

# Allium Medical Solutions

Initiation of coverage

Fast-growing innovative products player

Medical devices

2 November 2016

**Price\*** **NIS1.18**

**Market cap** **NIS63m**

\*Priced at 26 October 2016

US\$/NIS 3.85

Net cash (NISm) at Q216 18.8

Shares in issue 52.9m

Free float 85%

Code ALMD

Primary exchange TASE

Secondary exchange N/A

Allium Medical Solutions boasts a portfolio of products in diverse clinical areas such as urology and cardiovascular, with the majority of revenues derived from urology stents. Having achieved revenue CAGR of 19% in 2011-15, we expect Allium's growth to accelerate in the medium term, driven by new markets, resulting in 2015-20e revenue CAGR of 41%. We initiate coverage of Allium with a DCF valuation of NIS1.95-2.08/share.

Year end	Revenue (NISm)	PBT* (NISm)	EPS* (NIS)	DPS (NIS)	P/E (x)	Yield (%)
12/14	4.9	(20.1)	(1.09)	0.0	N/A	N/A
12/15	5.2	(18.5)	(0.65)	0.0	N/A	N/A
12/16e	7.4	(18.1)	(0.40)	0.0	N/A	N/A
12/17e	11.2	(15.0)	(0.28)	0.0	N/A	N/A

Note: \*PBT and EPS are normalised, excluding amortisation of acquired intangibles, exceptional items and share-based payments.

## Growing revenues in key markets

Allium's peripheral stents and EndoFast urogynecology devices generate the bulk of revenues (95% of NIS5.2m in 2015). The company has had a steady increase of revenues since 2011, which accelerated in the last year in key markets in Europe, Asia and other countries. Furthermore, new distribution agreements signed with regional partners worth NIS185m provide a revenue base of up to 10 years.

## Value drivers in the short and mid-term

In addition to the growing revenues and new distribution agreements signed, other products may provide upside in the short to medium term. Gardia Medical develops and markets a device to prevent embolism in interventional vascular procedures. It is currently being sold to selected excellence centres, mainly in Europe. The product is CE mark approved and marketed in Europe for all indications; it is FDA-approved in the US and TGA-approved in Australia and New Zealand for carotid stenting, with plans to expand it to other indications. Allium is in the process of engaging a leading global company for a strategic transaction, preferably M&A.

## Potential upside in the long run

Allium also has two devices in preclinical development: Allevetix for diabetes and obesity and BMV, a mitral valve replacement device. The company plans to run clinical trials for Allevetix in collaboration with the National University of Singapore (NUS) in 2017 and potentially market the product in a joint venture with NUS in 2018. Allium will develop BMV until completion of a successful First In Man Study.

## Valuation: DCF value of NIS1.95-2.08/share

We value Allium at NIS1.95-2.08 per undiluted share using a DCF approach based on a 12.5% discount rate (10% for terminal value), explicit free cash flow forecast to 2026 and a 2% terminal growth rate. Our valuation is predominantly driven by the anticipated increase in stent sales, which should to a significant extent come from the 'recently established' (South Korea, UK, Argentina) and 'emerging' (China, Russia, Mexico) markets.

## Share price performance



% 1m 3m 12m

Abs 4.6 (23.3) (35.0)

Rel (local) 6.4 (22.0) (29.3)

52-week high/low NIS1.8 NIS1.0

## 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 agreements in Asia, Europe and South America for Allium Stents and IBI Medical 2016-17

Design freeze of Allevetix product development Q416

Initiation of Allevetix clinical trial 2017

Potential agreement for Gardia Medical 2017

## Analysts

Juan Pedro Serrate +44 (0)20 3681 2534

Jonas Peculis +44 (0)20 3077 5728

[healthcare@edisongroup.com](mailto:healthcare@edisongroup.com)

[Edison profile page](#)

## Investment summary

---

### Company description: Minimally invasive solutions

Allium Medical is a medical technology company that develops, manufactures and markets minimally invasive surgical products grouped under four medical fields: peripheral stents, obesity/diabetes, cardiovascular and urogynecology. The company was originally incorporated as Elutex in 2004, dedicated to the development of a coating for medicated stents. It went public in 2007 on the Tel Aviv Stock Exchange (TASE). In 2010 it merged with Allium to form Allium Medical Solutions. Headquartered in Caesarea, Israel, Allium has about 40 employees.

### Valuation: NIS1.95-2.08/share

We value Allium at NIS1.95-2.08/share on an undiluted basis using a DCF approach based on a 12.5% discount rate (10% for TV), explicit free cash flow forecast for Allium stents, IBI and Gardia to 2026 and a 2% terminal growth rate. We arrived at a range by applying a 52-week low/high US\$/NIS exchange rate of 3.74-3.98. Our valuation is largely driven by the anticipated increase in stent sales, which should mainly come from the 'recently established' (South Korea, UK, Argentina) as well as 'emerging' (China, Russia, Mexico) markets. Our base case scenario, which is slightly more conservative than the company's projections, implies overall revenue CAGR of 41% for 2015-20e. Should the company fail to execute on its ambitious growth strategy, we see a significant downside risk to our valuation (and vice versa). Thus, a 50% slower sales roll-out in China, Russia, and Mexico in 2016-20 would lower our valuation by c 25%.

### Financials: Sales expansion to drive earnings

Revenue has grown at a CAGR of 5% in 2013-15, from NIS4.7m to NIS5.2m with a visible uptick in the first half of 2016 (NIS3.9m vs NIS2.5m in H115). We expect this trend to continue as the company has recently signed distribution agreements worth c NIS185m in new markets such as China, Russia and Latin America. We estimate operating expenses associated with these agreements to be small as distributors normally support regulatory and marketing activities in their local markets, while committing to purchase a minimum amount of products over a certain period of time. The company has announced that it is in the process of engaging a leading global company for a strategic transaction for Gardia, preferably M&A. Allevetix is being developed in partnership with the NUS and public funding and a partner will be sought for the development of BMV. The company has raised NIS14.9m in two equity raises in Q316, which we expect will bring cash and equivalents to NIS24m at end 2016. We forecast EBITDA break-even in 2019.

### Sensitivities: Execution is key

Our forecasts and valuation are based on Allium's ability to execute on its ambitious growth strategy, with revenues expanding at a double-digit rate as the company continues to gain market share in established and new regions. However, growth is heavily reliant on the distribution agreements with local partners and their ability to market and sell Allium's products (which in turn is significantly dependent on reimbursement). Such a reliance on third parties may add to earnings volatility and affect execution. In addition, stent pricing may represent a risk as distributors have certain bargaining power. While Allium has so far managed to keep costs under control, we note that stents are manufactured in house, but components depend on external suppliers. IBI's products may face challenges as a result of some safety issues seen in the products of other competitors. Gardia Medical has had limited commercialisation and revenue expansion depends on finding a strategic partner. Allevetix's and BMV's challenges are related to achieving successful manufacturing and clinical results and obtaining approval from regulatory authorities.

## Minimally invasive products for unmet needs

Allium Medical develops and markets products in four categories: peripheral stents, cardiovascular, urogynecology and metabolic diseases. The company has acquired most of these technologies from other companies through acquisition deals.

