EDISON

Allium Medical Solutions

Positive data, H117 results and forecasts update

Clinical data and H117 results

Medical devices

Allium has announced that Gardia Medical's Wirion device has met the primary endpoint of its clinical trial, an important milestone for strategic partnering discussions. In other news, on 13 August Allium reported H117 financial results, with revenues down 5.7% y-o-y to NIS3.7m. The company has also announced approval of its prostatic and urethral stents in Mexico and expects to launch sales in H217. However, registration of Allium Stents and IBI Medical in Russia is taking longer than expected due to a lengthier and more complex regulatory process. We note that regional expansion is crucial for the company's investment case in the long run. Updated for the recent newsflow, our valuation of Allium is now NIS1.89/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	9.7	(20.3)	(0.35)	0.0	N/A	N/A
12/18e	16.6	(7.3)	(0.11)	0.0	N/A	N/A

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

Gardia's clinical trial positive at interim analysis

After it was reported that the WISE-LE trial met the endpoint at an early stage, the Wirion device is on track to become the only protection system cleared for all atherectomy procedures in the US, including the rapidly growing large lower extremities indication, if approved. The company is in partnering discussions and we believe the chances of striking a deal have increased. We model NIS2.8m revenue on full launch of Wirion in 2018e, growing to NIS8.6m in 2020e.

H117 revenues lower, but expenses under control

Revenues in H117 were down 5.7% to NIS3.7m vs NIS3.9m in H116 due to the weaker euro and US dollar (Allium books c 90% of its revenues in these currencies) vs the shekel. As previously, sales have been driven mainly by Allium Stents in Europe, IBI (EndoFast urogynecology) in Europe and Israel, and Gardia (embolic protection system) in Europe and the US. R&D spend was up 21% to NIS7.1m, mostly due to the clinical trial costs associated with Gardia and the early-stage TruLeaf mitral valve replacement project. S&M and G&A expenses decreased 22% to NIS1.2m and 8% to NIS3.6m.

Mexico approved, Russia delayed, China on track

We expect Allium to receive approval for the remaining stent products and EndoFast in Mexico by YE17 and to launch sales in 2018. Due to the registration delays, we postpone the start of sales in Russia by one year. We expect full approval in China by YE17 and launch next year. Our revised near-term revenue forecast is NIS9.7m (from NIS11.2m) in FY17 and NIS16.6m (NIS17.5m) in FY18.

Valuation: NIS1.89/share, fresh funds to last into 2018

In July 2017 Allium raised NIS12.7m in gross proceeds by issuing 12.5m new shares (19% of the share capital). We estimate that net cash of NIS26m after the July raise provides runway until the end of 2018. Our updated DCF valuation is NIS124m (vs NIS105m), or NIS1.89/share (vs NIS1.98/share).

5 September 2017

Price*	**NIS0.94**
Market cap	**NIS62m**

*Priced at 01 September 2017

Net cash (NISm) at end June 2017, plus proceeds of July raise	25.6
Shares in issue at end July 2017	65.5m
Free float	59.3%
Code	ALMD
Primary exchange	TASE
Secondary exchange	N/A

Share price performance

%	1m	3m	12m
Abs	3.2	(18.2)	(38.1)
Rel (local)	6.5	(15.8)	(37.6)

52-week high/low	NIS1.6	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

Regulatory approval in additional markets for Allium and IBI	H217
TruLeaf study in large animals	H217
Start Allevetix first-in-man clinical trial	Q417

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Edison profile page

Positive Gardia data released

The WISE-LE study's independent Clinical Events Committee (CEC) has conducted an analysis of the interim clinical data. The CEC determined that Gardia's Wirion device successfully met the primary endpoint of freedom from major adverse events (MAEs) 30 days after procedure in patients undergoing lower extremity (LE) atherectomy for the treatment of peripheral arterial disease (PAD). According to the study's protocol, the threshold for success was 12% or fewer MAEs (meaning 18 or fewer MAEs in the 153 patients expected to be enrolled), and the study would be stopped early for success if the MAE count was 9% or less (9% in the first 100 patients) at an interim analysis stage. In the interim analysis Wirion recorded only one non-device related MAE in 100 patients (1%) after 30 days, as determined by the CEC. Wirion is currently approved in the US, Australia and New Zealand for embolic protection during carotid artery catheterisation procedures. It is also approved in Israel and Europe for use in interventional vascular procedures including carotid, coronary, renal and lower extremities. The company plans to submit a 510(k) application in the US for the lower extremities indication by this year end and we expect approval in H118. If approved, Wirion would become the only protection system cleared for all atherectomy procedures in the US.

