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29 July 2008

AOI Medical

Year End	Revenue (\$m)	PBT* (\$m)	EPS* (c)	DPS (c)	PE (x)	Yield (%)
12/06	0.0	(2.0)	(41.3)	0.0	N/A	N/A
12/07	0.0	(4.0)	(56.5)	0.0	N/A	N/A
12/08e	0.0	(11.2)	(132.8)	0.0	N/A	N/A
12/09e	11.7	(15.2)	(180.2)	0.0	N/A	N/A

Note: *PBT and EPS exclude goodwill amortisation and exceptional items.

Investment summary: Tapping into spinal market

AOI Medical's Ascendx device offers significant advantages over the current most-advanced surgical treatment of vertebral compression fractures. The investment case centres on AOI's completion of a 60-patient confirmatory clinical study before launching Ascendx in early 2009 and seeking a co-marketing partner. The firm operates in a consolidating sector and could be viewed as a potential takeover target.

US confirmatory clinical trial

A US FDA-mandated clinical study of Ascendx has started enrolling the required 60 patients, the first three of which have successfully undergone the procedure as of early June. The trial should generate data sufficient for filing under the 510(k) procedure later this year. Assuming a reasonably quick approval time, this should allow Ascendx to be launched in the US in early 2009.

Additional funding

In order to give AOI greater flexibility while running the trial, and to allow a salesforce build-up in preparation for market launch, we expect the company to seek to raise a significant amount of cash shortly. We note that AOI has just obtained investor approval to waive pre-emption rights over the issue of up to 15m new shares.

Partner or be acquired

AOI Medical intends to set up its own direct US sales presence, as well as seeking to enlist a co-marketing partner to drive up revenues. The company is expected to grow organically and could use a US IPO to broaden its shareholder base. It operates in a consolidating market, and a takeover is a possibility if Ascendx gains approval.

Valuation: DCF model suggests £44m

We have built a discounted cash-flow model that gives a current value for AOI Medical's business of around £44m – significantly above the company's EV of £15m. We also highlight as a comparator last year's acquisition of Kyphon by Medtronic for \$3.9bn, or almost 9x sales.

Price 226.5p
Market Cap £19m

Share price graph



Share details

Code AOI
Listing AIM
Sector Healthcare Equipment & Services
Shares in issue 8.4m

Price

52-week High 337.5 Low 206.0

Balance Sheet as at 31 December 2007

Debt/Equity (%) N/A
NAV per share (c) 127.8
Net cash (US\$m) 10.4

Business

AOI is based in Orlando, Florida, US, and focuses on developing minimally invasive medical devices for use in spinal and long-bone applications. It floated on AIM in June 2007.

Valuation

	2007	2008e	2009e
P/E relative	N/A	N/A	N/A
P/CF	N/A	N/A	N/A
EV/Sales	N/A	N/A	N/A
ROE	N/A	N/A	N/A

Revenues by geography

	UK	Europe	US	Other
0%	0%	0%	100%	0%

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Investment summary: Tapping into spinal market

Company description: Focus on spine surgery

AOI Medical is based in Orlando, Florida, US, and focuses on developing minimally invasive medical devices for use in treating vertebral compression fractures of the spine. It floated on AIM in June 2007, raising £8m.

Its investment case centres on the completion of a 60-patient confirmatory clinical study before launching its lead device, Ascendx, in early 2009 and seeking a co-marketing partner. A deal would expand the potential market by having the partner target spine surgeons while the new AOI salesforce focuses on specialist interventional radiologists, thus establishing two distinct call points for the two salesforces. AOI could use a future US IPO to broaden its investor base; it operates in a consolidating sector and could be viewed as a potential takeover target.

