

Allium Medical Solutions

Business update

Business progressing on multiple fronts

Allium Medical has made significant progress across business lines. The safety monitoring board has recommended continuing the study of Gardia's embolic protection device; clinical data will be reported by end Q317. A clinical trial of its urological stents in the local population will not be necessary for approval in China; this is in line with our expectations. We expect sales to start in 2018 via a NIS58m eight-year distribution agreement. Following positive preclinical data, Allevetix is on track to start a clinical trial by year-end 2017. We forecast revenue CAGR of 41% in 2016-20e and expect the company to break even in 2020. Our valuation is NIS1.95-2.08/share.

Year end	Revenue (NISm)	PBT* (NISm)	EPS* (NIS)	DPS (NIS)	P/E (x)	Yield (%)
12/15	5.2	(18.5)	(0.65)	0.0	N/A	N/A
12/16	7.4	(22.0)	(0.49)	0.0	N/A	N/A
12/17e	11.2	(15.7)	(0.30)	0.0	N/A	N/A
12/18e	17.5	(7.1)	(0.13)	0.0	N/A	N/A

Note: *Normalised, excluding amortisation of acquired intangibles and exceptionals.

Continue trial after positive safety assessment

A Data Safety Monitoring Board (DSMB) has recommended continuation of the study of the Wirion embolic prevention device; clinical data will be reported by end Q317. If data are positive, and FDA approves the product, Wirion will become the only protection system cleared for all atherectomy procedures in the US; at that point, we believe chances to strike a partnership will increase. There is strong interest in the market for atherectomy procedures, as demonstrated by the recent acquisition of Spectranetics Corporation by Philips for a total of €1.9bn.

A step closer to the Chinese and veterinary markets

The Chinese Food and Drug Administration (CFDA) has notified the company of the exemption to conduct a clinical trial in the local population. Therefore, Allium is on track for potential approval by this year's end and launch next year, as we expected. This will start the eight-year collaboration with Allium's distribution partner in China, worth NIS58m. Separately, Allium will enter the veterinary market after signing a global exclusive agreement with the American company Infiniti Medical for distribution of its stents for veterinary use, worth at least NIS1m over five years.

Allevetix and TruLeaf: Expanding the opportunities

The company has increased its rights and participation with the National University of Singapore (NUS) in the Allevetix R&D project from 50% to 100%. Allium has established a new company dedicated to this project with participation of senior management from the NUS and the National Hospital of Singapore. A clinical trial is due to start by end 2017. Additionally, the Israel Innovation Authority has approved a NIS2m non-dilutive grant for TruLeaf, Allium's subsidiary, which is developing a mitral valve replacement device. A trial in large animals is due later this year.

Valuation: DCF of NIS1.95-2.08/share unchanged

We maintain our DCF valuation of NIS1.95-2.08/share. We estimate end-2016 cash of NIS23.2m should be sufficient to fund operations into 2019, at which point further funds will be required depending on growth rates and cost control.

Medical devices

23 July 2017

Price* **NIS1.10**
Market cap **NIS58m**

*Priced at 18 July 2017

	US\$/NIS3.58
Net cash (NISm) at end 2016	23.2
Shares in issue	52.9m
Free float	55%
Code	ALMD
Primary exchange	TASE
Secondary exchange	N/A

Share price performance



%	1m	3m	12m
Abs	(0.7)	(2.4)	(34.2)
Rel (local)	(2.5)	(7.3)	(36.3)
52-week high/low	NIS1.7	NIS1.1	

Business description

Allium Medical Solutions is a company focused on developing and marketing minimally invasive devices in various areas: cardiovascular, metabolic, genitourinary and gastrointestinal. The company has three selling product lines: Allium Stents, IBI (EndoFast) and Gardia Medical. Allium markets its products mainly through distribution agreements.

Next events

H117 financial results	August 2017
Regulatory approval in additional markets for Allium and IBI	H217
TruLeaf study in large animals	H217
Gardia clinical trial data	Q317
Start Allevetix first in man clinical trial	Q417

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[Edison profile page](#)

Business progress

DSMB recommends continuing the Wirion trial

The DSMB overseeing Gardia Medical's Wirion trial has unanimously recommended that the study continues, as no safety concerns have been identified. Gardia Medical, a subsidiary of Allium Medical is conducting a clinical trial of the Wirion embolic protection device to expand the current FDA-approved indication (remove embolic material while performing angioplasty and stenting procedures in carotid arteries) to cover lower extremities. The safety assessment has been conducted in 69 subjects. Clinical data are expected to be available by end Q317. We note that the recent acquisition of Spectranetics Corporation by Philips for a total €1.9bn underscores the interest of large corporations in the space. Spectranetics (FY16 revenues of \$271m; EBIT of -\$44m) has a wide portfolio of products that treat blockage of coronary and peripheral arteries by laser and mechanical means. We believe FDA clearance would increase chances of striking a partnership.

Closer to the Chinese market; new entrant in veterinary market

Allium will submit additional technical and regulatory information to the CFDA in the next few weeks aiming for approval by end 2017. This is in line with our forecast launch in 2018. Furthermore, this will initiate the collaboration with Allium's Chinese partner for distribution of urology products. As we published in our [initiation report](#), the agreement involves the purchase of at least NIS58m worth of stents over a period of eight years. The partner will bear commercialisation and marketing costs. We believe this reinforces Allium's business case, particularly in emerging markets where we forecast sales of c NIS132m over the next five to eight years, out of a total of c NIS185m for its peripheral stents and IBI EndoFast urogynecology products. We expect the group of China, Russia and Mexico to grow from sales of NIS0.2m in 2016 to NIS10.4m at a CAGR of 176% into 2020, and become 46% of total revenue. Furthermore, the company has announced a deal with American veterinary company Infiniti Medical for the global distribution of its stents for multiple clinical indications. The deal is worth at least NIS1m over five years. We look to add this deal to our valuation and forecast on release of half-year results in August 2017.

