the mid-year backlog supports our estimated double-digit sales growth in 2016. The company is accelerating its capacity expansion with a new long-term research facility development project. If this goes according to plan, the total number of employees could be boosted by c 1,000 from the current 368 over the next 10 years. The progress of lead R&D product SEL24 into Phase I and the formation of Nodthera (Selvita's inflammasome inhibitor technology) were other recent highlights. We value Selvita at PLN376m.

Year end	Revenue (PLNm)	PBT* (PLNm)	EPS* (PLN)	DPS (PLN)	P/E (x)	Yield (%)
12/14	41.6	5.4	0.56	0.0	45.0	N/A
12/15	56.1	7.6	0.84	0.0	30.0	N/A
12/16e	66.3	3.6	0.24	0.0	105.0	N/A
12/17e	76.6	5.8	0.42	0.0	60.0	N/A

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

Order book "forecasts" good year

Total Q216 revenues of PLN15.1m were up 11.7% q-o-q (Q216 vs Q116) and 19.6% y-o-y. This was somewhat below our forecast PLN17.2m, mainly because we had expected higher Innovation segment sales (excluding subsidies). The profitability-driving Services segment (also excluding subsidies) delivered 14% growth q-o-q and an impressive 71% y-o-y. The order book as of August 2016 amounted to 84% of our FY16 revenue forecast and points to yet another strong growth year. Selvita is not slowing down its capacity expansion plans. Besides opening a new facility in Poznan in early 2017 and adding 70 new employees in 2016 alone, Selvita announced long-term expansion plans with a greenfield project and space for c 1,000 new employees.

Summer ends with major R&D news

Recently Selvita delivered a couple of major R&D announcements. In August, the FDA accepted the initial new drug application (IND) for SEL24, which can now proceed to Phase I/II in acute myeloid leukaemia (AML) patients; the trial is to start later this year. SEL24 is the first compound to progress to Phase I/II with a dual PIM/FLT3 inhibitor mechanism of action. In July, Selvita and Epidarex Capital announced the formation of Nodthera; its technology centres on NLRP3 inflammasome inhibitors, a first-in-class technology developed internally by Selvita. We consider the mechanism of carving out the asset and funding the research together with specialist investors as innovative, with the potential to speed up the preclinical development of Selvita's portfolio.

Valuation: Upped to PLN376m or PLN28.0/share

While our short-term forecasts are reduced due to increases in our costs estimates in line with the business expansion, our long-term growth expectations remain intact. We increase our success probability for SEL24 from 7.5% to 15%, while keeping other R&D project assumptions unchanged. Including the slightly higher cash position and rolling our model forward in time, we value Selvita at PLN376m or PLN28.0/share, compared to the previous PLN363m or PLN27.0/share.

14 October 2016

Price	**PLN25.2**
Market cap	**PLN338m**

Net cash (PLNm) as of 24 August 2016	30.7
Shares in issue	13.4m
Free float	44%
Code	SLV
Primary exchange	WSE
Secondary exchange	N/A

Share price performance

%	1m	3m	12m
Abs	3.3	17.2	17.2
Rel (local)	3.3	18.3	44.1
52-week high/low		27.01	16.6

Business description

Selvita is a drug discovery services provider based in Poland. It employs c 368 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

EGM	25 October 2016
Q316 results	9 November 2016
SEL24 Phase I start	Q416
SEL120 IND studies start	H216

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Edison profile page

Nodthera and inflammasome research

In July 2016, Selvita and Epidarex Capital announced the formation of a new company, Nodthera, headquartered in Edinburgh, Scotland. Nodthera centres on NLRP3 inflammasome inhibitors, a first-in-class small-molecule technology developed internally by Selvita.

History and current knowledge about inflammasome function

The inflammasome was discovered (and given its name) by a team led by Professor Jurg Tschopp at the University of Lausanne in 2002, when his team identified it as the molecular mechanism behind the activation cascade of interleukin (IL)-1. IL-1 is a family of pro-inflammatory cytokines (a broad term for small proteins responsible for cell signalling) that has been widely implicated in pain, inflammation and autoimmune conditions with several approved drugs targeting IL-1 subtype IL-1beta.[1,2]

There are two immune system types: innate and acquired. Innate is in-born, non-specific ability to defend against infections; acquired immunity is specific to a pathogen and is responsible for a long-lasting effect, eg vaccination. There are several classes of innate immune system receptors, with the two most researched ones being toll-like receptors (TLRs), located on cell membranes; and nucleotide-binding oligomerization domain-like receptors (NLRs) located inside the cells.[3] Both classes recognise microbial infection, which leads to secretion of proinflammatory cytokines like IL-1beta. Inflammasomes (there are several subtypes described) are molecular mechanisms in the middle of this cascade and in some cases can also be stimulated by internal chemical signals without the presence of an infection. This may lead to autoimmune disorders. A unique subtype of inflammasomes – NLRP3 – is able to sense both external and internal signals.

