EDISON

Selvita

Clinical hold lifted

Phase I/II with SEL24 to continue

Pharma & biotech

On 16 December 2017, Selvita announced that the FDA had lifted the clinical hold on the Phase I/II clinical trial with the company's lead drug candidate SEL24 (dual PIM/FLT3 kinase inhibitor) for refractory/relapsed acute myeloid leukaemia (r/r AML). The asset is now out-licensed to Menarini Group, therefore the two companies worked together with the FDA to resolve the issues. The trial can now be restarted with some modifications to the design. While only few details have been disclosed, Selvita mentioned that the dose-finding scheme will be revised to the usual "3+3" design and the trial will resume.

Year end	Revenue (PLNm)	PBT* (PLNm)	EPS* (PLN)	DPS (PLN)	P/E (x)	Yield (%)
12/15	56.1	7.5	0.84	0.0	N/M	N/A
12/16	66.7	4.6	0.64	0.0	N/M	N/A
12/17e	106.0	11.4	0.81	0.0	N/M	N/A
12/18e	99.2	0.3	0.02	0.0	N/M	N/A

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

Modification to dose escalation Part 1

As a reminder, the clinical hold was announced on 7 October 2017 after a fatal venous haemorrhagic stroke post thrombosis in one patient enrolled in the cohort 5 in Part 1 of the study. The stroke was classified as possibly related to the study treatment, which prompted the FDA to issue the clinical hold. The fatal stroke was associated with the treatment mainly because of the timing (the patient received four doses of SEL24); however, to actually prove it or disprove it is not straightforward, in our view, as AML patients already can have thrombosis risk factors. According to the original clinical trial design, the dose-finding Part 1 of the study had an accelerated dose escalation design, which will now be switched to the more comprehensive standard "3+3", and restarted with a lower dose. According to Selvita, this could delay the study by around six months, which in oncology R&D is not very substantial, in our view. As previously stated, Menarini should take over the development as the study resumes. The study is expected to be completed by around end-2018.

Valuation: Upped to PLN1.09bn or PLN79.1/share

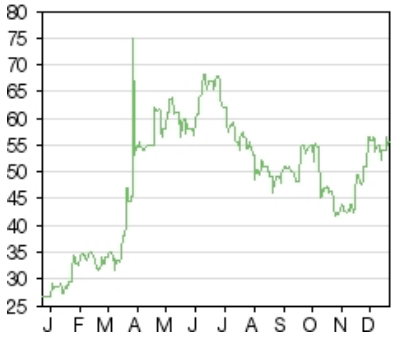
In our previous report we decreased the probability of success for SEL24 from 15% to 7.5% to reflect the uncertainty related to the clinical hold. We now increase it back to 15% and raise our valuation to PLN1.09bn or PLN79.1/share, from PLN1.04bn or PLN75/share. As a next step, Selvita should update on its fund-raise plans to fund the R&D expansion over 2018-21. This was introduced by the company in August 2017, but was put on hold due to the Phase I/II issues. Our forecasts and other valuation assumptions remain unchanged.

21 December 2017

Price	**PLN55.50**
Market cap	**PLN764m**

Net cash (PLNm) at end-Q317	32.0
Shares in issue	13.8m
Free float	45%
Code	SLV
Primary exchange	WSE
Secondary exchange	N/A

Share price performance



%	1m	3m	12m
Abs	16.0	1.0	111.8
Rel (local)	16.5	2.6	67.1
52-week high/low	PLN75.0		PLN26.5

Business description

Selvita is an R&D and drug discovery services company. It operates two main business units: Innovations Platform (internal R&D pipeline) and Research Services (medicinal chemistry/biology, biochemistry).

