

Allium Medical Solutions

Positive data, H117 results and forecasts update

Medical devices

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

Analysts

Juan Pedro Serrate +44 (0)20 3681 2534

Jonas Peculis +44 (0)20 3077 5728

healthcare@edisongroup.com

[Edison profile page](#)

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).

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	
	Previous	Current	Previous	Current
Revised revenues				
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 Gardia'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

Edison is an investment research and advisory company, with offices in North America, Europe, the Middle East and AsiaPac. The heart of Edison is our world-renowned equity research platform and deep multi-sector expertise. At Edison Investment Research, our research is widely read by international investors, advisers and stakeholders. Edison Advisors leverages our core research platform to provide differentiated services including investor relations and strategic consulting, is authorised and regulated by the [Financial Conduct Authority](#). Edison Investment Research (NZ) Limited (Edison NZ) is the New Zealand subsidiary of Edison. Edison NZ is registered on the New Zealand Financial Service Providers Register (FSP number 247505) and is registered to provide wholesale and/or generic financial adviser services only. Edison Investment Research Inc (Edison US) is the US subsidiary of Edison and is regulated by the Securities and Exchange Commission. Edison Investment Research Limited (Edison Aus) [46085869] is the Australian subsidiary of Edison and is not regulated by the Australian Securities and Investment Commission. Edison Germany is a branch entity of Edison Investment Research Limited [4794244]. www.edisongroup.com

EDISON ISRAEL DISCLAIMER

Disclosure regarding the scheme to enhance the awareness of investors to public companies in the technology and biomed sectors that are listed on the Tel Aviv Stock Exchange and participate in the scheme (hereinafter respectively "the Scheme", "TASE", "Participant" and/or "Participants"). Edison Investment Research (Israel) Ltd, the Israeli subsidiary of Edison Investment Research Ltd (hereinafter respectively "Edison Israel" and "Edison"), has entered into an agreement with the TASE for the purpose of providing research analysis (hereinafter "the Agreement"), regarding the Participants and according to the Scheme (hereinafter "the Analysis" or "Analyses"). The Analysis will be distributed and published on the TASE website (Maya), Israel Security Authority (hereinafter "the ISA") website (Magna), and through various other distribution channels. The Analysis for each participant will be published at least four times a year, after publication of quarterly or annual financial reports, and shall be updated as necessary after publication of an immediate report with respect to the occurrence of a material event regarding a Participant. As set forth in the Agreement, Edison Israel is entitled to fees for providing its investment research services. The fees shall be paid by the Participants directly to the TASE, and TASE shall pay the fees directly to Edison. Subject to the terms and principals of the Agreement, the Annual fees that Edison Israel shall be entitled to for each Participant shall be in the range of \$35,000-50,000. As set forth in the Agreement and subject to its terms, the Analyses shall include a description of the Participant and its business activities, which shall inter alia relate to matters such as: shareholders; management; products; relevant intellectual property; the business environment in which the Participant operates; the Participant's standing in such an environment including current and forecasted trends; a description of past and current financial positions of the Participant; and a forecast regarding future developments in and of such a position and any other matter which in the professional view of the Edison (as defined below) should be addressed in a research report (of the nature published) and which may affect the decision of a reasonable investor contemplating an investment in the Participant's securities. To the extent it is relevant, the Analysis shall include a schedule of scientific analysis of an expert in the field of life sciences. An "equity research abstract" shall accompany each Equity Research Report, describing the main points addressed. The full scope reports and reports where the investment case has materially changed will include a thorough analysis and discussion. Short update notes, where the investment case has not materially changed, will include a summary valuation discussion. The Agreement with TASE regarding the participation of Edison in the scheme for the research analysis of public companies does not and shall not constitute an approval or consent on the part of TASE or the ISA or any other exchange on which securities of the Company are listed, or any other securities' regulatory authority which regulates the issuance of securities by the Company to the content of the Report or to the recommendation contained therein. A summary of this report is also published in the Hebrew language. In the event of any contradiction, inconsistency, discrepancy, ambiguity or variance between the English Report and the Hebrew summary of said Report, the English version shall prevail; and a note to this effect shall appear in any Hebrew summary of a Report. Edison is regulated by the Financial Conduct Authority. According to Article 12.3.2, Chapter 12 of the Conduct of Business Sourcebook, Edison, which produces or disseminates non-independent research, must ensure that it: 1) is clearly identified as a marketing communication; and 2) contains a clear and prominent statement that (or, in the case of an oral recommendation, to the effect that) it: a) has not been prepared in accordance with legal requirements designed to promote the independence of investment research; and b) is not subject to any prohibition on dealing ahead of the dissemination of investment research. The financial promotion rules apply to non-independent research as though it were a marketing communication.