Existing clinical applications targeting IL-1beta

Nodthera's technology is first-in-class, small molecule and targets NLRP3 inflammasome, therefore it is clearly differentiated and acts more upstream than therapies targeting IL-1beta. The first drug to target IL-1beta was anakinra (Kineret), an IL-1beta receptor antagonist, developed by Amgen and approved by the FDA for rheumatoid arthritis in 2001 and later licensed by Swedish Orphan Biovitrum (now Sobi). Inconsistent clinical results, a short half-life requiring daily dosing and painful subcutaneous injections discouraged practitioners from using it. Currently the drug is also approved for cryopyrin-associated autoinflammatory syndrome (CAPS), a very rare condition characterised by a number of inflammatory responses such as fevers, rash, joint pain, headaches, conjunctivitis and many other symptoms. Kineret peak sales flat-lined in 2008-11 at around $60m, increasing to $96m following the approval of an additional indication in 2015 (EvaluatePharma).

Several other IL-1beta targeted therapies aim to address issues related to anakinra, with the marketed ones being rilonacept and canakinumab, and there are other projects at different stages of R&D. Canakinumab (Ilaris, Novartis) is a neutralising humanised monoclonal antibody originally approved in 2009 for CAPS, with the label now expanded to acute attacks in gouty arthritis and systemic juvenile idiopathic arthritis. Peak sales reached $236m in 2015. Rilonacept (Arcalyst,

1 F. Martinon et al. The Inflammasome: A Molecular Platform Triggering Activation of Inflammatory Caspases and Processing of proIL-beta. Molecular Cell, Vol. 10, 417–426, August, 2002.

2 M. Dagenai et al. The inflammasome: in memory of Dr. Jurg Tschopp. Cell Death and Differentiation (2012) 19, 5–12.

3 H. Hoffman and A. Wanderer. Inflammasome and IL-1β-Mediated Disorders. Curr Allergy Asthma Rep (2010) 10:229–235.

Regeneron Pharmaceuticals) is a decoy IL-1beta receptor and was first approved for CAPS in 2008, with sales reaching $14m in 2015 (EvaluatePharma).

Potential therapeutic areas for targeting inflammasomes

Inflammasomes can either cause the inflammation or aggravate the underlying condition. Besides CAPS there are several other rare conditions that have been explored as potential targets for targeted inflammasome and IL-1beta therapies, such as familial Mediterranean fever, pyogenic sterile arthritis, hyperimmunoglobulinemia D syndrome and TNF receptor-associated syndrome.[4] However, these conditions are rare to extremely rare, and therefore more of a subject of academic research. Industry funded research is focused on more prevalent diseases, including neurodegenerative diseases (multiple sclerosis, Alzheimer's disease and Parkinson's disease) and metabolic disorders (atherosclerosis, type 2 diabetes and obesity).[5] Although neurologic and metabolic disorders are not traditionally considered to be inflammatory, the contribution of the inflammatory component is increasingly being recognised.[5]

Next steps

While Nodthera's technology is still in an early preclinical stage with few details released, the inflammasome's role in immune system response and its modulation is attracting private funding, with Inflazome and IFM Therapeutics being recent examples. In September 2016, Dublin-based Inflazome closed a Series A funding round with €15m in new capital co-led by Novartis Venture Funds and Fountain Healthcare Partners. The company is developing small molecule inhibitors of the inflammasome. IFM Therapeutics finalised a Series A financing round with $27m co-led by Atlas Ventures and Abingworth in June 2016. The company is developing inflammasome modulators for cancer and inflammatory diseases. Notably, IFM was seeded with just $2m in October 2015.

We consider this approach, to carve out the asset and fund the research together with specialist investors such as Epidarex, as innovative, with the potential to speed up the preclinical development in Selvita's portfolio. Potentially we could see more asset financing solutions like Nodthera. For the time being we do not include this asset in our valuation due to its early stage and the lack of development details, eg indications. However, as the R&D progresses, we will revisit Nodthera.