Valuation

We have built a discounted cash-flow model based around sales of the Ascendx device taken out to 2015. This is based on first market launch in 2009, a price per single-use tool set broadly in line with kyphoplasty (\$4,000), and initial sales of AOI's two other products. This gives a current value for AOI Medical's business in the region of \$87m, or roughly £44m – significantly above the company's current enterprise value of around £15m. We also highlight last year's acquisition of Kyphon by Medtronic for \$3.9bn, or almost 9x sales. If AOI raises additional funds to complete development of Ascendx, and additional clinical trial data become available, we will examine in greater detail the potential value of the company.

Sensitivities

Investors in AOI Medical face the usual risks associated with buying into a loss-making development-stage company, although significant value could be reached in the event of a licensing deal with a major partner or the launch of an attractively priced takeover. Sensitivities, both on the up- and the downside, include: potential litigation issues; clinical trial/regulatory delays beyond the company's control; insufficient adoption by physicians following market launch; the need to price Ascendx aggressively; potential upside if development of BAMF Trauma and Cervical Plate is expanded; the promise of other technologies offering advantages over kyphoplasty; and failure to strike a co-marketing deal to maximise the sales potential of Ascendx.

Financials

AOI finished 2007 with \$10.4m in cash and equivalents, and its success on the current assumptions depends on the company securing further funding. We note that AOI has obtained investor approval to waive pre-emption rights over the issue of up to 15m new shares, and estimate that around \$20m will be needed over the next 18 months to meet operating requirements – ie to build up AOI's small, direct salesforce targeting interventional radiologists.

Company description: Device focus on spinal applications

AOI Medical, a US-based company focusing on the development of medical devices to treat spinal and long-bone fractures, floated on AIM in June 2007, raising £8m. In the near term, its investment case rests on successfully carrying out a clinical study of its lead spinal surgery technology, before bringing it to the market through a direct salesforce (potentially with the help of a co-marketing partner). We expect the company to grow organically, although an alternative and very realistic scenario for investors is a takeover; AOI operates in a consolidating sector, and last year Kyphon – a competitor that developed less-advanced technology for the same use as AOI's lead product – was acquired by Medtronic for \$3.9bn (almost 9x sales).

AOI Medical was incorporated in November 2004; since then, it has developed two technologies based on balloon-assisted management of fractures (BAMF) in-house, as well as licensing in a third, Cervical Plate, from Bone Runner Technologies. At present, its efforts are focused predominantly on developing the vertebral compression fracture technology trademarked as Ascendx and bringing it to the market as quickly as possible, before undertaking expanded development of the other two technologies.

We fully expect AOI to raise more cash in order to complete development of Ascendx, including regulatory filing and launch, and our financial model suggests that around \$20m will be needed to achieve this. The company has just received shareholder approval to waive pre-emption rights, enabling it to seek a significant fund-raising through the issue of up to 15m new shares to give it sufficient flexibility while developing Ascendx through to market launch.

Its combined development pipeline is outlined in Exhibit 1.

Exhibit 1: AOI Medical's development pipeline

Product	Description	Stage	Notes
Ascendx (BAMF Spine)	Set of tools for restoring the anatomy of vertebrae, for use in compression fractures of the spine caused by osteoporosis, cancer or trauma.	Filed in 2007 under 510(k) procedure, but US FDA requested a confirmatory clinical study, which has begun patient enrolment.	Improvement over current most-advanced surgical treatment (kyphoplasty). If the 60-patient confirmatory study goes to plan, a launch in early 2009 is possible.
BAMF Trauma	Inflatable fracture-reduction device for the stabilisation of fractures of the long bones of the arms and legs; it is inserted into the intramedullar canal of the fractured bone and then inflated to fill the space.	Will require a clinical study, the design of which has yet to be agreed.	Could have particular application in treating children, in whom growth of the affected limb can be impaired if a traditional device is left in place. A relatively low-priority project until Ascendx development is complete.
Cervical Plate	Artificial ligament for use in spine-disc replacement in severe intractable disc disease; designed to allow translational and rotational motion and prevent spinal stiffness common with current treatments.	Further preclinical work needed.	Least advanced of AOI Medical's projects. A relatively low-priority project until Ascendx development is complete.