Allium has products in different stages, from in-house development to marketed products through its group of companies. In particular, the company offers fully covered stents in Europe, and other countries, through Allium Stents (sales of NIS3.8m in 2015). Allium provides soft tissue fixation devices sold in the EU through IBI (sales of NIS1.13m in 2015) and embolic protection devices through its subsidiary Gardia Medical (sales of NIS0.25m in 2015). Additionally, the company is developing a gastroduodenal sleeve to treat obesity and Type 2 diabetes through Allevetix in preclinical studies. Lastly, BMV has a transcatheter mitral valve replacement (TMVR) device in preclinical development.

**Exhibit 1: Product summary**

Company	Products	Product description	Status	Comments
Allium Stents	Bulbar urethra stent (BUS)	Covered, expandable and retrievable metal stents, anatomically and functionally compatible to specific organs for the treatment of obstructions in the urinary tract and bile duct.	Approved in EU, Israel, Australia, South Africa and South Korea. In regulatory process in China, Russia and Mexico. Urological stents approved in Argentina and Canada.	Marketed in Europe, Australia and South Africa. Upcoming marketing activities in South America and Asia.
	Triangular Prostatic (TPS)			
	Round Posterior Stent (RPS)			
	Ureteral Stent (URS)			
	Biliary Stent (BIS)			
IBI Medical	EndoFast Reliant	Product comprises a mesh and a fixation device for pelvic organ prolapse and urinary incontinence.	Approved in EU and US. In regulatory process in Russia and Mexico.	Marketed in Europe and Israel. Business development activities for a partner in China.
	EndoFast SCP			
	EndoFast MN			
Gardia Medical	Wirion	System that protects against blood clots and embolisms occurring in the course of catheterisation aimed at unblocking blood vessels	Approved in US, Australia and New Zealand for carotid artery stenting. In clinical study for approval for lower limb stenting. Approved in the EU and Israel for all indications.	Distribution limited to selected KOLs and centres. Currently in the process of engaging a strategic partner.
Allevetix	Gastro-Duodenal Sleeve (GDS)	Internal bypass in the small intestine for the treatment of obesity and Type 2 diabetes.	In development stage.	CE submission in next 12-18 months.
BMV	Transcatheter Mitral Valve Replacement (TMVR)	Synthetic device for mitral valve regurgitation.	In development stage.	Planned final design, animal and human studies to achieve CE mark.

Source: Edison Investment Research, Allium Medical Solutions

## Allium Stents: Covered stents in a growing market

Lower urinary tract symptoms (LUTS) are voiding and storage disturbances that affect the lower urinary tract. LUTS may be caused by a number of conditions such as bladder cancer, nocturnal polyuria prostatitis and, in a significant number of cases, by benign prostatic hyperplasia (BPH). There were [16m diagnosed cases of BPH](#) in the world's seven major markets (US, Japan and EU5) in 2014. Surgery remains the standard of care to treat BPH; however, around 10-15% of men present contraindications for surgery. The prevalence of urolithiasis (presence of kidney stones) in Western countries is around 10%, with an annual incidence of [ureteral colic of 1-2 cases in 1,000 people](#). Approximately [3% to 11% of patients](#) undergoing ureteroscopy for calculus management develop ureteral stenosis. Bile duct stenosis (or biliary stricture) is a partial or complete obstruction of the common biliary duct caused after surgical removal of the gallbladder (called benign biliary strictures) or as a result of pancreatic cancer (called malignant biliary strictures). Stents can be an option for patients who are looking for a minimally invasive alternative to surgery.

Stents are expected to be biocompatible, easily inserted and removed, avoid obstruction, are resistant to infection, resistant to migration and radiopaque for confirmation of placement via radiography. Most stents used at present are self-expandable and spiralled. According to the latest

[European Association of Urology \(EAU\) guidelines](#), prostatic stents have a limited role in the treatment of moderate-to-severe LUTS due to a high failure rate and significant side effects.

Allium manufactures and commercialises self-expandable, metal stents made of nitinol (nickel titanium), fully covered with a biomaterial that prevents encrustation, tissue ingrowth, stone formation and calcification. Allium’s stents are intended to address stenosis in the urethra, ureters, prostate and biliary duct. Allium has designed different products with their own characteristics to adjust to the anatomy of the genitourinary system as shown in Exhibit 2.

Exhibit 2: Description of Allium’s stents products			
Product	Target organ	Description	Comments
Ureteral stent (URS)	Ureters	A thin tube inserted antegrade or retrograde into the ureter or directly into the urethra to prevent or treat obstruction of the urine flow from the kidney. It is used in most cases after surgery for different conditions of the urinary tract.	In this <a href="#">study</a> , 49 stents were inserted in 49 renal units (40 patients), from 2005 to 2011 during a mean indwelling time of 17 months. Migration was observed in seven (14.2%) patients, and the stent had to be removed. This is lower than the industry standard of 20% (according to Allium). Only one stent was obstructed after 11 months.
Round Posterior Stent (RPS)	Posterior urethra	For patients with prostate cancer or bladder cancer undergoing prostate resection. Up to 21% of radical prostatectomy patients develop stenosis.	Data from a <a href="#">small trial</a> in 10 patients showed 2 stents migrated; mean indwelling time was 5.5 months. It can be an alternative to repeated dilations or endoscopic procedures.
Triangular Prostatic Stent (TPS)	Prostatic urethra	Has a large-calibre, triangular cross-section to match the anatomy of the prostatic urethral lumen and can generate varying degrees of radial force adapting to the anatomy.	<a href="#">Clinical data</a> in 51 patients with benign prostatic obstruction who were unwilling or unfit to undergo classic prostatic surgery showed that Allium’s TPS reduced the international prostate symptom score (IPSS <sup>1</sup> ) by 18.7 points and increased Qmax (maximal urinary flow) by 10.5ml/second. One-year failure rate of 3.9%
Bulbar Stent (BUS)	Urethra	Treatment of stenosis along the bulbar urethra. Owing to its biomaterial cover, Allium’s BUS is less likely to result in tissue ingrowth vs bare metal stents.	Three-year <a href="#">study</a> in 40 men. Permanent recanalization without voiding problems was reported in 85% of cases. At one year after insertion, only 12.5% reported a stenosis in the distal end of the stent.
Biliary Stent (BIS)	Biliary duct	Stent for common bile duct. Allows free flow of bile from gall bladder and liver to the duodenum. Intended to remain in place for up to 3 years.	<a href="#">Clinical study</a> in 11 patients showed 92% success rate. 34 stents were placed, complications seen in six stentings (18%)

Source: Edison Investment Research, Allium Medical Solutions

Although with the limitation of the small number of patients, Allium’s TPS is similar in terms of IPSS and Qmax and better for failure rate (stent migration, incorrect placement, encrustations, urinary retention and incontinence) to its main competitor Memokath (Pnn Medical), which had a reduction of 11-19 points in the IPSS, Qmax increase of 3 to 11ml/second and failure rates as high as 48% in [a review of 14 case series](#) in 839 patients.

Stents for the lower urinary tract is considered a niche market. Benign prostate (BPH) happens when the prostate enlarges and is associated with age. It is [estimated](#) that about 40-50% of men between the ages of 51 and 60 and 80-90% of men older than 70 have it. Each year around [150,000 men](#) in the US have transurethral resection of the prostate (TURP), the most common surgery for BPH. However, it is associated with up to [20% morbidity](#), and risks such as bleeding. Therefore, for patients unfit for TURP or other modalities, minimally invasive solutions such as stenting are needed.

Ureteral stents are placed in pathologies such as kidney stones, urinary incontinence and kidney transplant, to prevent or treat obstruction of the urine flow from the kidney to the bladder. Traditional ureteral stents are 24-30cm long and are called JJ stents or double J stents due to the curl at both ends.