Financials

Q216 performance: Near-term cost hit

Total Q216 revenues of PLN15.1m grew 11.7% quarter-on-quarter (Q216 vs Q116) and 19.6% year-on-year and came in somewhat below our forecast of PLN17.2m. Excluding subsidies and other revenues, this corresponded to a contraction of 1.0% quarter-on-quarter, and growth of 27.5% year-on-year. The main reason for the flattish quarter-on-quarter performance was lower sales from the Innovation segment (to external clients and excluding subsidies), with Q216 revenues of PLN2.6m versus PLN3.9m in Q116 (Exhibit 1). Notably, the Innovation segment (R&D activities) includes revenues in the form of milestones payments from drug discovery partnerships, which tend to be volatile from quarter to quarter. Since this segment includes advanced research agreements with large international pharmaceutical corporations offering potentially higher margins, it is a long-term focus for Selvita.

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[4] L. Campbell. The Relationship between NALP3 and Autoinflammatory Syndromes. Int. J. Mol. Sci. 2016, 17, 725.

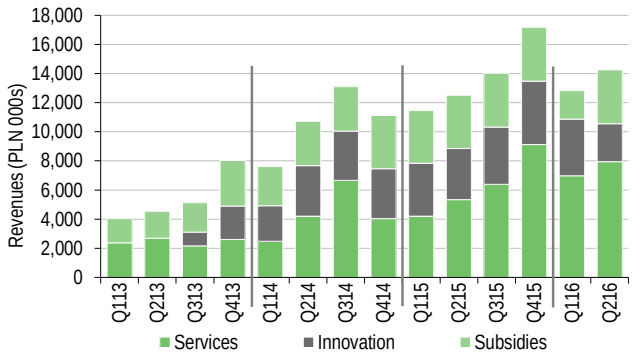
[5] H. Guo. Inflammasomes: mechanism of action, role in disease, and therapeutics. Nature Medicine 21, 677–687 (2015).

The profitability- driving Services segment (excluding subsidies) on the other hand delivered growth of 14% quarter-on-quarter and an impressive 71% year-on-year. The newly established bioinformatics segment (Ardigen spin-out in October 2015, which Selvita consolidates, see our previous reports) recorded H116 external sales of PLN1.25m in its first full six-months of operations.

Group subsidies, which are reported as a part of Innovation or Services segments, were PLN3.7m, flat year-on-year, but up 88.4% quarter-on-quarter as subsidies in Q116 were exceptionally low compared to 2015, as Selvita switched EU Financial Frameworks (completed significant R&D projects in 2015 and started new ones in 2016). Selvita so far has been very successful in obtaining subsidized funding for its innovative projects and we expect that this should continue in the near term.

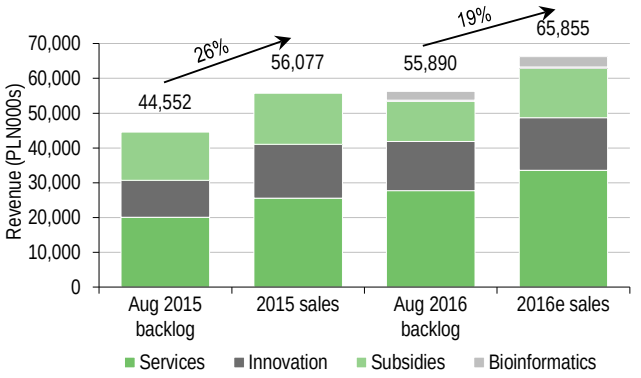
Total Q216 operating expenses of PLN16.8m included a non-cash cost of PLN899k (PLN4.0m in H116 so far) related to the employee stock options programme (ESOP). Adjusted for this, operating loss was PLN792k versus operating profit of PLN581k in Q116 and PLN1.9m in Q215, mainly reflecting increased internal R&D spend and the capacity expansion, including new personnel hires as well as the opening of new facilities and international sales offices. For example the total number of employees increased from 264 in August 2015 to 368 in August 2016.

Exhibit 1: Quarterly revenue performance



Source: Edison Investment Research, Selvita

Exhibit 2: Mid-year backlog vs year-end sales



Source: Edison Investment Research, Selvita

Order book "forecasts" good 2016

The commercial backlog (Exhibit 2) as of August was PLN55.9m for 2016, a 25% increase compared to the same period last year. The reported order backlog amounts to 84% of our FY16 revenue forecast. Notably, actual 2015 sales ended up 26% higher than the mid-year's backlog, while our 2016 sales estimate is 19% higher than the mid-year backlog. We believe the attractive organic sales growth will be further underpinned by the rapid expansion of Selvita's capacity.