Source: Edison Investment Research

AOI Medical was founded as Advanced Orthologics by John Feltman, its current chairman and largest shareholder (43.6% equity stake). The company has assembled a board of directors and scientific advisers with business experience in venture capital/medical devices/healthcare, including William Christy, president and CEO, who joined in June 2005.

The clinical advisory board includes: Dr Melvin Rosenwasser, a professor at Columbia University College of Physicians and Surgeons and director of the International Orthopaedic Trauma Association; Dr Federico Vinas, a staff neurosurgeon of neurosurgery services at Halifax Medical Centre; and Dr Douglas Beall, a musculoskeletal radiologist and associate professor in orthopaedic surgery and rehabilitation at the Oklahoma University College of Medicine.

Ascendx intellectual property position

AOI has one issued US patent and four US patent applications covering the Ascendx technology – two of these have also been filed under the international Patent Co-operation Treaty (PCT) application. This intellectual property centres on the method of carrying out the procedure of cutting, expanding the device and injecting PMMA cement through just one vertebral pedicle (the pedicles are two short processes that project backward, one on either side, from the upper part of the body of the vertebra, at the junction of its posterior and lateral surfaces).

AOI also has rights to EU patent applications covering the Ascendx technology.

Exhibit 2: Summary of AOI Medical's patents/patent applications covering the Ascendx technology

US patent/application number	Status	Estimated expiry	Type	Notes
11/600,313	pending	15 Nov 2026	method and apparatus	Covers tissue cavitation device and method. Also under international application (No PCT/US2006/044340).
11/559,993	pending	15 Nov 2026	method and apparatus	Covers inflatable device for restoring anatomy of fractured bone. Also under international application (No PCT/US2006/044443).
6,746,451	issued	1 Jun 2021	apparatus and method	Covers tissue cavitation device and method. Assigned to Cavitech LLC and licensed to AOI in return for a small royalty and milestones in cash and stock.
10/818,452	pending	1 Jun 2021	apparatus and method	Covers tissue cavitation device and method. Assigned to Cavitech LLC and licensed to AOI in return for a small royalty and milestones in cash and stock.

Source: Frost Brown Todd patent attorneys

Lead technology focus – Ascendx

The lead technology being developed by AOI Medical is Ascendx, and it is on this that the company is predominantly focusing its near-term R&D efforts. The product comprises a single-use set of tools intended to be used by physicians carrying out procedures for restoring the height and function of vertebra in vertebral compression fractures caused by osteoporosis, cancer or trauma.

The tools enable cutting into the vertebral bone – creating a large cavity in the vertebral body which is held open and then filled with cement – and consist of two instruments:

- Cuity, a cutting device designed to cut into and create a cavity in cancellous bone (the less dense bone found in the middle of vertebrae), into which polymethyl methacrylate (PMMA) cement is then slowly pushed to fill the resulting space.
- An inflatable tamp in three possible sizes. This contains a balloon that is inflated during the procedure, restoring height to the vertebra while the PMMA cement is being introduced. Once the initial cement has begun to set within the main cavity, the reduction device is deflated and the whole device retracted.

Key advantages

Ascendx represents a key improvement over the current most-advanced minimally invasive procedure for treating vertebral compression fractures – a procedure known as kyphoplasty, using the KyphX device being sold by the US company Medtronic. While kyphoplasty follows a broadly similar method of inflating a balloon tamp within the cavity and then removing the balloon before introducing PMMA cement into the space, its drawback is that two incisions are needed (via each vertebral pedicle, giving two access points to the vertebra). The ability of kyphoplasty to restore height to the vertebra is limited by the fact that the balloon has to be removed before cement is injected.

Ascendx is an even less invasive procedure, the process being carried out through only one access point in the vertebra by virtue of the patent-protected design of the tools involved, as a result being carried out through fewer steps than involved with the KyphX device. It is reasonable to expect surgeons familiar with kyphoplasty to be able to carry out the Ascendx procedure without significant new training.