Most of Allium’s product competitors are double J stents, meant for short periods of time and associated with potential tissue ingrowth and incrustation. Hence Allium’s stents are positioned as premium product due to their safety profile and data, as demonstrated in small clinical studies. Importantly, being intended for long-term use, the healthcare cost savings are considerable as demonstrated in an [economic costs study](#) conducted by Pnn Medical with its Memokath ureteral

<sup>1</sup> The IPSS is an eight-item questionnaire with a score categorised as asymptomatic (0 points); mildly symptomatic (1-7 points); moderately symptomatic (8-19 points); and severely symptomatic (20-35 points).

stent. Over the course of two years €6,900 was saved, most of it during the second year in materials and hospital-related costs. Exhibit 3 shows the main competitors.

Exhibit 3: Competitor table			
Company	Product/s	Organ	Comments
Pnn Medical	Memokath	Ureter/Urethra/Prostate	Nitinol stent covered with biocompatible material, thermoformable. Different types for all sections of the urinary tract.
TaeWoong	Niti-S/Uventa	Biliary/Urethra	Nitinol, self-expandable metal stents, covered and uncovered. Launched in Iran in Oct 2016.
Boston Scientific	Percuflex	Ureter	Double J stent with biocompatible material intended for one-year indwelling time. Urology and Pelvic Health division generated revenues of c \$700m in 2015.
Urotech	Yellow/Green/Black/White-Star	Ureter	Aliphatic polyurethane (PUR), radiopaque.
Olympus	Sof-Curl	Ureter	Double J stents, with a patented kidney curl for ease of placement and removal.
Optimed	Opti line	Ureter	Steerable ureteral stent
Gohar Shafa	Various	Ureter	Aliphatic polyurethane (PUR). Hydrophilic, anti-microbial, anti-encrustation ureteral stents, visible under X-ray during fluoroscopic placement.
Rocamed	RocaJJ	Ureter	Thermo sensitive, polyurethane ureteral double J stent.
SRS	Spanner	Prostate	Temporary stent, approved in the US.
Bard	E-Luminexx, Lifestent, Valeo	Biliary and ureter	Flexible, expandable, radiopaque mesh stents. \$845m revenues for the urology division in 2015.

Source: Edison Investment Research

Most competitor ureteral products are similar, with short-term, nitinol double J stents covered by biomaterials being the most predominantly used stents. Therefore, we see it as a somewhat commoditised market. There is little room for differentiation among products and revenues rely mostly on marketing. The competitive advantage of Allium's stents is their positioning as high-quality premium products intended for long periods or even permanently, resulting in the associated cost savings previously described. Moreover, the market for genitourinary stents is expanding due to ageing and the growing number of people reluctant to undergo surgery. Allium's stent products have the CE mark, and have been approved by health authorities in Australia, South Korea and Canada.

## IBI Medical: A pull-out force for soft tissue fixation

Through Israel Biomedical Innovations (IBI), Allium develops and markets soft tissue fixation products. These products are based on the EndoFast fastening technology, which consists of a device that attaches to soft tissue (ligament, muscle and fascia) and deploys a pull-out force. It is composed of a surgical mesh placed with the Spider Fastener fixation device in the desired anatomic location. Meshes can be retrieved and repositioned, without causing pain or tissue damage.

Exhibit 4: Description of IBI Medical's products			
Product	Condition	Description	Comments
EndoFast Reliant	Pelvic Organ Prolapse	Transvaginal approach	Most procedures use this approach. Kit has five fixation devices plus mesh. FDA and CE approved.
EndoFast SCP	Pelvic Organ Prolapse	Laparoscopic approach	It is the laparoscopic extension of EndoFast Reliant. Kit has five fixation devices plus mesh. FDA and CE approved.
EndoFast MN	Male Stress Urinary Incontinence	Surgical sling technique	Provides suburethral support. Kit has five fixation devices plus mesh. CE approval.

Source: Edison Investment Research, Allium Medical Solutions

EndoFast products are trocarless (ie do not use a sharp-pointed instrument to puncture), as opposed to most soft tissue fixation products used nowadays, which have trocars that may cause irritation and damage to internal organs as they pass blindly through the pelvis walls.

**Exhibit 5: EndoFast Reliant clinical data**

Study	Number of patients	Results	Comments
<a href="#">Braun N. et al</a>	29	Results considered "perfect" and "very satisfactory" for 25 patients. 1 year POP-Q = 0; 6 cases of de novo SUI (24%)	One-year follow-up retrospective study. March 2007-January 2010.
<a href="#">Braun N</a>	110	2 cases of de novo SUI (1.8%), 3 dyspareunia (2.7%), 1 chronic pain (0.9%). Overall re-operation seven patients (6.3%); 3 for prolapse, 2 for SUI and 2 for mesh release due to dyspareunia, which resolved	Retrospective analysis. Mean follow up 12 months (3-26).
<a href="#">Bettin St et al</a>	80	11 cases of de novo SUI (13.8%). No chronic pain induced by the procedure. Three (3.8%) patients needed surgery for recurrent prolapse.	Prospective analysis. 80 patients reached 1 -3 years since surgery (mean: 17 months, range: 12-36 month). March 2009.
<a href="#">Alcalay M. et al</a>	20	Statistically significant change in POP-Q anatomical measurements in two cases of de novo SUI (10%). 85% satisfactory anatomical outcome. 95% resolve of prolapse symptoms. No visceral injury.	One-year follow-up prospective study.

Source: Edison Investment Research

Regarding clinical data, the most complete study by Alcalay M. et al, showed Pelvic Organ Prolapse Quantification ([POP-Q](#)) anatomical measurements and staging and Pelvic Floor Distress Inventory (PFDI) scoring up to 12 months afterwards. POP-Q is a system that describes and stages POP in women. The POP-Q stages go from 0 (no prolapse at all) to IV (complete prolapse). The PFDI is a test with [20 questions](#) in its short version, which measure the problems and distress caused by pelvic floor symptoms. In this study satisfactory anatomical outcome (stage 0 or 1) was reached in 90% at six months and in 85% at one-year follow-up (17 out of 20 patients). However, further data from larger trials would help understand the benefits of EndoFast devices in the context of clinical practice. For instance, incidence of de novo SUI after POP surgery in previously continent [women is low in general](#) (4%), with other studies reporting a wide range between 2% and 43%.

A number of companies were developing products for POP and SUI, including Boston Scientific, Coloplast, Johnson & Johnson's Ethicon, Endo Pharmaceuticals's American Medical Systems and Bard Medical. While each company made its own product, most were similar and due to the use of trocars by untrained physicians, likely to produce erosion and organ perforation. As a result, [thousands of lawsuits](#) were filed in US courts, leading to many of these products being recalled. The FDA issued [notifications](#) in 2008 and 2011 and [requested manufacturers](#) to conduct post-marketing surveillance studies. Most of these companies stopped marketing their products. Current competitors include Boston Scientific, which has five products for pelvic floor reconstruction; Coloplast, which offers 13 products for POP and SUI, mostly accessories such as meshes (the Restorelle line); human biologic materials to be grafted in POP/SUI patients (Axis and Suspend); a transvaginal fixation device (Stat Tack) and a suture delivery system (Digitex). Bard Medical markets the Alyte Y-Mesh Graft for the laparoscopic approach and the Fixt suturing device. IBI's competitive advantage is its complete presentation, as a full kit with mesh and fixation devices, preferred by urogynecologists who use the transvaginal approach (currently the majority of procedures). Furthermore, its strong pull-out force, ease of use and clinical data, particularly its safety due to being trocarless, provide an additional competitive edge. The company is exploring options to enter the US market through a distributor.