Next events

Update on fund-raise plans	Q117
SEL120 Phase I study start	H218
Data from preclinical projects	2018

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Exhibit 1: Financial summary

PLN000s	2015	2016	2017e	2018e
Year end 31 December	IFRS	IFRS	IFRS	IFRS
PROFIT & LOSS				
Revenue	56,077	66,721	105,994	99,167
of which: Services (research outsourcing)	23,052	32,404	43,746	54,682
Innovation platform	15,416	18,353	38,638	20,189
Subsidies	14,700	12,067	16,290	16,290
Bioinformatics	2,561	3,431	6,855	7,541
EBITDA	10,235	8,264	17,915	5,770
Operating Profit (before amort. and except.)	6,802	4,646	13,212	1,067
Intangible Amortisation	0	0	0	0
Exceptionals/Other*	(4,729)	(5,860)	(583)	0
Operating Profit	2,073	(1,214)	12,629	1,067
Net Interest	748	947	(1,050)	20
Share in profit/(loss) of associates and JVs**	0	(1,016)	(808)	(808)
Other	0	0	0	0
Profit Before Tax (norm)	7,540	4,577	11,354	279
Profit Before Tax (reported)	2,821	(1,283)	10,771	279
Tax	(5)	0	(323)	(14)
Deferred tax	3,417	3,968	0	0
Profit After Tax (norm)	10,952	8,545	11,031	265
Profit After Tax (reported)	6,233	2,685	10,448	265
Average Number of Shares Outstanding (m)	13.1	13.4	13.6	13.6
EPS - normalised (gr)	83.58	64.22	81.31	1.96
EPS - reported (gr)	47.52	20.36	77.02	1.96
Dividend per share (gr)	0.0	0.0	0.0	0.0
BALANCE SHEET				
Fixed Assets	16,718	41,451	46,543	85,140
Intangible Assets	2,274	6,640	435	435
Tangible Assets	8,597	21,833	33,130	71,727
Other	5,847	12,979	12,979	12,979
Current Assets	48,524	47,669	60,692	49,882
Stocks	1,174	1,403	1,384	1,365
Debtors	17,961	16,320	16,320	16,320
Cash	28,807	29,095	40,688	29,897
Other	582	851	2,300	2,300
Current Liabilities	(16,319)	(18,933)	(23,665)	(23,355)
Creditors	(3,927)	(7,883)	(9,400)	(9,400)
Provisions	(3,327)	(3,600)	(6,650)	(6,650)
Deferred revenues	(7,384)	(5,469)	(5,069)	(5,069)
Short term borrowings	(33)	(859)	(950)	(950)
Other	(1,648)	(1,122)	(1,595)	(1,286)
Long Term Liabilities	(2,043)	(14,477)	(13,728)	(38,728)
Long term borrowings	0	(4,792)	(4,200)	(29,200)
Deferred revenues	(1,513)	(6,382)	(6,700)	(6,700)
Other long term liabilities	(529)	(3,303)	(2,828)	(2,828)
Net Assets	46,880	55,710	69,843	72,939
CASH FLOW				
Operating Cash Flow	(16,430)	(6,280)	12,176	(8,459)
Net Interest	0	0	0	0
Tax	0	0	0	(323)
Capex	(5,190)	(21,210)	(16,000)	(43,300)
Acquisitions/disposals	0	0	0	0
Financing	27,314	303	328	0
Dividends	0	0	0	0
Other (incl. subsidies)	18,354	21,859	15,590	16,290
Net Cash Flow	24,049	(5,329)	12,094	(35,791)
Opening net debt/(cash)	(4,787)	(28,773)	(23,445)	(35,538)
HP finance leases initiated	0	0	0	0
Exchange rate movements	0	0	0	0
Other	(63)	1	(1)	0
Closing net debt/(cash)	(28,773)	(23,445)	(35,538)	253

Source: Selvita accounts, Edison Investment Research. Note: *Non-cash cost related to the employee stock options programme. **Profit and loss from 2016 include share in Nodthera's earnings according to an equity method valuation. Please note that the share changed in 2017 as a result of Nodthera's capital increase.

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