New chapter in Selvita's story

Selvita is not slowing down with its capacity increase. In February 2016, the company initiated an expansion to a new location in Poznan with employee numbers increasing by 70 to 368 in 2016 alone. On 21 September 2016, Selvita announced a new laboratory infrastructure development to be located close to the current Selvita facilities in Krakow, with the works estimated to be completed in 2019. The plan includes a newly built laboratory and office complex with a total area of 150,000 sq ft and space available for c 1,000 employees. To finance the project Selvita will use a mix of cash, bank financing, tax incentives (the property will be located in a special economic zone) and public grants. The purchase price for the land is PLN7.5m, while the total costs of the development project are being refined. The final decision on the investment will be made during the extraordinary general meeting on 25 October. Subject to it being approved, we will revise our model to reflect the

new capex requirement, as well as future growth rates given the additional capacity. Notably, Selvita has also signed a separate agreement with the Ministry of Development, which will provide a grant of PLN9.0m for the expansion of Selvita's current research facilities with the total value of the project PLN19.9m. This will add to the company's R&D capacity.

Meanwhile, we have made several revisions to our estimates (Exhibit 3). Q216 Services sales (excl. subsidies) were spot on our estimate; we therefore leave it virtually unchanged. We have cut our expected 2016 and 2017 Innovation revenues and also slightly reduce the Subsidies figure, but slightly increase sales from the Bioinformatics segments. The net effect on our 2016 revenue forecast is negligible. The main effect on our profit estimates was from our revision of operating costs reflecting the company's expansion. Total operating expenses were PLN12.9m in Q116 (excluding ESOP) versus PLN15.9m in Q216. We increase our total 2016 opex estimate from PLN55.5m to PLN58.2m, which results in a reduction to our 2016 operating profit forecast from PLN5.8m to PLN2.6m.

Exhibit 3: Changes to estimates

PLN000s	2015 Actual	2016e Old	2016e New	% change	2017e Old	2017e New	% change
Revenue	56,077	66,862	66,252	-1%	76,456	76,571	+0%
EBITDA	10,235	9,262	5,939	-36%	12,792	9,922	-22%
EBITDA (%)	*18%*	13.9%	*9.0%*	*-4.9pp*	16.7%	*13.0%*	*-3.7pp*
Operating Profit*	6,802	5,823	2,560	-56%	8,729	5,835	-33%
Operating Profit (%)	*12.1%*	8.7%	*3.9%*	*-4.8pp*	11.4%	*7.6%*	*-3.8pp*
Profit Before Tax*	7,550	5,838	3,618	-38%	8,739	5,845	-33%
Profit After Tax*	7,550	5,838	3,530	-39%	8,495	5,687	-33%
EPS (PLN)*	0.58	0.44	0.24	-40%	0.63	0.42	-35%

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

As of August 2016 the cash position was PLN30.7m with virtually no debt. Based on this and combined with the 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 thereafter we anticipate additional financing and/or a partnership deal will be needed.

Valuation

While we are reducing our short-term profitability forecasts to reflect increased costs, our long-term growth expectations remain intact. In line with the progress of SEL24 to the Phase I/II stage, we increase our success probability from 7.5% to 15%, while keeping other R&D assumptions unchanged. Applying this and including a slightly higher cash position together with rolling our model forward in time, we calculate Selvita's valuation at PLN376m or PLN28.0/share, compared to PLN363m or PLN27.0/share previously. Although our combined DCF and risk-adjusted NPV valuation is PLN376m, we note that due to the early stage of the lead R&D projects, the success probabilities typically range from 5% to 15%. In other words, if all programmes (in Exhibit 4) are a success, as per our model, the valuation would be PLN963m.