US FDA delay

In July 2007, AOI filed the Ascendx device for US approval under 510(k), the standard US approval procedure for medical devices. At that time it was thought that the product could potentially receive regulatory clearance without the need to carry out a clinical study, positioning it for a first market launch by the end of 2007/beginning of 2008.

However, the FDA informed AOI that a confirmatory clinical study would, after all, have to be performed. The agency then agreed to extend the consultation period in order to reconsider AOI's case. A further meeting took place with the FDA in October 2007, but the regulator decided to stand by its initial decision. The study was then to begin in Q108, but it was not until mid-April 2008 that the FDA approved an improved trial design.

As a result, the development timeline for Ascendx was pushed back by around a year – a possibility that had been recognised by AOI at the time of its float. The company additionally considered its financing options and decided that it would be prudent to raise more cash to fund the study fully, pay for registration and launch, and possibly allow for the build-up of a 75-strong salesforce to target early in-house promotion (in its IPO plans, AOI had considered the possibility of having to carry out a clinical study and made some budgetary provisions for a limited clinical programme; however, it has decided that more cash is needed to secure a successful market launch for Ascendx).

Recruitment into the clinical study began in May 2008, and the first three patients have undergone the procedure, with Ascendx meeting the acute procedural success criteria required by the protocol. The trial should generate data for filing with the FDA later this year, and depending on the speed of the agency's response, this could allow a possible approval and launch in early 2009.

Clinical trial design

The confirmatory clinical study mandated by the FDA will involve 60 patients in a single-arm trial with procedural and clinical endpoints. The primary endpoint will be acute procedural success, ie seeing whether the device can be successfully deployed, deliver the PMMA cement into the vertebral compression fracture site and be withdrawn without serious device-related complications or adverse events. The acute procedural success is known at the end of the procedure.

Sites started recruiting patients into this trial in mid-May 2008, and AOI intends to have a total of eight sites. The study is expected to complete enrolment of the last patient within around two months of starting, and the resulting data will be used as the clinical support for the 510(k) submission to the FDA.

The company has previously demonstrated the Ascendx procedure on a number of osteoporotic spines in cadaver tissue. In these studies, the latest of which was recently presented to the FDA, the device was shown to be capable of cutting into cancellous tissue, delivering PMMA cement into the cavity and being withdrawn. The success of the procedure, and the central facet of AOI's investment proposition, is that these results can be repeated in living patients in the new confirmatory clinical study now getting underway.

The spine surgery market

A vertebral compression fracture is a fracture in the body of a vertebra, causing that vertebra to collapse and leading the spinal column above it to assume an abnormal forward curve. This results in considerable back pain, gives the sufferer a hunchbacked appearance, and can progress further without treatment. Vertebral compression fractures can be caused by osteoporosis, certain types of trauma or by some cancers.

Although surgery previously tended to be avoided – owing to the risks associated with invasive procedures involving the spine and its association with the CNS – in the last decade or so, spinal procedures have become an increasingly common way of treating vertebral compression fractures. Lumbar surgery accounts for almost three-quarters of all spinal procedures, and the leading

medical device companies by market share in the spinal surgery space are Medtronic (with its acquisition of Kyphon), Johnson & Johnson and Stryker.

At present, there are two main procedures available for treating vertebral compression fractures: vertebroplasty, an older and more established technique, and kyphoplasty, a newer and less invasive procedure. There is a growing focus on minimally-invasive techniques that can allow for a relatively simple and inexpensive procedure, sometimes in an outpatient setting. Ascendx can be viewed as a further advance on Medtronic's kyphoplasty. All three are minimally invasive and allow patients to be discharged on the day of the surgery, after closing off the necessary surgical incision(s) with a single stitch. Each procedure can be performed under local or general anaesthetic, in either an inpatient or outpatient setting.

