

# Allium Medical Solutions

## Wirion approved by FDA; new stents in Europe

Allium has announced FDA approval of its subsidiary Gardia's Wirion, which has become the only embolic protection system approved for all atherectomy procedures. Allium has reported FY17 results, with revenues up 5% y-o-y to NIS7.7m, and announced its first order in Mexico for NIS300k and approval of some of its stents in Russia. However, registration of the remaining stents and IBI Medical (EndoFast soft tissue fixation) in Mexico and Russia and stents in China has been delayed; we believe approval is possible in 2018. Mexico, Russia and China are the bulk of the distribution deals (NIS132m) and delays are the major reason for the slight decline in our valuation to NIS1.64/share (NIS1.68/share previously).

Year end	Revenue (NISm)	PBT* (NISm)	EPS* (NIS)	DPS (NIS)	P/E (x)	Yield (%)
12/16	7.4	(22.0)	(0.49)	0.0	N/A	N/A
12/17	7.7	(21.4)	(0.37)	0.0	N/A	N/A
12/18e	14.0	(13.7)	(0.19)	0.0	N/A	N/A
12/19e	21.0	(9.6)	(0.13)	0.0	N/A	N/A

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

## FDA approves Wirion; chances of transaction higher

Gardia Medical's Wirion system has received FDA approval for leg artery catheterisation on the back of strong clinical data from the WISE-LE trial, which met its primary and secondary endpoints at interim analysis. Wirion captured a significant amount of debris in all clinical cases and across all atherectomy devices and is now the only embolic protection system cleared by the FDA for all atherectomy procedures. Allium is looking for a strategic transaction, preferably M&A; we believe the FDA approval could make Gardia more attractive to potential partners. We model Wirion as part of Allium's overall business and valuation and project revenue of NIS2.4m after full launch in 2018, rising to NIS8.6m in 2020 as we adjust our price forecast based on the most recent FY17 data.

## Mexico, Russia and China: Approvals and delays

Allium has received the first order for its urological stent products in Mexico for NIS300k, which was paid upfront in Q417. We now expect EndoFast (soft tissue fixation) and the remaining stents to be approved in Mexico and Russia during H118 vs YE17 before. Allium has also received approval in Russia for its stent products and EndoFast could be approved in 2018, as it could in China after it sent a full package to the Chinese FDA in Q417. We reduce our revenue forecast to c NIS14m in FY18 (from NIS16.6m) to reflect these delays, partially offset by a new deal worth NIS6.3m signed in 15 countries in Central and Eastern Europe.

## Launch of new stents; Allevetix starts clinical trial

Allium has launched two new CE-marked products in Europe: the Triangular Prostate Stent (TPS) Plus which is a new approach to treat benign prostate hyperplasia; and Ureteral Stent (URS) 200, which self-expands to 200mm length and 9mm diameter. Allium has started a clinical trial with the Allevetix indwelling gastroduodenal sleeve in 10 patients with obesity and diabetes for three months; Allium expects to complete the study by the YE and start a pivotal trial in 2019.

## Valuation: DCF of c NIS117m or NIS1.64/share

Our DCF valuation of Allium is NIS1.64/share (vs NIS1.68/share) as a result of updating the launch delays in Mexico, Russia and China and net cash.

FY17 results; business update

Medical devices

26 April 2018

Price\* NIS1.31

Market cap NIS94m

\*Priced at 20 April 2018

Net cash (NISm) at end 2017 22.95

Shares in issue 71.4m

Free float 60%

Code ALMD

Primary exchange TASE

Secondary exchange N/A

### Share price performance



% 1m 3m 12m

Abs 2.2 7.9 15.6

Rel (local) 3.3 9.5 6.4

52-week high/low NIS1.5 NIS0.8

### 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

Potential strategic agreements for Gardia 2018

Regulatory approval in additional markets for Allium and IBI 2018

Complete Allevetix first-in-human trial Q418

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## FY17 results overview and valuation update

Allium reported sales of NIS7.7m in FY17, up 5% vs NIS7.4m in FY16, but lower than our forecast of NIS9.7m. Allium has received the first order for its ureteral stent products in Mexico for NIS300k, fully paid in Q417. We now expect EndoFast (soft tissue fixation) and the remaining stents to be approved in Mexico and Russia during 2018 vs YE17 previously. The distribution deals are worth a total of NIS74m over five years. Separately, Allium has received approval in Russia for its stent products. Next is approval of EndoFast, potentially in 2018 (deal is NIS48m over five years). Approval in China could be possible in 2018; the company sent a full package to the CFDA in Q417 (deal is NIS58m over eight years). Additionally, Allium has been strengthening the distribution network and has replaced the distributor of stents in the Czech Republic and Slovakia and EndoFast with a new deal in 15 Central and Eastern European countries. The deal involves a minimum purchase of NIS6.3m over five years. Therefore, we reduce our near-term revenue forecast to reflect these delays, partially offset by the new commercial agreement to c NIS14m in FY18 (from NIS16.6m) and c NIS21m in FY19 (from NIS24.9m).