Wirion's sales so far have been low (NIS593k in FY16 or c 5% of total revenues of NIS7.4m); however, positive data place Wirion on track to address the lower extremities indication, which would significantly expand the market for this product and represent an important milestone in accelerating partnering discussions. Wirion is a third-generation embolic protection device (EPD), which has the competitive advantage of allowing doctors to use the guidewire of their choice and locate the filter anywhere along the guidewire during the procedure, as opposed to the only FDA-approved EPD for the LE indication, SpiderFX, which is limited to use with a specific atherectomy device. Although Allium is currently engaged in strategic discussions regarding Gardia, we continue to model it as part of the overall business and project revenue of NIS2.8m (from NIS2.6m) on US launch in all indications (including LE) in 2018, growing to NIS8.6m (from NIS3.5m) in 2020, which mainly reflects the expansion to the large LE indication. We highlight the fact that this projection relies on successful approval and market uptake of the Wirion device, which is a key sensitivity for the valuation.

The global EPD market could be around $0.5bn at present depending on the source. It was estimated at $200m in 2009, according to START-UP magazine. Another report points to $500m in 2015. In addition to carotid and coronary indications, the large underserved market of PAD could represent a significant opportunity. Med Device online estimates that there are around 10 million people in the US with PAD, although only 2.5 million are currently diagnosed, leading to 600,000 interventions including stenting, balloon angioplasty, plaque removal and even amputations. Finally, we note that there is strong interest in the market for atherectomy procedures, as demonstrated by the recent acquisition of Spectranetics Corporation by Philips for a total enterprise value of €1.9bn. Spectranetics is a medical devices company focused on cardiac devices and PAD. Spectranetics expects to record revenues of $300m in FY17.

Financial forecast and valuation update

We revised our forecasts following the release of the interim results and have updated our revenue forecasts in relation to sales of Allium Stents and EndoFast in Mexico and Russia. For the stents, we maintain our FY17 sales forecast for Mexico at NIS230k following the announcement of regulatory approval, as we model the imminent launch of the prostate and urethral stents in H217, and project revenues to increase significantly in 2018 to NIS575k when all types of stents and EndoFast devices are expected to be approved and launched. In Russia, we assume the approval

of all stents by year end 2017 is still a possibility and project sales to start in 2018 (NIS250k in FY18 vs NIS1.25m previously). This leads to our updated FY17 and FY18 stent revenue forecasts of NIS7.5m (from NIS7.7m) and NIS11.0m (NIS12.0m). Further, as a result of the delay in registration of EndoFast in both countries, we now expect IBI revenues of NIS1.5m in FY17 (from NIS2.2m) and NIS2.8m in FY18 (NIS2.9m).

We have also adjusted Gardia's revenues, lowering our FY17 estimate to NIS0.72m from NIS1.3m and noting that significant growth is expected from 2018 onwards as a result of the anticipated Wirion launch in lower limb indications next year (FY18e revenues of NIS2.8m vs NIS2.6m previously, as discussed above).

Overall, our revised revenue forecast for Allium is NIS9.7m (from NIS11.2m) in FY17 and NIS16.6m (from NIS17.5m) in FY18. At the same time, our FY20 revenue estimate moves from NIS29.6m to NIS33.5m. This is primarily driven by Gardia's upward revisions from 2018 onwards, which rest on the assumption of the successful approval and subsequent commercialisation of Wirion. Based on the revised estimates, our total revenue CAGR forecast for 2016-20 is now 46% vs 41% previously. We note that our top-line forecasts are based on explicit volume and price assumptions but, given that the company is at an early stage of its regional expansion, visibility on these remain relatively low at present.

Exhibit 1: Revised forecasts

NIS000s	2017e		2018e	
Revised revenues	**Previous**	**Current**	**Previous**	**Current**
Stents				
Mexico	230	230	575	575
Russia	250	0	1,250	250
IBI EndoFast	2,200	1,500	2,900	2,800
Gardia	1,300	720	2,600	2,800
Revised expenses				
R&D	10,000	14,000	5,000	5,000
S&M	2,911	2,520	3,500	3,046
G&A	7,250	7,250	7,000	7,000

Source: Edison Investment Research. Note: Numbers are rounded.

In addition, we have adjusted FY17 operating expenses to reflect the higher R&D costs (NIS14m vs NIS10m) of the ongoing Gardia clinical trial. We expect R&D expenses to drop significantly from 2018 as the company spends less on Gardia and anticipate most of the FY18 R&D expense of NIS5.0m to be associated with TruLeaf. We have trimmed S&M expenses for FY17 to NIS2.5m (vs the previous NIS2.9m) to reflect fewer professional services and commissions, and have maintained our growth assumptions. We expect G&A to remain at broadly the same levels, which should aid overall profitability. Our FY17 and FY18 EBITDA loss estimates for the company now stand at NIS19.5m (from NIS14.7m) and NIS6.8m (NIS6.3m). We continue to expect Allium to reach EBITDA break-even in 2019.

In July 2017 Allium raised NIS12.7m in gross proceeds by issuing 12.5m new shares (19% of the share capital). We estimate that net cash of NIS26m after the July raise provides runway until the end of 2018. The new funds will be spent on completing Wirion's clinical development; a first-in-man study with Allevetix's gastroduodenal sleeve (start in H217) and the animal study with TruLeaf.