According to Allium, market research by Millennium Research Group and other [sources](#), the global market is around \$1.2bn, with \$460m in the US, \$345m in Europe and \$345 in the rest of the world. This represents about 1m procedures worldwide. According to the same sources, the market grew at a 9.5% CAGR from 2008 to 2013.

## Gardia Medical: The Wirion Embolic Protection Device

About 86 million Americans are living with some form of cardiovascular disease and heart disease is the leading cause of death in the US, accounting for [one in every four deaths in 2013](#). Vascular

interventions such as angioplasty and stenting to open blocked arteries may dislodge plaque debris, which can cause distal embolisms (downstream obstruction). This can result in complications including heart attack, heart/renal failure, limb amputation, stroke or death. Embolic protection devices (EPDs) prevent or reduce debris from reaching and obstructing vessels, potentially reducing adverse outcomes. They are commonly used during carotid artery stenting (CAS), in saphenous vein grafts (SVG) and increasingly in lower extremity procedures.

## EPDs and the Wirion system

[Embolism protection devices](#) are based on 1) blocking blood flow either before/after the lesion (proximal/distal occlusion balloons) plus aspiration of debris, or 2) filtering the blood after the target lesion (distal filters). Key considerations are the EPD fit and ease of use in tortuous vessels, the 'landing zone', or space available to deploy the device in the vessel, whether it is feasible to stop blood flow in the location (occlusion systems), the risk of dislodging debris when passing through the plaque (a risk with distal systems), and the risk of microemboli passing through the filter. Filter systems maintain blood flow and are relatively easy to use: [seven out of the 10](#) EPDs currently available in the US are filter-based.

The Wirion EPD system consists of a filter pre-loaded into a delivery catheter, which can be fed along any guide wire of the physician's choice. It is delivered through the lesion to the required position along the wire and remotely locked into position. When the delivery catheter is withdrawn, the rugby ball-shaped nylon mesh filter expands inside the vessel (up to 6mm in diameter). Blood can flow through the 120µ pores, enabling physicians to use contrast media for visualisation. After stent deployment, a retrieval catheter captures and withdraws the filter containing the debris.

## Wirion competitive positioning

EPD products approved in the US include AccUNET and Emboshield NAV6 (Abbott Vascular), FilterWire EZ (Boston Scientific), Angioguard (Cordis Corp), SpiderFX (EV3/Covidien, acquired by Medtronic in 2015), FiberNet (Medtronic) and the Gore Filter (Gore). Wirion's advantage lies in the fact that it can be locked onto any commercial guide wire at any position along the wire (unlike pre-fixed dedicated wire systems), its single-size filter fits vessels up to 6mm and its small pore size should capture most clinically relevant emboli. By contrast, Wirion's closest competitor, the SpiderFX device, is fixed to its dedicated Capture Wire and has a more complex delivery involving a primary guide wire followed by the Capture Wire. SpiderFX comes in five filter sizes for different vessel diameters and has a larger pore size, which increases the risk of a microembolism passing through the filter.

## Clinical data: Regulatory pathway

Wirion clearly met its primary endpoint in the pivotal [WISE open label trial](#) in 120 high surgical risk patients undergoing carotid artery stenting (CAS) comparing safety and performance to historical data from approved filter EPDs. The MACCE (Major Adverse Cardiac and Cerebrovascular Events) rate at 30+/-7 days post treatment was 3.3% vs 6.3% for historical control (p=0.0008), as shown on the [product's label](#).

In June 2015 Wirion received [FDA clearance](#) (classified as Class II via the 510(k) pathway) and approval in Australia and New Zealand from the Therapeutic Goods Administration (TGA) for embolic protection during carotid artery catheterisation procedures. It has been approved in Israel (AMAR) and Europe (CE Mark) for use in interventional vascular procedures including carotid, coronary, renal and lower extremities. To date, the Wirion system has been used successfully in over 600 cases in a variety of clinical indications, receiving favourable feedback from leading European and US physicians, according to the company. Allium now has FDA IDE (Investigational Device Exemption) approval to conduct a further US clinical trial to expand the indication to cover

lower extremities and this is currently underway. The study ([NCT02780349](#)) will enrol 153 patients, with an interim analysis following the enrolment of 100 patients. The study is expected to complete in 2017.

## Market opportunity

The global embolic protection devices market is estimated to grow at a CAGR of around 10% during 2016-20, driven by the rise in cardiac disease and the shift towards minimally invasive, non-surgical procedures to unblock arteries, according to market research firm [Research and Markets](#). The global EPD market was estimated at \$200m in 2009, rising to over \$700m in 2013, according to Allium's research based on 2009 numbers published in START-UP magazine. Another [report](#) points to \$500m in 2015. In addition to carotid and coronary indications, the large underserved market of peripheral arterial disease (PAD: plaques in arteries serving legs, arms, stomach and kidneys) could represent a significant opportunity. There are thought to be around 10 million people in the US with PAD, though only 2.5 million are currently diagnosed, leading to 600,000 interventions including stenting, balloon angioplasty, plaque removal and even amputations (source: [Med Device online](#)). With ease-of-use advantages over its peers, Wirion has clear potential in this market but, in our opinion, needs to gain approval for use in lower extremities to present a competitive label. We would also expect Allium to seek a marketing partner to bolster forces against the market leader Medtronic, which markets SpiderFX following its acquisition of Covidien.

## Early-stage products may provide upside

---

### Allevetix: Addressing gastric surgery for obesity and diabetes

In a joint venture with the NUS Allium is developing Allevetix, a gastroduodenal sleeve (GDS), as a minimally invasive alternative to gastric bypass surgery for obese Type 2 diabetic patients. It is currently in development, with a clinical trial planned in Singapore starting in 2017, in preparation for CE mark submission in Q417. The R&D has been supported by non-dilutive funding from the Singapore-Israel Industrial R&D fund (SIIRD). Nearly 13% of the world's adults are obese (body mass index [BMI]  $\geq 30$ ) and 39% are overweight (BMI  $\geq 25$ ), according to [World Health Organization](#) data from 2014. In the US, one-third of the population is obese, and far more overweight ([Centers for Disease Control](#), CDC). Increased BMI is a [major risk factor](#) for diabetes, cardiovascular disease and cancer; over 85% of people with Type 2 diabetes are overweight/obese ([American Diabetes Association, ADA](#)). The ADA now recommends weight reduction (bariatric) surgery for diabetics with a BMI  $> 35$ , if glycaemic control by medication/diet is poor ([2016 ADA guidelines](#)).

The most common bariatric procedures in the US are laparoscopic sleeve gastrectomy (42%), Roux-en-Y gastric bypass (RYGB, 34%) and adjustable gastric band (14%); according to [data](#) from the American Society for Metabolic and Bariatric Surgery, there were 179,000 surgeries in total in 2013. Although effective, these procedures require general anaesthesia, have morbidity rates of 3-20% and, apart from banding, are irreversible. Average excess weight loss in obese patients is around 68% for gastrectomy, 62% for RYGB and 48% for gastric banding ([Buchwald et al, JAMA 2004](#)). Significantly, diabetes [has been shown](#) to completely resolve in 77% of patients and improve in 86%. Despite this, [only 1%](#) of the 18 million eligible US adults undergo bariatric surgery, as a result of perceived invasiveness, high morbidity, cost and restricted insurance coverage. [Average costs](#) in the US range from \$8,000 for balloon surgery, \$15,000 for banding, \$19,000 for gastrectomy to over \$24,000 for bypass surgery. Less invasive approaches, performed through the gastrointestinal tract using flexible endoscopes, may offer potentially superior safety, cost and patient access.