We expect R&D expenses to decrease in 2018 (NIS10m in FY18 vs NIS5m previously) due to public grants from the Israeli government. R&D expenses in 2018 are mainly associated with the continued clinical development of Allevetix and the preclinical study with TruLeaf. From 2019 onwards we expect a decrease in R&D expenses as the company completes clinical development of Allevetix. General and administrative expenses were NIS8.5m in FY17 vs NIS8.1m in FY16. This is above our estimate of NIS7.3m and is mainly related to non-cash, stock-based compensation.

EBITDA loss in FY17 was NIS20.8m vs NIS20.4m in FY16. This is slightly higher than our FY17 estimate of NIS19.5m. We forecast an EBITDA loss of NIS13.2m in FY18, from a loss of NIS6.8m previously. Net loss was NIS22.7m vs our forecast of a NIS21.9m loss. We now forecast a net loss of NIS15.2m in FY18 (vs NIS8.8m before). As a consequence of our revised forecast, we now expect Allium to reach EBITDA break-even in 2020, one year later than before.

### Exhibit 1: Key changes to our financial forecasts

NIS000s	FY16		FY17		FY18e		
	Act.	Est.	Act.	Change (%)	Old	New	Change (%)
Revenue	7,353	9,735	7,703	-21%	16,612	13,972	-16%
R&D expenses	(13,494)	(14,000)	(13,914)	-1%	(5,000)	(10,000)	100%
S&M expenses	(2,895)	(2,531)	(2,458)	-3%	(3,322)	(3,493)	5%
G&A expenses	(8,129)	(7,250)	(8,527)	18%	(7,000)	(7,000)	0%
<b>Operating profit/loss</b>	<b>(22,633)</b>	<b>(21,548)</b>	<b>(22,842)</b>	<b>6%</b>	<b>(8,624)</b>	<b>(15,100)</b>	<b>75%</b>
Profit/loss before tax	(23,917)	(21,909)	(22,679)	4%	(8,770)	(15,236)	74%
<b>Profit/loss after tax</b>	<b>(23,917)</b>	<b>(21,909)</b>	<b>(22,679)</b>	<b>4%</b>	<b>(8,770)</b>	<b>(15,236)</b>	<b>74%</b>
EPS (NIS)	(0.53)	(0.38)	(0.39)	3%	(0.12)	(0.21)	75%

Source: Allium Medical accounts, Edison Investment Research.

During 2017 Allium consumed NIS18.9m in cash vs NIS17.5m in FY16. This is lower than our FY17 estimate of NIS20.1m. Over the year, Allium raised total net proceeds of NIS19.1m. We estimate that net cash, cash equivalents and short-term deposits of c NIS23m provide runway until 2019 when we project a cash shortfall that for illustrative purposes we cover with long-term debt of NIS20m. Cash will be spent on the first-in-man study with Allevetix's gastroduodenal sleeve (recently started) and the ongoing animal study with TruLeaf.

## Valuation updated to NIS1.64/share

We were expecting approval of all stent products and EndoFast in Mexico in Q417, in Russia in H118 and approval of stents in China in Q118. For modelling purposes, we have lowered our

forecasts to reflect approval and launch in those countries in H218 instead of the initial dates. We have also updated the new deal in Central and Eastern Europe and distribute NIS6.3m over 2018 to 2023 as the company's distributor has already started selling.

As a result of these changes, our revised DCF valuation of Allium moves to NIS1.64 per share, or NIS117m, from NIS119m or NIS1.68/share, which includes net cash of c NIS23m at end 2017.

**Exhibit 2: Allium summary DCF valuation**

	Previous valuation		Current valuation	
	\$000s	NIS000s	\$000s	NIS000s
PV of explicit FCF forecast (2018-26e)	5,131*	18,577	4,733	16,319
Terminal value (2% TGR)	55,732	201,783	49,995	172,396
PV of Terminal value	19,308	69,905	19,485	67,190
Value attributed to Allevetix	2,680	9,703	3,071	10,588
<b>Total NPV</b>	<b>27,119</b>	<b>98,186</b>	<b>27,288</b>	<b>94,098</b>
Add net cash (end-2017)	5,723**	20,722	6,656	22,953
<b>Implied equity value</b>	<b>32,842</b>	<b>118,907</b>	<b>33,945</b>	<b>117,051</b>
Number of shares (m)	70,501	70,501	71,42	71,423
<b>Per basic share</b>	<b>\$0.47</b>	<b>NIS1.68</b>	<b>\$0.48</b>	<b>NIS1.64</b>

Source: Edison Investment Research. Note: US dollar values are based on the spot exchange rate. \*PV of explicit FCF forecast is 2017-26e. \*\*Net cash as per our estimate of 2017.