As a result of these changes, our revised DCF valuation of Allium moves to NIS1.89 per share, or NIS124m, from NIS1.98/share or NIS105m. To illustrate the impact of Wirion's commercial success on our valuation, we note that a 20% reduction in Guardia's revenues in 2017-20 would lower our valuation to NIS95m or NIS1.45/share.

Exhibit 2: Allium summary DCF valuation

	$000s	NIS000s
PV of explicit FCF forecast (2017-26e)	5,131	18,577
Terminal value (2% TGR)	55,732	201,783
PV of Terminal value	19,308	69,905
Value attributed to Allevetix (estimated BV)	2,680	9,703
Total NPV	**27,119**	**98,186**
Add net cash (after July 2017 raise)	7,075	25,614
Implied equity value	**34,193**	**123,800**
Number of shares (m)	65,478	65,478
Per basic share	**$0.52**	**NIS1.89**

Source: Edison Investment Research. Note: US dollar values are based on the spot exchange rate.

Exhibit 3: Financial summary

NIS000s	2014	2015	2016	2017e	2018e
Year end 31 December	IFRS	IFRS	IFRS	IFRS	IFRS
PROFIT & LOSS					
Revenue	4,916	5,178	7,353	9,735	16,612
Cost of Sales	(5,699)	(4,421)	(5,171)	(7,501)	(9,914)
Gross Profit	(783)	757	2,182	2,233	6,698
EBITDA	(20,373)	(16,333)	(20,377)	(19,492)	(6,772)
Operating Profit (before GW and except.)	(20,758)	(16,759)	(20,759)	(19,893)	(7,133)
Intangible Amortisation	(2,032)	(1,705)	(1,579)	(1,655)	(1,491)
Exceptionals	(1,262)	(720)	(295)	0	0
Operating Profit	(24,052)	(19,184)	(22,632)	(21,548)	(8,624)
Financial expenses	(593)	(1,748)	(1,284)	(361)	(178)
Exceptionals	0	0	0	0	0
Other	0	0	0	0	0
Profit Before Tax (norm)	(21,351)	(18,507)	(22,043)	(20,253)	(7,311)
Profit Before Tax (IFRS)	(24,645)	(20,932)	(23,917)	(21,909)	(8,802)
Tax	0	0	0	0	0
Profit After Tax (norm)	(21,351)	(18,507)	(22,043)	(20,253)	(7,311)
Profit After Tax (IFRS)	(24,645)	(20,932)	(23,917)	(21,909)	(8,802)
Average Number of Shares Outstanding (m)	18.43	28.53	44.97	58.57	65.48
EPS - normalised (NIS)	(1.16)	(0.65)	(0.49)	(0.35)	(0.11)
EPS - IFRS (NIS)	(1.34)	(0.73)	(0.53)	(0.37)	(0.13)
Dividend per share (NIS)	0.00	0.00	0.00	0.00	0.00
Gross Margin (%)	-16%	15%	30%	23%	40%
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
BALANCE SHEET					
Fixed Assets	28,218	25,612	23,616	21,660	19,908
Intangible Assets	26,438	24,059	22,465	20,810	19,319
Tangible Assets	1,780	1,472	1,025	725	464
Restricted cash	0	81	126	126	126
Current Assets	16,629	31,342	28,605	19,639	13,073
Stocks	2,330	2,277	2,516	2,249	2,664
Debtors	686	889	1,253	1,334	1,821
Cash	12,940	27,053	23,202	14,422	6,955
Other	673	1,123	1,634	1,634	1,634
Current Liabilities	(5,560)	(5,620)	(12,660)	(12,316)	(12,901)
Creditors	(1,516)	(1,524)	(1,890)	(1,546)	(2,131)
Accruals	(1,820)	(1,895)	(936)	(936)	(936)
Other short term liabilities	(2,224)	(2,201)	(4,124)	(4,124)	(4,124)
Long Term Liabilities	(7,127)	(6,207)	(1,368)	(1,268)	(1,168)
Long term borrowings	0	0	0	0	0
Other long term liabilities	(7,127)	(6,207)	(1,368)	(1,268)	(1,168)
Net Assets	32,160	45,127	38,193	27,714	18,912
CASH FLOW					
Operating Cash Flow	(19,026)	(15,874)	(17,259)	(20,010)	(7,267)
Net Interest	0	0	0	0	0
Tax	0	0	0	0	0
Capex	(349)	(164)	(220)	(100)	(100)
Acquisitions/disposals	0	0	0	0	0
Financing	25,191	31,992	13,956	11,430	0
Dividends	0	0	0	0	0
Other	(41)	(1,841)	(328)	(100)	(100)
Net Cash Flow	5,775	14,113	(3,851)	(8,780)	(7,467)
Opening net debt/(cash)	(7,165)	(12,940)	(27,053)	(23,202)	(14,422)
HP finance leases initiated	0	0	0	0	0
Other	0	0	0	0	0
Closing net debt/(cash)	(12,940)	(27,053)	(23,202)	(14,422)	(6,955)

Source: Edison Investment Research, Allium Medical Solutions accounts

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