There are four types of FDA-approved devices designed to treat obesity: gastric bands (Lap-Band, Realize), an electrical stimulation system (VBLOC Maestro), intragastric balloons (Orbera,

ReShape Duo, Obalon) and a gastric emptying system (AspireAssist). There are more devices commercially available outside the US, including additional balloons, a duodenal bypass liner (EndoBarrier) and endoscopic suturing devices for sleeve gastropasty (OverStitch, Incisionless Operating Platform and ACE stapler). Excess weight loss efficacy for balloons and barriers is between 20-40%, slightly lower than that of more invasive and irreversible gastropasty approaches.

Allium's GDS device is currently in the final stages of design development with a clinical trial in 20 patients planned at NUS starting in 2017, in preparation for CE mark submission in Q417 and potential commercialisation in 2018. Allium has stated that commercialisation will be handled by the NUS joint venture.

The [US, China, India and Russia](#) have the highest numbers of obese individuals. The market for bariatric surgery devices is expected to grow from \$1.4bn in 2015 to \$2.2bn by 2020, according to the [BCC Research 2016](#) market research report. Given the high cost and low utilisation rate of conventional procedures, there is room for minimally invasive therapies to expand patient uptake beyond the current c 200,000 procedures in the US.

## BMV: A design device for mitral valve replacement

BMV is a company focused on developing a device for minimally invasive TMVR. Allium hired the leading key engineers of BMV, a team with a strong background in cardiovascular companies.

In pulmonary circulation, oxygenated blood leaves the lungs and reaches the left atrium via the left pulmonary veins. Blood flow in the heart from the left atrium to the left ventricle is regulated by the mitral valve. As the ventricle relaxes and fills, the mitral valve (MV) is open allowing blood to flow passively into the dilating left ventricle. The mitral valve has two flaps held in place by chords attached to the interior wall of the ventricle which makes it relatively complex. Once full, the left ventricle contracts strongly, circulating blood around the body. The mitral valve stops this pressurised blood flowing back into the atrium. When regurgitation is present, blood flows backwards and the body does not get the necessary amount of blood. In moderate to severe mitral regurgitation (MR), the heart changes to adapt to pumping more blood. These changes occur over the years and may lead to heart failure.

MR is treated by surgery, in most cases by MV repair, in which the surgeon either reinforces the valve by sewing a ring around it (annuloplasty) or shapes, trims or rebuilds the flaps of the valve. If the valve has too much damage, the MV will be replaced with a new one made of titanium, carbon or biologic materials. Allium's BMV device is intended for MV replacement.

Allium's device is based on IP filed with the US Patent and Trademark Office (USPTO). The patent titled [Method for implanting prosthetic valve](#) was filed on 8 July 2010 (priority date) with number 12/803,849 and was granted on 2 April 2013. Allium's development plan will run for three years and is expected to cost \$5-6m until animal proof of concept has been achieved and the product is ready to enter a first-in-human study in collaboration with a partner to achieve CE mark. Exhibit 6 shows the development plan.

Exhibit 6: Development plan				
Milestone	Activity	Year 1	Year 2	Year 3
Milestone I – Final design	New valve development	█		
	Ex vivo animal trials	█		
	Valve design	█	█	
	Preliminary animal study		█	
Milestone II – Start human study	Verification and validation (V&V)		█	
	Animal GLP study			█
Milestone III – CE approval	Human study			█

Source: Edison Investment Research, Allium Medical

In the EU the BMV device will need to get Class III CE mark approval. A clinical trial will be required but in surgical devices this will be open label. In the US the company will likely have to first run an Early Feasibility Study (EFS), which is a clinical study conducted in a small number of subjects to obtain initial insights into the efficacy and safety of the device. For significant risk devices (devices intended for implant and representing a serious risk for the health, safety or welfare of a subject), the US FDA grants an [Investigational Device Exemption \(IDE\)](#) that allows sponsors to conduct an EFS. For this type of device, the sponsor must first submit an IDE application and obtain FDA approval. Larger trials will be needed to gain full approval as a Class III product. It will need to follow the premarket approval (PMA) route. We believe the company may need to partner to achieve this.

There are a number of companies developing minimally invasive mitral valve replacement devices, with CardiAQ (Edwards Lifesciences) and Tiara (Neovasc) potentially entering the market as soon as 2017. Tendyne (Abbott), Twelve (Medtronic) and Fortis (Edwards Lifesciences) are undergoing EFS. Among other TMVRs in development are Valtech Cardio's Cardiovalve, HighLife Medical's TMV, Micro Interventional Devices's EndoValve, Gorman's TMV, MitrAssist and MValve's TMV. There is little information available as no data have been published.

Challenges remain as the MV is different from the aortic valve, especially in terms of anatomy and haemodynamics. Additionally, patients subject to MV replacement are usually very sick and not suitable for surgery, which results in increased mortality and morbidity. Clinical data from the first patients treated with CardiAQ, Tendyne, Twelve, Tiara and Fortis have shown [mortality rates](#) in the range of 25-38.5% at 30 days post-implantation. Results from the First Multicenter Global Registry in 64 patients with mitral annular calcification (MAC) that underwent TMVR with balloon-expandable valves showed a 30-day, all-cause mortality rate of 29.7%. The [study](#) concluded that this procedure may be an alternative for selected high-risk patients with limited treatment options. This contrasts with pooled data from 127 very high risk patients from the EVEREST II high risk registry and REALISM studies, which showed 30-day mortality of 6.3% with MitraClip vs the 13.2% predicted mortality of the Society of Thoracic Surgeons (STS) for MV replacement. Given the fact that Allium is at least three years behind the most advanced competitors, the success of the BMV device will be predicated on addressing the [challenges](#) of this type of device and will be part of the next generation of devices with a sound risk/benefit balance. An estimated four million people in the US have significant (>2+) MR, with an annual incidence of 250,000 newly diagnosed patients. In the EU approximately 20,000 mitral valve repair procedures are performed annually. As no TMVR devices are currently commercialised, the most similar benchmark is Abbott's MitraClip for MV repair, which sells for \$30,000. The procedure is not fully reimbursed under Medicare, where the payment is based on a standard, fast, coronary angioplasty. MitraClip is limited to patients who are too ill for open heart surgery. A [2014 report](#) states that 10,000 procedures had used the device and that implantation now takes about 100 minutes.

## Commercialisation strategy

---

Allium markets its products through distribution agreements with local partners. These agreements are exclusive and require the partner to purchase a minimal amount of product; the partner is also responsible for regulatory approval and marketing of the product. Exhibit 7 shows the recent distribution deals signed, including the value and period of time.