**Exhibit 3: Financial summary**

	NIS'000	2015	2016	2017	2018e	2019e
Year end 31 December		IFRS	IFRS	IFRS	IFRS	IFRS
<b>PROFIT &amp; LOSS</b>						
Revenue		5,178	7,353	7,703	13,972	20,993
Cost of Sales		(4,421)	(5,171)	(5,687)	(8,579)	(10,520)
Gross Profit		757	2,182	2,016	5,392	10,474
EBITDA		(16,333)	(20,377)	(20,826)	(13,174)	(9,014)
Operating Profit (before amort. and except.)		(16,759)	(20,759)	(21,219)	(13,549)	(9,347)
Intangible Amortisation		(1,705)	(1,579)	(1,623)	(1,551)	(1,378)
Exceptionals		(720)	(295)	0	0	0
Operating Profit		(19,184)	(22,632)	(22,842)	(15,100)	(10,725)
Net Interest		(1,748)	(1,283)	(163)	(135)	(202)
Exceptionals		0	0	0	0	0
Other		0	0	0	0	0
Profit Before Tax (norm)		(18,507)	(22,042)	(21,382)	(13,684)	(9,550)
Profit Before Tax (IFRS)		(20,932)	(23,916)	(22,679)	(15,236)	(10,928)
Tax		0	0	0	0	0
Profit After Tax (norm)		(18,507)	(22,042)	(21,382)	(13,684)	(9,550)
Profit After Tax (IFRS)		(20,932)	(23,916)	(22,679)	(15,236)	(10,928)
Average Number of Shares Outstanding (m)		28.53	44.97	58.19	71.42	71.42
EPS - normalised (NIS)		(0.65)	(0.49)	(0.37)	(0.19)	(0.13)
EPS - IFRS (NIS)		(0.73)	(0.53)	(0.39)	(0.21)	(0.15)
Dividend per share (NIS)		0.00	0.00	0.00	0.00	0.00
Gross Margin (%)		15%	30%	26%	39%	50%
EBITDA Margin (%)		N/A	N/A	N/A	N/A	N/A
Operating Margin (before GW and except.) (%)		N/A	N/A	N/A	N/A	N/A
<b>BALANCE SHEET</b>						
Fixed Assets		25,612	23,616	22,244	20,417	18,806
Intangible Assets		24,059	22,465	20,916	19,364	17,986
Tangible Assets		1,472	1,025	1,059	784	550
Restricted cash		81	126	269	269	269
Current Assets		31,342	28,606	29,609	15,815	26,627
Stocks		2,277	2,516	2,661	2,278	2,534
Debtors		889	1,253	1,491	1,531	2,013
Cash, equivalents and short term deposits		27,053	23,203	22,953	9,501	19,576
Other		1,123	1,634	2,504	2,504	2,504
Current Liabilities		(5,620)	(12,660)	(11,962)	(11,798)	(12,147)
Creditors		(1,524)	(1,890)	(1,987)	(1,823)	(2,172)
Accruals		(1,895)	(936)	(185)	(185)	(185)
Other short term liabilities		(2,201)	(4,124)	(4,373)	(4,373)	(4,373)
Long Term Liabilities		(6,207)	(1,368)	(1,134)	(913)	(20,692)
Long term borrowings		0	0	0	0	(20,000)
Other long term liabilities		(6,207)	(1,368)	(1,134)	(913)	(692)
Net Assets		45,127	38,194	38,757	23,521	12,593
<b>CASH FLOW</b>						
Operating Cash Flow		(15,874)	(17,258)	(18,418)	(13,131)	(9,605)
Net Interest		0	0	0	0	0
Tax		0	0	0	0	0
Capex		(164)	(220)	(501)	(100)	(100)
Acquisitions/disposals		0	0	(4,005)	0	0
Financing		31,992	13,956	19,125	0	0
Dividends		0	0	0	0	0
Other		(1,841)	(328)	(456)	(221)	(221)
Net Cash Flow		14,113	(3,850)	(4,255)	(13,452)	(9,926)
Opening net debt/(cash)		(12,940)	(27,053)	(23,203)	(22,953)	(9,501)
HP finance leases initiated		0	0	0	0	0
Other		0	0	4,005	0	0
Closing net debt/(cash)		(27,053)	(23,203)	(22,953)	(9,501)	424

Source: Edison Investment Research, Allium Medical Solutions accounts

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