Morning Note – 18th July 2024

SPINEGUARD 510K filing for a new medical device (US future approval) France - Medtech Buy

- DSG's first "non-spinal" usage
- A real business opportunity
- A future contribution to the growth scenario

First extension of the scope of use of DSG technology

SpineGuard announced last night that it had filed for US registration (510K regulatory pathway) of a new device designed to assist posterior sacroiliac joint fusion surgery (PsiF). This device, called PsifGuard, is an addition to the PediGuard range, which until now has been dedicated to assisting with the placement of pedicle screws implanted in arthrodesis procedures (fusion of weakened vertebral stages or requiring long-term alignment correction). PsifGuard takes the form of a needle fitted with a connected handle,

PsifGuard takes the form of a needle fitted with a connected handle, enabling the surgeon to differentiate between bone tissue and joint cartilage, and to check the correct positioning of implants placed to promote fusion of the two bony zones (sacrum and ilium). This device enables SpineGuard and its American partner Omnia Medical to extend the scope of application of DSG technology beyond the *spine sensu stricto*.

Osteoarthritis of the sacroiliac joint: a widespread problem

The pelvis withstands considerable pressure and force. It's hardly surprising, then, that the joint connecting the sacrum and the ilium wears out over time. The pain induced is intense and frequently localized in the buttock. They are often incapacitating. To accurately diagnose this joint damage, a test infiltration of local anaesthetic is performed under X-ray or CT scan control. According to various studies, 10% to 15% of low-back pain is caused by osteoarthritis of the sacroiliac joint. Bone fusion is the most effective treatment option. This approach does not call into question the patient's subsequent mobility. This joint has no real role in flexion or other relative movement of the bones involved. The procedure does, however, require optimal placement of the implants, so that they do not rest on the cartilage. The new PsifGuard device ensures optimal implant insertion, while also limiting X-ray exposure time during the procedure. SpineGuard and Omnia Medical offer surgeons a useful solution that should find its place in the operating theatre.

Valuation and rating

The filing of this dossier was eagerly awaited. FDA review time is expected to be around 6 months. PsifGuard should be launched in the United States in mid-2025. We have anticipated this contribution in our recently adjusted model. This announcement therefore confirms our scenario, and we reiterate our positive recommendation on the stock.

Next communication: HY results - September 11th

Fair value (EUR) Price (EUR) 0.75 0.1578

+375.3%

Lionel Labourdette, PhD, MBA

lionel@biostrategic-research.com +33 617 965 019

Stock data (2024-07-17)

Upside/down side

ISIN	FR0011464452
Ticker	ALSGD.PA
Price (EUR)	0.1578
Market capitalisation (EURm)	8.5
Free float (%) est.	95.2
Floating capitalisation (EURm)	8.1
Number of shares (,000)	53,501
Average daily volume (3 m)	119,520



Change (%)	1 m	3 m	12m
Absolute	-21.5	-33.7	-73.0
Rel. to CAC SM190	-22.3	-29.7	-70.0
Rel. to Next Biotech	-35.7	-49.4	-63.3

Financials (31/12)

EURm	2023	2024E	2025E	2026E
Sales	4.3	5.4	7.0	8.5
EBITDA	-3.7	-2.6	-1.5	-0.6
EBIT	-4.0	-2.9	-1.8	-1.0
Net income	-4.2	-3.2	-2.0	-1.1
EPS (EUR)	-0.08	-0.06	-0.03	-0.02
Net debt	-0.8	0.4	1.2	0.8

Key ratios

,				
	2023	2024E	2025E	2026E
EV/Sales	2.0X	2.3X	1.9X	1.5X
EV/EBITDA	na	na	na	na
EV/EBIT	na	na	na	na
PER	na	na	na	na
ROIC	na	na	na	na
ROE	na	na	na	na
EV/IC	1.7X	2.3X	2.5X	2.4X
Gearing	-13%	7%	31%	19%





Profit and Loss

As of 31/12 (EURm)	2019	2020	2021	2022	2023	2024E	2025E	2026E
Sales	6.83	4.85	4.41	5.60	4.31	5-39	6.99	8.49
Change n-1	-9.9%	-29.0%	-9.2%	27.1%	-23.0%	25.1%	29.6%	21.3%
Other revenues	-	-	-	-	-	-	-	-
Total revenues	6.83	4.85	4.41	5.60	4.31	5-39	6.99	8.49
Gross margin	5.77	4.04	3.61	4.71	3.38	4.37	5.85	7.19
EBITDA	-0.14	-1.49	-1.04	-1.37	-3.68	-2.56	-1.45	-0.59
Change n-1	84%	-993%	30%	-31%	-169%	31%	43%	59%
Depreciation & amortisation	0.30	0.35	0.31	0.43	0.16	0.25	0.25	0.26
Goodwill	-	-	-	-	-	-	-	-
EBIT	-0.43	-1.84	-1.35	-1.66	-3.98	-2.93	-1.83	-0.98
Change n-1	61%	-326%	27%	-23%	-139%	26%	37%	46%
Net financial income	-0.64	-0.84	-0.30	-0.43	-0.23	-0.20	-0.13	-0.06
Minorities	_	_	_	_	_	_	_	_
Other	-	-	-	-	-	-	-	-
Net profit before tax	-1.07	-2.68	-1.65	-2.09	-4.20	-3.14	-1.96	-1.05
Tax	0.39	-0.04	-0.08	-0.30	0.02	-0.07	-0.07	-0.07
Net in come	-0.69	-2.72	-1.72	-2.39	-4.18	-3.21	-2.03	-1.12
Change n-1	71%	-296%	37%	-39%	-75%	23%	37%	45%
EPS	-0.05	-0.12	-0.06	-0.07	-0.09	-0.06	-0.03	-0.02
EPS fully diluted	-0.05	-0.10	-0.05	-0.07	-0.08	-0.06	-0.03	-0.02
Gross margin (% of sales)	84.5%	83.2%	81.9%	84.2%	78.3%	81.0%	83.6%	84.8%
EBITDA (% of sales)	na	na	na	na	na	na	na	na
EBIT (% of sales)	na	na	na	na	na	na	na	na
Net margin (% of sales)	na	na	na	na	na	na	na	na