Vertebroplasty is essentially intended only to stabilise fractured vertebrae rather than restore them to their original height. It involves the surgeon making a small incision and injecting cement into the fractured vertebra, with the cement filling in the gaps caused by the fracture, hardening and thus stabilising the spine and reducing pain.

Kyphoplasty (also known as balloon-assisted vertebroplasty) involves an additional step, whereby a void is created in cancellous bone by compressing the bone into the crevices of the fracture and then filling the void with PMMA. A balloon tamp is inserted and inflated creating a void, but is then removed before cement is injected into the resulting cavity. This is a clear advance over vertebroplasty, not only because of some restoration of vertebral height but also because a more viscous cement (PMMA) can be used, reducing the chances of cement leakage into the vertebral body because of the creation of a cavity. However, it does require two incisions to be made – to receive balloon tamps and create voids on each side of the vertebral body.

Ascendx represents a further advance over kyphoplasty by using a single incision rather than two, requiring fewer steps (10 rather than 24) and being less susceptible to cement leakage, as well as restoring the height of the vertebra.

There are three companies selling vertebroplasty products – Medtronic (Arcuate/Arcuate XP systems), Somatex (Somatex/Somix cement) and ArthroCare (Parallax acrylic resin), the last of which recently put itself up for sale. Medtronic, through last year \$3.9bn acquisition of Kyphon, is also the only company involved in kyphoplasty. Kyphon had developed the KyphX bone-tamp used in the procedure. There are also a few other companies specialising in alternatives to vertebroplasty and kyphoplasty, such as Spineology (OptiMesh grafting material) and Spine Wave (StaXx-controlled fracture reduction system), but these account for a relatively small share of the present market. Listed companies in the bone-graft/spine-surgery space include Alphatec (\$210m market cap, 2.6x sales), Nuvasive (\$1.9bn, 12.6x) and Orthovita (\$201m, 3.5x).

A report carried out in 2006 by Robert Young Consultants estimated that over 80,000 vertebral compression fracture procedures were carried out worldwide in 2005, of which kyphoplasty accounted for the lion's share (54,000 procedures in the US and 11,000 outside the US), with vertebroplasty (6,000 US, 10,000 ex-US) and other technologies (400 procedures) accounting for the remainder. The study estimated that the total market was growing at around 17% a year. The most recent kyphoplasty sales reports amounted to around \$150m per quarter.

Clinical/partnering strategy

In our opinion, the completion of the US confirmatory clinical study and the publication of data could serve as a key trigger for either a co-marketing partnership for Ascendx or even a takeover of AOI Medical, given that the company operates in a consolidating sector and has a potential breakthrough technology in development. Therefore, late 2008 could represent an important inflection point for AOI Medical's stock.

If AOI wants to generate the most value from Ascendx, it will have to sign a partnership with a major orthopaedics company in the US – its most important market – booking a share of the co-marketer's sales in addition to revenue generated by a direct US salesforce (around 80 reps), which it plans to build up. Thus the salesforces would call at two distinct points – interventional radiologists and spine surgeons.

In the EU, meanwhile, a more realistic approach would be to grant marketing rights to a single, major healthcare concern.

Remaining technology portfolio

The other two products in AOI Medical's development portfolio are the BAMF Trauma and Cervical Plate devices. These are further from potential market launch than Ascendx and, because of the company's decision to focus mainly on Ascendx in the near term, their development has slowed until Ascendx reaches the market. Accordingly, we are providing only a brief overview of BAMF Trauma and Cervical Plate, and will provide a more detailed analysis should they enter full development.

BAMF Trauma consists of a removable inflatable nail for the stabilisation and repair of fractures of the long bones of the arms and legs; it is inserted into the intramedullary canal of the fractured bone and then inflated to fill the space. Intramedullary nailing is a well-established and growing technique for the stabilisation of long bone fractures. BAMF Trauma requires a smaller gauge at the point of insertion than current techniques and can be easily removed by deflating the balloon, possibly making its use popular in treating children, in whom growth of the affected limb can be impaired if a traditional device is left in place. The device will require a clinical study in 100–300 patients who will be followed for up to two years to support a filing via 510(k).