**Exhibit 7: Significant distribution deals signed by Allium**

Country	Value (NISm)	Period (years)	Start year
<b>Allium Stents</b>			
China	58.0	8	2018
India	5.6	6	2018
Canada	3.7	5	2015
<b>Allium Stents and IBI (EndoFast)</b>			
Russia	48.0	5	2017
Czech Republic & Slovakia	2.0	5	2015
Kazakhstan	5.0	5	2017
Taiwan	3.0	5	2016
Turkey	9.0	5	2015
Argentina	4.5	5	2015
Spain	8.7	5	2015
Mexico	26.0	5	2017
South Korea	4.5	5	2016
<b>IBI (EndoFast)</b>			
Italy	6.5	6	2016
<b>Total</b>	<b>184.5</b>		

Source: Allium Medical Solutions

According to Allium, the partner initially sells to private centres and markets to public centres once reimbursement has been achieved. Allium sells its products to distributors at an agreed transfer price, which is lower than the prevailing end-user market price (an average of c NIS2,500 per stent in 2015). We understand that a distributor generates around a 50% margin on the final selling price and that distributors are subject to penalties in the case of breaching agreement terms (for example for not being able to sell pre-agreed volumes). Allium has the right to terminate the agreement, terminate exclusivity or raise prices.

Historically, Allium has followed this model in certain countries in Europe as well as Israel, Australia and South Africa. It plans to expand to new markets, mainly China, Mexico and Russia. Exhibit 8 shows the main markets and the strategy followed there.

The main risks to achieve the sales level set in the agreements and grow revenues in established markets pertain to achieving marketing approval within reasonable timelines, achieving reimbursement, increasing prices and maintaining a stable collaboration with the local distributor. Allium has only changed distributors in two countries in its history of commercialisation.

**Exhibit 8: Key markets overview**

Market	2015 sales	Projected sales* (2016-20)	Comments
<b>Established markets (relatively mature markets providing the majority of historic revenues)</b>			
Germany, France, Italy, Spain, Turkey, Australia and South Africa	NIS3.1m (81% of stent sales)	From NIS3.5m in 2016 to NIS7.4m at a CAGR of 20% (33% of total revenue in 2020e)	Revenues are heavily dependent on reimbursement. Sales grew significantly in Italy, France and Germany after reimbursement was achieved. Turkey has recently changed distributors to a new, larger one.
<b>Emerging markets (virtually no sales in 2014/15, the strongest growth potential)</b>			
China, Mexico, Russia	Sales to China at only 1% of total revenue	From NIS0.2m to NIS10.4m at a CAGR of 176% (46% of total revenue in 2020e)	Sales in China have been small due to lengthy regulatory process. The company expects to obtain an approval in Russia and China by end 2017 and in Mexico in the next six months. Russia is expected to be partly reimbursed.
<b>New markets (some sales were generated in 2015, strong growth is expected)</b>			
UK, Israel, Argentina, South Korea	Sales of NIS0.3m in 2015, mainly from the UK, Argentina	From NIS0.9m to NIS3.5m at a 41% CAGR (15% of total revenue in 2020e)	South Korea is expected to grow at a fast pace once reimbursement has been achieved (Q316). Strong growth in the UK, but from a low base.

Source: Edison Investment Research, Allium Medical Solutions. Note: \*Edison estimates based on company guidance.

## Sensitivities

---

Our forecasts and valuation are based on Allium's ability to execute on its ambitious growth strategy, with revenues expanding at a double-digit rate as the company continues to gain market share in established and new regions. However, growth is heavily reliant on the distribution agreements with local partners and their ability to market and sell Allium's products (which in turn is significantly dependent on reimbursement). Such a reliance on third parties may add to earnings volatility and affect execution. In addition, stent pricing may represent a risk as distributors have certain bargaining power. While Allium has so far managed to keep costs under control, we note that stents are manufactured in house, but components depend on external suppliers.

EndoFast devices are advanced soft fixation devices, which are believed to be less invasive than those of competitors. However, given previous experience with the first generation of these devices and the fact that certain companies pulled their products from the market, we believe that marketing in the US and other regions may bring challenges in gaining acceptance by doctors and regulators.

Gardia Medical has had limited commercialisation and revenue expansion depends on finding partners for target regions or a major player with global reach. Allium has indicated that it is in the process of engaging a leading global company for a strategic transaction. Allevetix and BMV face challenges prior to achieving commercial production, which include successful design and manufacturing, positive clinical trial and study results and obtaining regulatory approval from regulatory authorities. This is a significant undertaking and may require the company to partner with larger and more experienced market players.

Competition is intense in all divisions and the position of Allium's products as differentiated premium products, as well as the marketing capabilities of its partners, will be crucial to grow revenues.

## Valuation

---

We value Allium at NIS1.95-2.08 per share using a DCF approach based on a 12.5% discount rate (10% for terminal value), explicit free cash flow forecast for Allium Stents, IBI and Gardia to 2026 and a 2% terminal growth rate. We arrived at a range by applying a 52-week low/high US\$/NIS exchange rate of 3.74-3.98. Our valuation is largely driven by the anticipated increase in stent sales, which should mainly come from the 'recently established' (South Korea, UK, Argentina) as well as 'emerging' (China, Russia, Mexico) markets. We see 'established' markets (Europe, South Africa, Australia) growing at a relatively slower pace (Exhibit 8). Our base case scenario implies overall revenue CAGR of 41% for 2015-20e (43% for Allium stents). While this compares to somewhat slower sales expansion in 2011-15 (19% total revenue CAGR; 5% in 2013-15), we note that the company has recently been actively signing new distribution agreements, largely aimed at penetrating new markets (Exhibit 7). This has resulted in a healthy revenue uptick in H116 (NIS3.9m vs NIS2.5m in H115) and some margin expansion. We expect this trend to continue in the foreseeable future. However, should the company fail to execute on its aggressive growth strategy, we see a significant downside risk to our valuation (and vice versa). Thus, a 50% slower sales roll-out in China, Russia and Mexico in 2016-20 would lower our DCF valuation by c 25%. Overall, we expect these 'emerging' markets to contribute c 45% to Allium stents revenue by 2020 (Exhibit 10) compared to virtually zero contribution in 2015.

Given its relatively early (preclinical) stage, we have ascribed a book value to Allevetix based on estimated historic and future R&D spent (we understand that the company invests c 18% of total R&D in Allevetix). We have not included BMV in our valuation, as the company has not yet outlined a clear development plan for this project and we therefore have very low visibility on its potential. We expect to include both Allevetix and BMV in our valuation as human data are released.

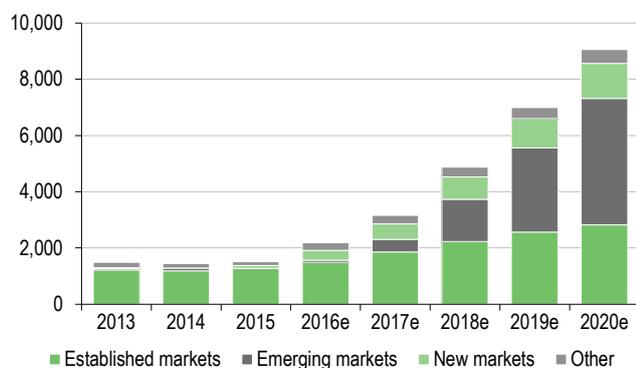
Finally, we note that the company is currently not paying taxes due to the loss-making nature of the business. We understand that it will be able to use tax credits to offset future tax losses. We estimate that these credits will be enough to cover the explicit forecast period to 2026. For the terminal cash flow we assumed a corporate tax rate of 25%.