Cash Flow statement

Au 31/12 (MEUR)	2019	2020	2021	2022	2023	2024E	2025E	2026E
Net income	-0.69	-2.72	-1.72	-2.39	-4.18	-3.21	-2.03	-1.12
Depreciation and amortisation	0.30	0.35	0.31	0.43	0.16	0.25	0.25	0.26
Goodwill	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
Change in WCR	0.27	0.64	-0.09	-0.51	-0.10	-0.48	-0.28	-0.32
Others	0.71	1.04	0.35	1.07	0.51	0.43	0.36	0.29
Cash-flow from operations	0.60	-0.68	-1.16	-1.40	-3.62	-3.01	-1.70	-0.89
Capex	-0.08	-0.05	-0.04	-0.14	-0.07	-0.08	-0.08	-0.08
Free cash flow	0.52	-0.73	-1.19	-1.54	-3.69	-3.09	-1.78	-0.97
Acquisitions	-	-	-	-	-	-	-	-
Divestments	-	-	-	-	-	-	-	-
Dividends	-	-	-	-	-	-	-	-
Capital increase	1.75	1.75	6.51	1.20	4.77	1.50	1.00	1.00
Financing (bank and others)	0.22	0.00	-	-	-	-	-	-
Others	-1.54	-0.99	-0.91	-1.09	-1.09	-0.65	-0.61	-0.08
Change in cash over the period	0.96	0.03	4.41	-1.44	-0.01	-2.24	-1.40	-0.04
Opening cash position	1.16	2.12	2.15	6.56	5.12	5.11	2.87	1.48
Closing cash position	2.12	2.15	6.56	5.12	5.11	2.87	1.48	1.43





Balance sheet

Au 31/12 (MEUR)	2019	2020	2021	2022	2023	2024E	2025E	2026E
Fixed assets	0.63	0.50	0.37	0.28	0.23	0.14	0.05	-0.05
Intangible assets	0.72	0.69	0.89	1.27	1.24	1.03	0.82	0.61
Goodwill	3.08	3.08	3.08	3.08	3.08	3.08	3.08	3.08
Financial assets	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
Inventories	0.66	0.66	0.68	0.87	0.95	0.84	1.09	1.32
Account receivables	0.95	0.71	0.62	1.10	0.75	1.06	1.37	1.66
Other receivables	0.55	0.67	0.57	0.63	0.73	0.56	0.70	0.91
Cash and cash equivalents	1.40	1.22	5.21	4.12	3.89	1.65	0.26	0.21
Prepaid expenses	-	-	-	-	-	-	-	-
Other non-current assets	0.50	0.51	0.48	0.17	0.17	0.17	0.17	0.17
Total assets	8.50	8.06	11.90	11.50	11.04	8.53	7.54	7.92
Equity	0.59	-0.01	5.06	5.14	6.03	4.92	3.93	4.24
Others	-	-	-	-	-	-	-	-
Provisions	0.05	0.05	0.05	0.18	0.03	0.16	0.29	0.42
Financial debt	6.08	5.64	4.47	3.83	3.09	2.02	1.47	1.00
Account payables	1.04	1.34	1.00	1.14	1.21	0.68	0.89	1.08
Other debts	0.62	0.88	1.00	1.00	0.67	0.75	0.97	1.19
Deferred income and other liabilities	0.11	0.15	0.32	0.21	-	-	-	-
Total liabilities	8.50	8.06	11.90	11.50	11.04	8.53	7-54	7.92





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Swiss Life Banque Privée

Société Anonyme au capital de 37.092.080 €
Code établissement bancaire n°11 238
RCS Paris 382 490 001
7. place Vendôme - F75041 Paris Cedex 01 – France
Tél.: +33 1 53 29 14 14

BioStrategic Partners SAS

Société par Actions Simplifiée au capital de 30. 000 €

RCS Paris 530 430 487

140 bis. rue de Rennes - F 75006 Paris – France

Tél.: +33 6 17 96 50 19

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