Cervical Plate is an artificial ligament for use in spine-disc replacement in severe intractable disc disease; this is the least advanced of AOI Medical's R&D projects, and targets conditions in which discs in the cervical region (ie towards the top end of the spine) have thinned or degenerated. The current treatment for severe intractable disc disease is spinal fusion, but this causes stiffness of the spine and could have a failure rate of over 30%. Several other non-fusion approaches are in development. The Cervical Plate device is designed to allow some translational and rotational motion and prevent the spinal stiffness commonly experienced with current treatments, and aims to return patients to a normal range of motion when used in combination with alternatives to fusion; its small size could make it less disruptive than other devices.

The device is still at the preclinical design stage, with AOI having completed the engineering design and 3D modelling of the plate device and screws for attaching to vertebrae. Cervical Plate is the most invasive of AOI Medical's technologies, and it is likely that further work will be needed before beginning a clinical study to support a 510(k) regulatory filing.

Sensitivities

Investors in AOI Medical face the usual risks associated with buying into a loss-making development-stage company, although significant value could be reached in the event of a licensing deal with a major partner or an attractively priced takeover. Sensitivities, both on the up- and the downside, include the following:

- Strength of intellectual property: AOI could find itself having to fund costly litigation if its patents are infringed, and while its IP estate appears strong, litigation against a large and well-funded company could put a significant strain on finances.
- Clinical trial/regulatory delays: studies can yield negative or contradictory results, as well as showing unexpected side-effect issues. Nevertheless, we do not believe this to be a significant risk given that Ascendx is effectively an improvement on a currently accepted and widely used procedure. Once filed, there is no guarantee that the FDA will proceed speedily, and regulatory delays beyond the company's control are possible.
- Insufficient adoption by physicians following market launch: if Ascendx successfully reaches the market, there still remains a risk that physicians will be reluctant to switch to it, preferring either the more established techniques of vertebroplasty and kyphoplasty, or the alternatives recently developed by, for instance, Spineology and Spine Wave.
- Pricing and reimbursement: even though Ascendx will offer clear advantages if it is launched, it might struggle to gain physician acceptance unless aggressively priced. AOI intends to price Ascendx in parallel with kyphoplasty. Meanwhile, thanks to vertebroplasty and kyphoplasty, reimbursement codes are already in place.
- BAMF Trauma and Cervical Plate: because Ascendx represents the predominant focus of AOI Medical's near-term development effort, our research and valuation basis focuses only on that. However, AOI also has two other technologies, BAMF Trauma and Cervical Plate, which represent potential upside if their development is expanded at a later date.
- Reliance on licensees: AOI's investment case involves the company striking a co-marketing deal with a significant orthopaedics player to maximise the potential of the Ascendx technology (as well as striking an EU deal with a major healthcare concern). A delay in the partnering process could result in Ascendx failing to capture a significant market share, although forecasts for the first and second years of launch can probably be met by in-house promotion alone. There also exists a risk common to all medical device firms – that the licensee fails to promote the product sufficiently.
- Other technologies offering advantages over kyphoplasty: technologies such as Spineology and Spine Wave might generate more interest among potential

licensees/acquirers than Ascendx, with the result that AOI Medical's technology is effectively overtaken in the market.

Valuation

We have built a discounted cash-flow model based around sales of the Ascendx device taken out to 2015. This is based on first market launch in 2009, a price per single-use tool set broadly in line with kyphoplasty, and spine surgery market size assumptions forecast in the Robert Young Consultants report as described above. We have also assumed some initial sales of Cervical Plate and BAMF Trauma (first launches due in 2012) and costs associated with their development. We assume that AOI can achieve a gross margin of around 65% on product sales, but most important on the cost side is the building up of a small, direct salesforce. We forecast that 100 reps will be in place by 2012 (starting at 25 by the end of 2008) at an average cost of \$250,000 per rep.