Exhibit 4: Selvita valuation model

Division	Metric	Non risk adj. value (PLNm)	Probability (%)	Risk-adj. value (PLNm)	Value per share (PLN)	Notes
Services/ research collaborations	DCF (Q216-2021)	73	100%	73	5.44	Services: sliding scale pa growth from 25% in 2016 to 15% in 2021; research collaborations: +7.0% pa growth; subsidies: +5.0% pa growth; tax = 2-11% sliding scale (2016-21); 10% WACC.
	Terminal value	160.1	100%	160.1	11.91	0.75% growth on 2021 FCF
	Subtotal	233.2		233.2	17.35	
Internal pipeline	SEL24	318.9	15%	69.1	5.14	$750m indicative peak sales (2029); launch in 2023; 5% royalty (pre-clinical); 15% probability of success (pre-clinical). Includes deal milestone estimates: $15m upfront 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	292.8	5%	34.6	2.58	$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.
	Collaborations	87.0	5%	8.2	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 $31.5m each relate to candidate selection, start 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	698.7		111.9	8.33	
Net cash		30.7		30.7	2.28	
Selvita total		962.6		375.8	28.0	Based on 13.4m shares outstanding.

Source: Edison Investment Research

Exhibit 5: Financial summary

PLN000s	2013	2014	2015	2016e	2017e
Year end 31 December	IFRS	IFRS	IFRS	IFRS	IFRS
PROFIT & LOSS					
Revenue	21,914	41,557	56,077	66,252	76,571
of which: Services (research outsourcing)	9,812	16,121	25,612	33,605	42,006
Innovation pipeline funding	3,241	12,744	15,416	15,127	16,338
Subsidies	8,688	12,430	14,700	14,154	14,861
EBITDA	(146)	7,626	10,235	5,939	9,922
Operating Profit (before GW and except.)	(2,228)	5,272	6,802	2,560	5,835
Intangible Amortisation	0	0	0	0	0
Exceptionals/Other	0	0	(4,729)	(5,860)*	(583)*
Operating Profit	(2,228)	5,272	2,073	(3,300)	5,252
Net Interest	(198)	155	748	1,059	10
Exceptionals/Other	0	0	0	0	0
Profit Before Tax (norm)	(2,427)	5,427	7,550	3,618	5,845
Profit Before Tax (reported)	(2,427)	5,427	2,821	(2,242)	5,262
Tax	(19)	(45)	(5)	(88)	(158)
Deferred tax	0	468	3,417	0	0
Profit After Tax (norm)	(2,445)	5,850	10,962	3,530	5,687
Profit After Tax (reported)	(2,445)	5,850	6,233	(2,330)	5,104
Average Number of Shares Outstanding (m)	10.5	10.5	13.1	13.3	13.4
EPS - normalised (PLN)	(0.23)	0.56	0.84	0.24	0.42
EPS - reported (PLN)	(0.23)	0.56	0.48	(0.21)	0.38
Dividend per share (PLN)	0.0	0.0	0.0	0.0	0.0
BALANCE SHEET					
Fixed Assets	7,067	9,494	16,718	18,338	17,751
Intangible Assets	282	331	2,274	2,274	2,274
Tangible Assets	4,932	6,845	8,597	10,217	9,630
Other	1,854	2,318	5,847	5,847	5,847
Current Assets	11,191	17,310	48,524	40,037	44,771
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	20,336	25,086
Other	221	1,411	582	582	582
Current Liabilities	(11,401)	(15,271)	(16,319)	(18,080)	(18,150)
Creditors	(3,481)	(6,055)	(3,927)	(5,604)	(5,604)
Provisions	(2,104)	(2,801)	(3,327)	(3,327)	(3,327)
Deferred revenues	(5,455)	(4,617)	(7,384)	(7,384)	(7,384)
Short term borrowings	(161)	(91)	(33)	(33)	(33)
Other	(200)	(1,708)	(1,648)	(1,731)	(1,801)
Long Term Liabilities	(3,454)	(2,278)	(2,043)	(2,043)	(2,043)
Long term borrowings	0	0	0	0	0
Deferred revenues	(3,222)	(2,010)	(1,513)	(1,513)	(1,513)
Other long term liabilities	(232)	(268)	(529)	(529)	(529)
Net Assets	3,403	9,254	46,880	38,253	42,330
CASH FLOW					
Operating Cash Flow	(7,198)	(4,902)	(16,430)	(17,619)	(6,523)
Net Interest	0	0	0	0	0
Tax	0	0	0	(4)	(88)
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	14,154	14,861
Net Cash Flow	202	(540)	24,049	(8,470)	4,750
Opening net debt/(cash)	(5,192)	(5,257)	(4,787)	(28,773)	(20,302)
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)	(20,302)	(25,052)

Source: Edison Investment Research, Selvita accounts. Note: *Non-cash cost related to the employee stock options programme.

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