EDISON INVESTMENT RESEARCH DISCLAIMER

Copyright 2017 Edison Investment Research Limited. All rights reserved. This report has been prepared and issued by Edison for publication globally. All information used in the publication of this report has been compiled from publicly available sources that are believed to be reliable, however we do not guarantee the accuracy or completeness of this report. Opinions contained in this report represent those of the research department of Edison at the time of publication. The securities described in the Investment Research may not be eligible for sale in all jurisdictions or to certain categories of investors. This research is issued in Australia by Edison Aus and any access to it, is intended only for "wholesale clients" within the meaning of the Australian Corporations Act. The Investment Research is distributed in the United States by Edison US to major US institutional investors only. Edison US is registered as an investment adviser with the Securities and Exchange Commission. Edison US relies upon the "publishers' exclusion" from the definition of investment adviser under Section 202(a)(11) of the Investment Advisers Act of 1940 and corresponding state securities laws. As such, Edison does not offer or provide personalised advice. We publish information about companies in which we believe our readers may be interested and this information reflects our sincere opinions. The information that we provide or that is derived from our website is not intended to be, and should not be construed in any manner whatsoever as, personalised advice. Also, our website and the information provided by us should not be construed by any subscriber or prospective subscriber as Edison's solicitation to effect, or attempt to effect, any transaction in a security. The research in this document is intended for New Zealand resident professional financial advisers or brokers (for use in their roles as financial advisers or brokers) and habitual investors who are "wholesale clients" for the purpose of the Financial Advisers Act 2008 (FAA) (as described in sections 5(c) (1)(a), (b) and (c) of the FAA). This is not a solicitation or inducement to buy, sell, subscribe, or underwrite any securities mentioned or in the topic of this document. This document is provided for information purposes only and should not be construed as an offer or solicitation for investment in any securities mentioned or in the topic of this document. A marketing communication under FCA Rules, this document has not been prepared in accordance with the legal requirements designed to promote the independence of investment research and is not subject to any prohibition on dealing ahead of the dissemination of investment research. Edison has a restrictive policy relating to personal dealing. Edison Group does not conduct any investment business and, accordingly, does not itself hold any positions in the securities mentioned in this report. However, the respective directors, officers, employees and contractors of Edison may have a position in any or related securities mentioned in this report. Edison or its affiliates may perform services or solicit business from any of the companies mentioned in this report. The value of securities mentioned in this report can fall as well as rise and are subject to large and sudden swings. In addition it may be difficult or not possible to buy, sell or obtain accurate information about the value of securities mentioned in this report. Past performance is not necessarily a guide to future performance. Forward-looking information or statements in this report contain information that is based on assumptions, forecasts of future results, estimates of amounts not yet determinable, and therefore involve known and unknown risks, uncertainties and other factors which may cause the actual results, performance or achievements of their subject matter to be materially different from current expectations. For the purpose of the FAA, the content of this report is of a general nature, is intended as a source of general information only and is not intended to constitute a recommendation or opinion in relation to acquiring or disposing (including refraining from acquiring or disposing) of securities. The distribution of this document is not a "personalised service" and, to the extent that it contains any financial advice, is intended only as a "class service" provided by Edison within the meaning of the FAA (ie without taking into account the particular financial situation or goals of any person). As such, it should not be relied upon in making an investment decision. To the maximum extent permitted by law, Edison, its affiliates and contractors, and their respective directors, officers and employees will not be liable for any loss or damage arising as a result of reliance being placed on any of the information contained in this report and do not guarantee the returns on investments in the products discussed in this publication. FTSE International Limited ("FTSE") © FTSE 2017. "FTSE®" is a trade mark of the London Stock Exchange Group companies and is used by FTSE International Limited under license. All rights in the FTSE indices and/or FTSE ratings vest in FTSE and/or its licensors. Neither FTSE nor its licensors accept any liability for any errors or omissions in the FTSE indices and/or FTSE ratings or underlying data. No further distribution of FTSE Data is permitted without FTSE's express written consent.