We have calculated the terminal value of the business in 2015, applying an aggressive 15% discount rate to that value and a 1% steady-state growth rate, and added this to the present value of the discounted cash flows for earlier years. Even though the combined elements of pricing, market share and discount rate are all relatively conservative, the model gives a current value for AOI Medical's Ascendx business in the region of \$87m, or roughly £44m. This is significantly above the company's current enterprise value (market capitalisation less net cash) of around £15m.

The market is putting a heavy discount on AOI Medical's stock, probably as a result of perceived uncertainty over the clinical trial hurdle for Ascendx and general adverse conditions. Nevertheless, we note that positive clinical data and approval of Ascendx could provide an important trigger for investors. Established publicly traded companies operating in the US spine sector tend to trade on an EV/sales multiple of around four (Alphatec 2.6x, Nuvasive 12.6x, Orthoviva 3.5x), and we stress again last year's acquisition of Kyphon by Medtronic for \$3.9bn, or almost 9x sales.

Financials

AOI Medical finished 2007 with \$10.4m in cash and equivalents. Success on the current assumptions depends on the company securing further funding, and we estimate that around \$20m will be needed solely to fund operating needs over the next 18 months (to build up AOI's small, direct salesforce targeting interventional radiologists). We note that AOI has obtained investor approval to waive pre-emption rights over the issue of up to 15m new shares.

We are forecasting that R&D expenditure (mainly on Ascendx) will be \$2.7m in 2008, and that sales and marketing spending will rise to \$6.0m in 2008 and \$17.5m in 2009 as the salesforce is built up. We expect Ascendx to start generating first (modest) revenues in 2009. We are also factoring in some R&D spending for the other pipeline projects, although note that this is discretionary and could be reduced or increased as necessary. Our model makes no assumptions for either upfront/milestone payments under possible co-marketing deal(s), or any fund-raising activities.

Our estimate of the \$20m funding needed to meet operational requirements – to launch Ascendx and build a salesforce – is expressed in the model as an increase in long-term borrowings.

Exhibit 3: AOI Medical financial results and forecast

Note: Excludes upfront/milestone fees under possible licensing deals.

	US\$'000s	2006	2007	2008e	2009e
Year end 31 December					
PROFIT & LOSS					
Revenue		0	0	0	11,730
Cost of sales		0	0	0	(4,106)
Gross profit		0	0	0	7,625
EBITDA		(1,716)	(4,281)	(11,545)	(15,521)
Operating profit (before GW and except.)		(1,730)	(4,328)	(11,595)	(15,591)
Goodwill amortisation		(15)	(21)	0	0
Exceptionals		0	0	0	0
Share-based payment		(50)	(436)	(500)	(500)
Operating profit		(1,795)	(4,785)	(12,095)	(16,091)
Net Interest		(314)	298	400	400
Profit before tax (norm)		(2,044)	(4,030)	(11,195)	(15,191)
Profit before tax (FRS 3)		(2,109)	(4,487)	(11,695)	(15,691)
Tax		0	0	0	0
Profit after tax (norm)		(2,044)	(4,030)	(11,195)	(15,191)
Profit after tax (FRS3)		(2,109)	(4,487)	(11,695)	(15,691)
Average number of shares outstanding (m)		4.9	7.1	8.4	8.4
EPS - normalised (c)		(41.3)	(56.5)	(132.8)	(180.2)
EPS - FRS 3 (c)		(42.6)	(63.0)	(138.7)	(186.1)
Gross margin (%)		N/M	N/M	N/M	N/M
EBITDA margin (%)		N/M	N/M	N/M	N/M
Operating margin (before GW and except.) (%)		N/M	N/M	N/M	N/M
BALANCE SHEET					
Fixed assets		360	972	1,319	1,649
Intangible assets		297	402	400	400
Tangible assets		47	539	889	1,219
Investment in associates		0	0	0	0
Deferred tax & long-term other debtors		16	31	30	30
Current assets		975	10,618	893	4,201
Stocks		0	0	200	978
Debtors		0	0	400	2,892
Cash		957	10,403	93	131
Other		18	215	200	200
Current liabilities		(1,455)	(765)	(1,000)	(1,928)
Creditors		(251)	(765)	(1,000)	(1,928)
Other creditors		0	0	0	0
Short-term borrowings		(1,204)	0	0	0
Minority interests		0	0	0	0
Long-term liabilities		(260)	(47)	(1,647)	(20,047)
Long-term borrowings		(260)	0	(1,600)	(20,000)
Other long-term liabilities		0	(47)	(47)	(47)
Net assets		(380)	10,778	(435)	(16,126)
CASH FLOW					
Operating cash flow		(2,103)	(3,383)	(11,910)	(18,362)
Net interest		16	12	400	400
Tax		0	0	0	0
Capex		(36)	(554)	(400)	(400)
Acquisitions/disposals		0	13	0	0
Financing		1,996	13,416	0	0
Dividends		0	0	0	0
Other		0	0	0	0
Net cash flow		(127)	9,504	(11,910)	(18,362)
Opening net debt/(cash)		380	507	(10,403)	1,507
HP finance leases initiated		0	0	0	0
Other		0	1,406	0	0
Closing net debt/(cash)		507	(10,403)	1,507	19,869