**Exhibit 9: Allium summary DCF valuation**

	\$'000s	NIS'000s
PV of explicit FCF forecast (2017-26e)	3,958	15,223
Terminal Value (2% TGR)	44,211	170,042
PV of Terminal Value	15,316	58,909
Value attributed to Allevetix (estimated BV)	2,219	8,535
<b>Total NPV</b>	<b>21,493</b>	<b>82,667</b>
Add net cash (2016e)	6,179	23,765
<b>Implied equity value</b>	<b>27,672</b>	<b>106,432</b>
Number of shares, m	52.9	52.9
<b>Per basic share</b>	<b>\$0.52</b>	<b>NIS2.01</b>

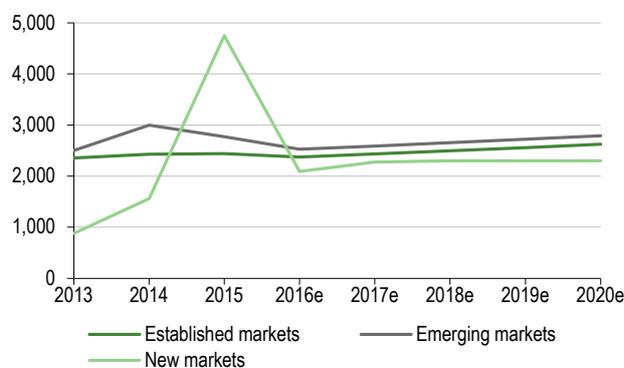
Source: Edison Investment Research. Note: US\$ values are based on the spot exchange rate.

**Exhibit 10: Allium stents unit sales forecast**



Source: Allium, Edison Investment Research. Note: Regional classification is subjective and based on Edison's view on growth.

**Exhibit 11: Allium stents price forecasts, NIS**



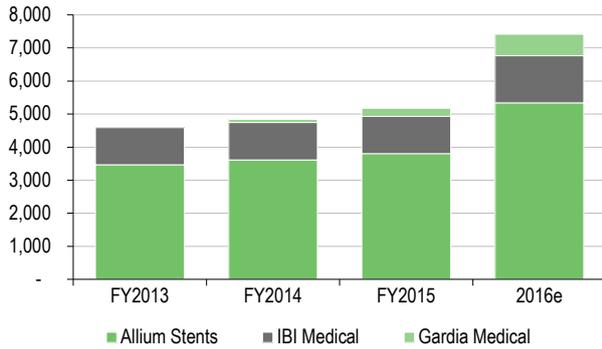
Source: Allium, Edison Investment Research. Note: 2013 pricing in 'new markets' was affected by a insignificant transaction in China.

In addition to DCF, we cross-check our valuation using a target multiples approach. We note that Allium currently trades on FY16e EV/Sales of 5.9x. This compares to FY17e (to April 2017) EV/Sales of 4.4x for Medtronic, a significantly larger peer of Allium's. Given Allium's superior growth profile (albeit coupled with more pronounced earnings volatility and execution risks), we believe that some valuation premium to more established peers might be justified. Applying a multiple of 5.5x to our 2020e revenue forecast of NIS30m and then discounting back to 2016 would result in an implied equity value of NIS2.00/share, which is in line with our DCF valuation.

## Financials

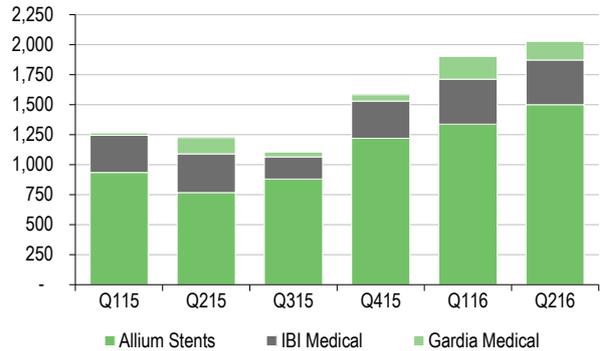
Allium gets the bulk of its revenues from the stents division (c 73% in 2015), followed by IBI Medical (c 22%) and Gardia Medical (c 5%). Total revenue grew at a 5% CAGR in 2013-15, reaching NIS5.2m in FY15 (2011-15 CAGR of 19%). Based on the reported half year results and our projections for H216, we forecast revenue growth of c 43% to NIS7.4m in 2016 as we expect to see the benefits of the recently increased partnering activity. On a quarterly basis, sales have grown at a CAGR of 10% from Q115 to the last reported quarter of Q216. We note the seasonal impact on the quarterly performance as sales tend to decline during the summer period, normally resulting in lower revenues in the third quarter compared to the second quarter.

**Exhibit 12: Allium sales by division, NIS000s**



Source: Edison Investment Research, Allium Medical Solutions

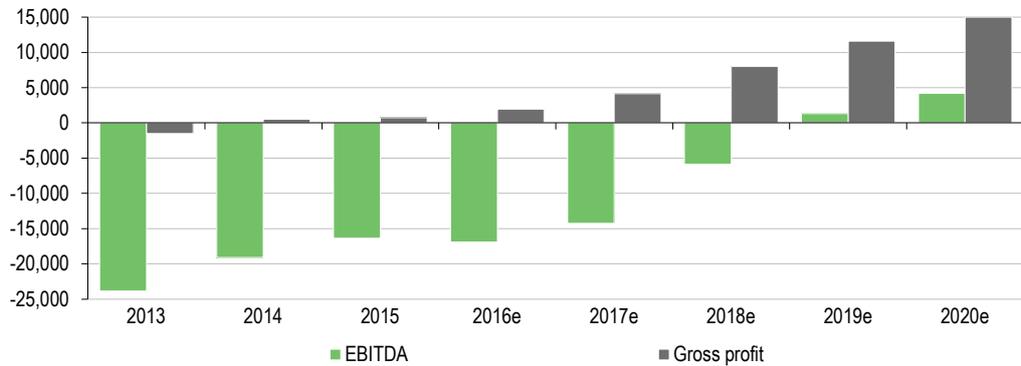
**Exhibit 13: Quarterly sales by division, NIS000s**



Source: Edison Investment Research, Allium Medical Solutions

Allium reported gross margin of 15% in FY15, rising to 29% in Q216. We model gross margin of 27% in FY16 rising to 37% in FY17 and further to c 50% by 2020 driven by the increase in sales and operating leverage. Apart from direct production costs, cash operating expenses are primarily made up of R&D, G&A and sales and marketing (S&M) costs. While S&M are likely to continue to grow gradually and G&A to remain at broadly the same levels as partners bear the majority of regulatory and marketing costs, we expect R&D to decline materially from 2018 as Allium spends less on Allevetix and Gardia (we understand that Allium considers different options regarding Gardia, but for now continue to model it as part of the overall business and valuation.) This should aid overall profitability and we expect the company to reach EBITDA break-even in 2019.

**Exhibit 14: Allium's gross profit and EBITDA evolution, NIS000s**



Source: Allium, Edison Investment Research. Note: Gross profit is adjusted for one-offs.

Allium has recently undertaken two equity raises. In the first raise, its German distributor invested NIS1.1m (597,000 shares at NIS1.8/share); in the second, the company raised NIS13.8m in a private placement by offering 10.6m shares at NIS1.3 per share. In addition, the company reported cash and short-term deposits of NIS18.8m as of the end of June 2016. Based on our revenue and cost forecasts, we believe that the available funds should largely be enough to see the company through to profitability. We also note that Allium has c 19m options (c 36% of the outstanding share capital) which, if exercised, could bring extra cash (albeit with a likely dilution).

