

aap Implantate

Continuing to execute strategy on core focus

Q216 results were in line with the upper end of company guidance, with sales of €3.4m and an EBITDA loss of €1.4m. aap Implantate continues to focus on its strategic transition to being a pure trauma company, following the recent sale of its Biomaterials business. As the company continues to drive sales of LOQTEQ in Western Europe and the US alongside the implementation of cost reduction measures, we could see a return to sustained growth.

Q216 results

aap Implantate reported sales and EBITDA in line with the upper end of its guidance. It reported sales of €3.4m (guidance €2.5-3.5m) and an EBITDA loss of €1.4m (guidance loss of €1.5-2.5m). This was achieved against the backdrop highlighted by the company in which a number of BRICS and SMIT states' markets remain volatile such as China, Russia and Turkey and continue to make no contribution to sales. It is encouraging that aap Implantate delivered on guidance as it announced in Q1 that it had started a number of initiatives to drive Trauma sales in more established markets (Western Europe and the US). US sales were reported at €0.7m in Q2, an increase of 250% from Q215 (€0.2m). In our opinion, the progress of uptake in the US market is key to the success of LOQTEQ.

Key growth drivers

Key growth drivers in FY16 and FY17 include growing sales in more established markets (Western Europe and the US), increasing LOQTEQ indication coverage, CE marking and submission for FDA approval for its antibacterial silver coating. Management guidance remains at 20% revenue growth for Trauma products in FY16.

Valuation: Upside potential with continued focus

Q2 results demonstrate that aap has taken the first step to move back to revenue growth through various initiatives. The company is well funded following the sale of its Biomaterials business in Q2, with reported cash of €32.2m for the group at 30 June 2016. It intends to use part of the proceeds from the sale of its Biomaterials business to drive its pipeline forward and distribute part of it to its shareholders, for example, a dividend payment possibly in FY17. We expect upside potential if the increased initiatives to drive sales in the more established markets (US and Western Europe) continue to prove fruitful. In addition, a final feedback from the EU authorities on the CE mark for aap's silver coating is expected for late 2016/early 2017. The submission of the documents for FDA is planned for 2017.

Consensus estimates

| Year end | Revenue (€m) | PBT (€m) | EPS (c) | DPS (c) | P/E (x) | Yield (%) |
|----------|--------------|----------|---------|---------|---------|-----------|
| 12/14 | 30.6 | (1.7) | 0.0 | 0.0 | N/A | N/A |
| 12/15 | 28.0 | (5.3) | (0.2) | 0.0 | N/A | N/A |
| 12/16e | 31.8 | (1.7) | (0.2) | 0.0 | N/A | N/A |
| 12/17e | 34.5 | (0.3) | (0.0) | 0.0 | N/A | N/A |

Source: Bloomberg, aap Implantate accounts

Healthcare equipment & services

7 September 2016

Price €1.22
Market cap €38m

Share price graph



Share details

Code AAQ
Listing XETRA
Shares in issue 30.8m

Business description

aap Implantate is a German medtech company, focused on developing, manufacturing and selling products for bone fractures. This is primarily the LOQTEQ trauma plating system alongside earlier-stage innovations including antibacterial silver coating technology and magnesium-based implants.

Bull

- Proven technology and strong IP protection.
- Transition to a pure trauma player enables a focus on building the core business.
- Focused on driving sales in more established markets – increased distributors in the US and an experienced head of US sales engaged.

Bear

- FY15 sales were down by 9% on FY14. Trauma sales were down 16%. Q2 demonstrated an improvement, but risk remains in the execution of the strategy.
- The orthopaedic space is dominated by a few large players, making it difficult for a small player to gain traction.
- Impact of increased sales focus on established markets will not be fully demonstrated until H216.

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Core business now focused on trauma

In March, aap announced that it had signed a share purchase agreement for the disposal of its subsidiary, aap Biomaterials, to a European private equity firm for an assumed enterprise value of €36m. As a result of the disposal, aap has become a fully focused trauma player.

The trauma portfolio centres on three technologies: aap's anatomical plating system (LOQTEQ) for fracture repair; its antibacterial silver coating technology, which prevents the formation of biofilm and therefore reduces infection; and magnesium-based implants, which are biodegradable in the body.

Plating system – LOQTEQ

Anatomically shaped trauma plates are used in orthopaedic surgery to join fractured bones. This is referred to as internal fixation, as opposed to external fixation of a fracture via a splint or plaster cast. Internal fixation has been widely available for around the past 50 years, and plate and screw technology has evolved and developed to improve healing and repair.

The most recent advances combine the use of “locking” and “compression” technology, where screws have been designed to lock into the plates themselves, while at the same time allowing bone fracture compression, all with minimal bone-plate interaction, shown in Exhibit 1. This approach provides support and stability, even in weak or multi-fragment fractures.

Exhibit 1: Locking and compression schematic



Source: aap Implantate presentation

The market leader is currently Synthes' Locking Compression Plate (LCP) system. LOQTEQ's design could offer a number of advantages over the traditional locking compression plating systems, including:

- locking mechanism: LOQTEQ's locking and compression is achieved by one screw in one hole with one step;
- potential clinical advantage if the design is proved to avoid 'cold welding' (locking screw becomes jammed in the plate) at the point of plate removal (none reported since its launch in 2012); and
- variable compression length (stepwise compression of 0, 1mm and 2mm) offering the surgeon choice and flexibility.