Allevetix increases participation in joint venture to 100%

Allium is developing Allevetix, a gastroduodenal implant, in a joint venture with the NUS. Allevetix is a minimally invasive alternative to gastric bypass surgery for obese Type 2 diabetic patients. The partners have recently signed a conclusive agreement in which Allium's participation has gone from 50% to 100%, granting Allium all IP and commercialisation rights. Allium has established a new subsidiary in which senior management from NUS and the National Hospital of Singapore (NHS) will receive a 7% equity stake. A clinical trial is planned to start in Q417 and a partner will be sought for commercialisation. We believe this is positive for Allium as it allows it to increase the commercial prospects of Allevetix. Allium has informed the market that Michael Ilan, an existing shareholder which holds c 10% of the company's shares, has invested NIS1m in Allevetix at a pre-money valuation of \$7m with a conversion feature to the company's shares. The market for bariatric surgery devices is expected to grow from \$1.4bn in 2015 to \$2.2bn by 2020, according to [BCC Research 2016](#).

TruLeaf

The Israeli Government has approved a NIS2m non-dilutive grant for TruLeaf for the development of its mitral valve replacement device. For the first year of development the grant was approved with the highest applicable participation ratio of 50%. After meeting the specified milestones, the company will apply for additional grants for this project. TruLeaf's development plan will run for three years and is expected to cost \$5-6m until a successful first-in-human study. Allium will

conduct trials of its mitral valve replacement device in big animals this year. We note that Mike Berman has been appointed as a member of the Board of Directors of TruLeaf. He was a president of Boston Scientific's cardiology division and a member of the company's executive committee. An estimated four million people in the US have significant mitral regurgitation, with an incidence of 250,000 new patients/year.

Exhibit 1: Financial summary

	NIS000	2015	2016	2017e	2018e
Year end 31 December		IFRS	IFRS	IFRS	IFRS
PROFIT & LOSS					
Revenue		5,178	7,353	11,196	17,470
Cost of sales		(4,421)	(5,171)	(7,819)	(10,126)
Gross profit		757	2,182	3,377	7,343
EBITDA		(16,333)	(20,375)	(14,728)	(6,299)
Operating profit (before GW and except.)		(16,759)	(20,757)	(15,349)	(6,858)
Intangible amortisation		(1,705)	(1,579)	(1,436)	(1,293)
Exceptionals		(720)	(297)	0	0
Operating profit		(19,184)	(22,632)	(16,784)	(8,151)
Net interest		(1,748)	(1,284)	(361)	(213)
Exceptionals		0	0	0	0
Other		0	0	0	0
Profit before tax (norm)		(18,507)	(22,041)	(15,709)	(7,070)
Profit before tax (IFRS)		(20,932)	(23,917)	(17,145)	(8,363)
Tax		0	0	0	0
Profit after tax (norm)		(18,507)	(22,041)	(15,709)	(7,070)
Profit after tax (IFRS)		(20,932)	(23,917)	(17,145)	(8,363)
Average number of shares outstanding (m)		28.53	44.97	52.94	52.94
EPS – normalised (NIS)		(0.65)	(0.49)	(0.30)	(0.13)
EPS – IFRS (NIS)		(0.73)	(0.53)	(0.32)	(0.16)
Dividend per share (NIS)		0.00	0.00	0.00	0.00
Gross margin (%)		15%	30%	30%	42%
EBITDA margin (%)		N/A	N/A	N/A	N/A
Operating margin (before GW and except.) (%)		N/A	N/A	N/A	N/A
BALANCE SHEET					
Fixed assets		25,612	23,616	21,660	19,908
Intangible assets		24,059	22,465	21,029	19,736
Tangible assets		1,472	1,025	505	46
Restricted cash		81	126	126	126
Current assets		31,342	28,605	13,163	6,981
Stocks		2,277	2,516	2,527	2,834
Debtors		889	1,253	1,534	1,914
Cash		27,053	23,202	7,469	599
Other		1,123	1,634	1,634	1,634
Current liabilities		(5,620)	(12,660)	(12,507)	(13,037)
Creditors		(1,524)	(1,890)	(1,737)	(2,267)
Accruals		(1,895)	(936)	(936)	(936)
Other short-term liabilities		(2,201)	(4,124)	(4,124)	(4,124)
Long-term liabilities		(6,207)	(1,368)	(1,268)	(1,168)
Long-term borrowings		0	0	0	0
Other long-term liabilities		(6,207)	(1,368)	(1,268)	(1,168)
Net Assets		45,127	38,193	21,048	12,685
CASH FLOW					
Operating cash flow		(15,874)	(17,259)	(15,533)	(6,670)
Net interest		0	0	0	0
Tax		0	0	0	0
Capex		(164)	(220)	(100)	(100)
Acquisitions/disposals		0	0	0	0
Financing		31,992	13,956	0	0
Dividends		0	0	0	0
Other		(1,841)	(328)	(100)	(100)
Net cash flow		14,113	(3,851)	(15,733)	(6,870)
Opening net debt/(cash)		(12,940)	(27,053)	(23,202)	(7,469)
HP finance leases initiated		0	0	0	0
Other		0	0	0	0
Closing net debt/(cash)		(27,053)	(23,202)	(7,469)	(599)

Source: Edison Investment Research, Allium Medical Solutions accounts

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