Source: Edison Investment Research/company accounts

Growth	Profitability	Balance sheet strength	Sensitivities evaluation	
N/A	N/A	N/A	Litigation/regulatory	●
			Pensions	○
			Currency	◐
			Stock overhang	◐
			Interest rates	◐
			Oil/commodity prices	○

Growth metrics	%	Profitability metrics	%	Balance sheet metrics		Company details	
EPS CAGR 06-10e	N/A	ROCE 09e	N/A	Gearing 09e	N/A	Address:	
EPS CAGR 08-10e	53.2	Avg ROCE 08-10e	N/A	Interest cover 09e	29.0	2100 N Alfaya Trail, Suite 100, Orlando, FL 32826	
EBITDA CAGR 06-10e	N/A	ROE 09e	N/A	CA/CL 09e	0.9		
EBITDA CAGR 08-10e	64.2	Gross margin 09e	N/A	Stock turn 09e	30	Phone	(+1)4077701800
Sales CAGR 06-10e	N/A	Operating margin 09e	N/A	Debtor days 09e	90	Fax	(+1)4077701801
Sales CAGR 08-10e	N/A	Gr mgn/Op mgn 09e	N/A	Creditor days 09e	60	www.aoimedical.net	

Principal shareholders	%	Management team
John Feltman	43.6	President & CEO: William Christy
ING Belgium	8.6	Joined AOI in June 2005, having previously worked as president and CEO of Ortheon Medical. Previous experience includes ESD Medical, and Synergistic Medical Technologies. One of the founders of Ethicon Endo-Surgery.
MDY Healthcare	8.6	
William Christy	5.5	
Numis Securities	5.1	Chief financial officer: Angela Johnston
Roy Nominees	4.8	Joined AOI in August 2005, having previously worked at Arthur Andersen and as financial controller of Capital Cargo International Holdings.
Credit Suisse Nominees	3.4	
Forthcoming announcements/catalysts	Date *	Vice-president of R&D and operations: Mark Goldin
Possible fund-raising/US OTCQX listing	Q3 2008	Previously vice-president of R&D and operations at Ortheon Medical, and design engineer at Ethicon Endo-Surgery (J&J).
Results of Ascendx clinical trial	late 2008	
Ascendx US filing	late 2008	Non-executive chairman: John Feltman
		Previously chairman, president and CEO of IMED Devices. Is also chairman and CEO of Brookhaven Capital. Previously held senior positions at JC Bradford, Bear Stearns, Commonwealth Associates and Interstate/Johnson Lane.
<i>Note: * = estimated</i>		

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