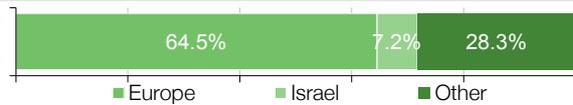
**Exhibit 15: Financial summary**

	NIS'000	2014	2015	2016e	2017e	2018e
Year end 31 December		IFRS	IFRS	IFRS	IFRS	IFRS
<b>PROFIT &amp; LOSS</b>						
Revenue		4,916	5,178	7,420	11,196	17,470
Cost of Sales		(4,407)	(4,421)	(5,453)	(7,069)	(9,471)
Gross Profit		509	757	1,967	4,127	7,999
EBITDA		(19,080)	(16,333)	(16,887)	(14,223)	(5,835)
Operating Profit (before GW and except.)		(19,465)	(16,759)	(17,278)	(14,585)	(6,167)
Intangible Amortisation		(2,032)	(1,705)	(1,564)	(1,450)	(1,328)
Exceptionals		(2,554)	(720)	0	0	0
Operating Profit		(24,051)	(19,184)	(18,842)	(16,034)	(7,495)
Net Interest		(592)	(1,748)	(850)	(449)	(239)
Exceptionals		0	0	0	0	0
Other		0	0	0	0	0
Profit Before Tax (norm)		(20,057)	(18,507)	(18,128)	(15,033)	(6,407)
Profit Before Tax (IFRS)		(24,643)	(20,932)	(19,692)	(16,483)	(7,735)
Tax		0	0	0	0	0
Profit After Tax (norm)		(20,057)	(18,507)	(18,128)	(15,033)	(6,407)
Profit After Tax (IFRS)		(24,643)	(20,932)	(19,692)	(16,483)	(7,735)
Average Number of Shares Outstanding (m)		18.43	28.53	44.97	52.94	52.94
EPS - normalised (NIS)		(1.09)	(0.65)	(0.40)	(0.28)	(0.12)
EPS - IFRS (NIS)		(1.34)	(0.73)	(0.44)	(0.31)	(0.15)
Dividend per share (NIS)		0.00	0.00	0.00	0.00	0.00
Gross Margin (%)		10	15	27	37	46
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		28,218	46,619	28,764	27,052	25,492
Intangible Assets		26,438	24,059	22,495	21,045	19,717
Tangible Assets		1,780	1,472	1,181	919	687
Other		0	21,088	5,088	5,088	5,088
Current Assets		16,631	31,344	28,323	13,749	8,004
Stocks		2,330	2,277	2,215	2,527	2,834
Debtors		686	889	1,220	1,534	1,914
Cash		12,942	27,055	23,765	8,566	2,133
Other		673	1,123	1,123	1,123	1,123
Current Liabilities		(5,560)	(5,620)	(5,536)	(5,833)	(6,363)
Creditors		(1,516)	(1,524)	(1,440)	(1,737)	(2,267)
Deferred revenues		(1,820)	(1,895)	(1,895)	(1,895)	(1,895)
Other short term liabilities		(2,224)	(2,201)	(2,201)	(2,201)	(2,201)
Long Term Liabilities		(8,947)	(8,102)	(8,002)	(7,902)	(7,802)
Long term borrowings		0	0	0	0	0
Deferred revenues		(1,820)	(1,895)	(1,895)	(1,895)	(1,895)
Other long term liabilities		(7,127)	(6,207)	(6,107)	(6,007)	(5,907)
Net Assets		30,342	64,241	43,549	27,066	19,332
<b>CASH FLOW</b>						
Operating Cash Flow		(19,024)	(15,874)	(18,090)	(14,999)	(6,233)
Net Interest		0	0	0	0	0
Tax		0	0	0	0	0
Capex		(349)	(164)	(100)	(100)	(100)
Acquisitions/disposals		0	0	0	0	0
Financing		25,191	31,992	15,000	0	0
Dividends		0	0	0	0	0
Other		(41)	(1,841)	(100)	(100)	(100)
Net Cash Flow		5,777	14,113	(3,290)	(15,199)	(6,433)
Opening net debt/(cash)		(7,165)	(12,942)	(27,055)	(23,765)	(8,566)
HP finance leases initiated		0	0	0	0	0
Other		0	0	0	0	0
Closing net debt/(cash)		(12,942)	(27,055)	(23,765)	(8,566)	(2,133)

Source: Edison Investment Research, Allium Medical Solutions accounts

**Contact details**

2 Ha'Eshel St., PO Box 3081  
 Caesarea Industrial Park South, 3088900 Israel  
 +972 4 6277166  
 www.allium-medical.com

**Revenue by geography**

**Management team**
**CEO: Asaf Alperovitz**

Mr Alperovitz is a Certified Public Accountant and holds a Bachelor's degree in Accounting and Economics and an MB from Tel Aviv University. He has held C-suite positions at several pharmaceutical and medical devices companies. Prior to his career in the healthcare industry, he was CFO of software company Corigin and later CFO of textile company Tefron. He then went on to become CFO of Omrix Biopharmaceuticals, acquired by Johnson & Johnson in 2008. Mr Alperovitz later became CFO of Syneron. He has held several management positions in the high-tech area of Ernst & Young, both in Israel and in California for eight years. He joined Allium Medical in 2012.

**CFO: Ariel Rubashkin**

Mr Rubashkin is a Certified Public Accountant and holds a Bachelor's degree in Accounting and Economics from Haifa University and an MBA from Tel Aviv University. Before joining Allium Medical in 2014, he was global VP of Finance for medical devices company Syneron and controller at Plastro Gvat.

**COO: Shay Arotchas**

Mr Arotchas has a BSc in Engineering and Management from Coventry University in London and more than 14 years' experience in IT and operations in the medical device industry. He has been strategic project manager and later head of strategic material planning at Converse Technologies. He served as the VP of operations in Disc-O-Tech Medical Technologies which was acquired by Kyphon/Medtronic Corp, before becoming COO of Allium Medical in 2012.

**VP of Sales and Marketing: Itay Jacob**

Mr Jacob has a BA in Medical Business Management from Ben-Gurion University of the Negev and an MBA from Ono Academic College. He joined Allium Medical in 2014 after holding sales roles at Mennen Medical & MTRE. Prior to that he started his own company, Innovative Marketing Solutions, a consulting firm specialising in the medical device sector.

**Principal shareholders**

	(%)
Filvest	25.69
Michael Ilan Management and Investments	9.89
The David Milch Family 2010 Trust and David Milch	9.35
Meitav	7.67

**Companies named in this report**

Pnn Medical, TaeWoong (044490 KS), Boston Scientific (BSX US), Urotech, Olympus (7733 JP), Optimed, Gohar Shafa, Rocamed, SRS and CR Bard (BCR US), Johnson & Johnson (JNJ US), Endo Pharmaceuticals (ENDP US), Coloplast (COLOB DC), Orbera, Realize, Edwards LifeSciences (EWE US), Abbott (ABT US), Medtronic (MDT US), Neovasc (NVC CN), MitrAssist, Valtech Cardio, High Life Medical, Micro Interventional Devices, Gorman Cardiovascular Research Group, MValve Technologies

Edison, the investment intelligence firm, is the future of investor interaction with corporates. Our team of over 100 analysts and investment professionals work with leading companies, fund managers and investment banks worldwide to support their capital markets activity. We provide services to more than 400 retained corporate and investor clients from our offices in London, New York, Frankfurt, Sydney and Wellington. Edison 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](http://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 2016 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 2016. "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.