IP update

In the Q2 results the company announced a notice of allowance for a further US patent, which it terms an 'umbrella patent'. This patent reportedly integrates the claims from previous patents and, according to the company, offers comprehensive protection in the US and builds on its patent portfolio for the core technology of LOQTEQ.

Commercialising LOQTEQ key to unlocking potential in Trauma

The company's strategic aim is to drive sales in more established markets in Western Europe and the US, with the BRICS and SMIT markets such as China, Turkey and Russia continuing to make no contribution to sales due to the current difficult economic conditions. Q2 results are encouraging as aap has reported sales at the upper end of its guidance, which indicates that the sales initiatives it has been putting in place in 2016 are starting to deliver results. These measures have included growing its distributor base in the US and hiring an experienced head of US sales. In our opinion, the US market will be a key factor in the growth of the trauma business.

The company has indicated that its LOQTEQ indication coverage is over 90% for large bone fractures. The expansion of this coverage remains one of aap's targets, which is important as it will enable the company to better leverage its organisation's salesforce, build scale that can enable bundling offers to assist with uptake and enable surgeons to be consistent in their treatment approach, which could drive more conversions to the technology.

Potential advantage of a silver coating – platform technology

aap is working to commercialise its internally developed silver coating technology to improve infection prevention. It is a platform technology with potential in a number of different areas such as orthopaedics, cardiology, dentistry and other medical instruments.

It has the potential of addressing a critical problem found in surgery - infection. During a procedure it is possible for a medical implant to become colonised by bacteria, creating a biofilm around the implant. This can result in serious infection and is therefore important to prevent at an early stage. The silver coating technology could prevent the bacterial colonisation of the implants' surface and could therefore prevent infections and improve healing. Finally, the company also indicated that it has good biocompatibility and is cost-efficient to apply the technology due to the relatively short coating time and low level of capital investment required for the coating machines.

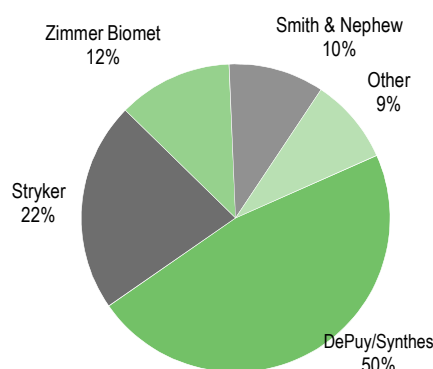
aap is actively engaged with both the European and US regulatory authorities to gain CE marking and FDA approval respectively. In the EU the company is currently in the process of a CE conformity assessment procedure for a silver coated LOQTEQ plate and in the US the company has indicated it has had an encouraging pre-submission meeting with the FDA. aap has also indicated it has had positive meetings with the EU authorities and is making amendments following feedback. We expect final feedback on the application in late 2016/early 2017. In the US, aap intends to submit the necessary forms for a 510k assessment in 2017.

Potential future prospect for implants – magnesium

Another aspect of aap's Trauma portfolio, which is being developed, is the fact that it is focused on leveraging its proprietary coating technology, in this case on magnesium based implants, to develop resorbable magnesium implants. Such implants could be used in trauma applications, particularly for small implants in, for example, hands and feet, and would remove the need for later explantation (removal) of the implant. The company has indicated that it has successfully tested coating a third-party magnesium implant. It expects to move this innovative development stream forward in 2017 if it can form a co-operation with a third party, whereby the third party would bring an approved alloy to the partnership and aap would bring its coating technology.

Valuation: Upside potential with continued focus

According to Smith and Nephew worldwide sales of orthopaedic products was estimated at c \$45.9bn in 2014 and growing at 7%. The trauma segment has demonstrated strong growth over recent years, driven primarily by an increase in fractures with increased participation in sport and an ageing population.

Exhibit 2: Trauma market (by company)


Source: S&N company presentation and Edison Investment Research

M&A has been a significant factor, which has led to considerable consolidation in the trauma market. For example, Synthes, the market leader in trauma, was acquired by J&J/DePuy alongside other mega deals such as Zimmer Biomet and Wright Medical – Tornier. Exhibit 2 above outlines the Trauma market share in respect of the various competing companies. We expect a gradual shift away from these scale-based acquisitions towards transactions that enhance value through innovation and enable a focus on category leadership and portfolio depth. In the longer term, providing aap delivers on its strategy, we consider that by becoming a trauma-focused company with proven technology, strong IP protection and with increased sales, it could attract M&A value.

We note that the average price paid in recent trauma-focused deals is 5.7x sales (see Exhibit 3 below). Per FY15 annual reports, aap has generated Trauma related sales of €12.3m in FY15.

Exhibit 3: Recent trauma-focused deals

| Acquirer | Target | Deal value (\$m) | LTM* sales (\$m) | Price/sales (x) |
|----------------|------------------------|------------------|------------------|-----------------|
| Stryker | Small Bone Innovations | 375 | 48 | 7.8 |
| Wright Medical | Biotech International | 80 | 15 | 5.3 |
| Tornier | OrthoHelix | 135 | 29 | 4.7 |
| Stryker | Memometal | 150 | 30 | 5.0 |
| Average | | | | 5.7 |

Source: Edison Investment Research. Note: *Last 12 months.

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