AorTech International PLC

The Phoenix continues to rise

19 February 2020

After a twenty-year history, AorTech has started to live up to its rich asset base in medical devices. A management restructuring, reduced cost base and business alignment was complemented by a fund raising in June 2018. The progress made since the fund raising has been noted by investors and the share price has nearly tripled in 20 months. Investors may worry that they have missed the opportunity in AorTech, but we think the alignment and maximisation of assets has probably only just begun.

Greater than the sum of its parts

The AorTech of 2020 is quite different to that of 15 years ago and the company starts the new decade in a good position. AorTech has **royalties from Elast-Eon** – its biostable family of co-polymers for medical devices – plus two other product divisions that now comprise AorTech. **AorTech Vascular** and **AorTech Heart Valve** are the two product-focussed division of AorTech where the collaboration with RUA Medical or their long development heritage respectively, are generating medical devices that are expected to have improved outcomes for patients and payers. The three divisions within AorTech demonstrate a **diversified portfolio of businesses**. The royalties in **AorTech Royalty** is a low risk, growing business. The **Elast-Eon**-coated graft and surgical patch products are medium-risk and near-term when compared to the **AorTech Heart Valve** which we view as having the highest risk and the highest potential value.

We use a sum of the parts methodology to value AorTech. That means taking an average comparable service company multiple to value AorTech Royalty at a 9.8X multiple of 2019 revenues (without any growth component). This is despite **revenues increasing 27% in the six months** to the end of September 2019. This implies a valuation of £4.5m for AorTech Royalty alone. For AorTech Vascular and AorTech Heart Valve, we have used the average value of acquisitions of similar companies in Lerner's venture capital method, discounted by the number of years we expect for a transaction to occur, and then risk-adjusted by 40% and 30%, respectively.

After many years in the making, AorTech is now in the right place at the right time – as demonstrated by the many historical transactions that have taken place in the heart valve and graft space – for the company to generate significant value. Our sum of the parts valuation for AorTech suggests that there could be much further to run than in the share price appreciation in the last year as this value becomes recognised. **We value AorTech at £99.2m or 676p per share.**

Summary Financials

£'000s, y/e 31 March	2017A	2018A	2019A	2020E	2021E
Revenues	614	404	463	500	580
EBIT	55	185	-413	-579	-918
Basic EPS (US c / UK p)	-4.26c	-0.61c	-4.72p	-3.94p	-5.70p
Net Assets	1318	1016	3000	2421	1584
Net Cash	114	422	2412	1895	1028

Source: Company historic data, ED estimates

EPIC	**AOR**
Price (last close)	77p
52week Hi/Lo	112p / 44p
Market cap	£11.4m
ED value / share	£99.2m / 676p
Proforma net cash to Sep '19	£2.3m
Avg. daily volume	28,152

Share Price, p

Source: ADVFN

Description

AorTech International PLC is incorporated in the UK and focused on the commercialization of its own world leading biostable co-polymer technology, Elast-Eon.

Elast-Eon is a basis for medical devices with improved clinical outcomes and durability. AorTech has three divisions, AorTech Royalty that receives the licensing and royalty fees on Elast-Eon, AorTech Vascular that is a collaboration with RUA Medical to develop biostable surgical patches and grafts, and the AorTech Heart valve.

AorTech's shares are listed on the UK London Stock Exchange's Alternative Investment Market.

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Investment proposition

Aortech International PLC is a medical device and biomaterials company with royalty revenues and its own products in development. These are all based on its patent-protected Elast-Eon biocompatible co-polymer. AorTech's heritage goes back to its incorporation in 1996 and it listed on the London Stock Exchange in 1997, initially on AIM. It subsequently moved to the LSE main board before moving back to AIM at the end of 2002.

After fifteen years during which it focussed first on its products, and then on licensing its technology, AortTech raised £2.6m before expenses in a placing and open offer in June 2018. This was at 30p per share and by the start of 2020 the stock price had started to recover to 99p per share.

Whatever investors knew about AorTech's history can now be ignored, since the company has restructured under its new management and refocussed into its three components. With the renaissance already underway, AorTech today retains the intellectual property, clinical heritage and potential of Elast-Eon in a cost-effect holding company that has both royalties and products in development.

Results

AorTech's revenues increased 27% to £299,000 (*vs.* £236,000 for the six months to September 2018). Administration costs, which included product development costs and patent maintenance, increased 29% to £451,000. The increased R&D expenditure was softened by the recognition of an R&D Tax credit of £81,000 in the six months to 30 September 2019 and we expect this to increase in line with AorTech's R&D expenditure. AorTech's net loss for the six months to 30 September 2019 was £158,000, having declined from £225,000 at the end of H1 2018.

The increased product development investment was countered by the increase in AorTech Royalty revenues and the R&D Tax credit. To continue to advance AorTech's investment in its new products, we anticipate a fund raising at some time in the next two years. AorTech finished the six months to 30 September 2019 with £2.3m in cash.

Our valuation

We combine the implied 9.8X sales multiple valuation of AorTech Royalty with the intrinsic risk-adjusted valuations of AorTech Vascular and AorTech Heart Valve. The valuations of later two divisions have be determined from comparative medical device transactions that have been discounted back to AorTech's stage of development and further risk-adjusted.

After adding AorTech's cash at the end of September 2019, we determine a valuation for the whole business of £99.2m or 676 pence per share.

Introduction

Aortech International PLC is a medical device and biomaterials company with royalty revenues and its own products in development. These are all based on its patent-protected Elast-Eon biocompatible co-polymer. Elast-Eon and its variants are a proven biostable enhancement to medical devices, particularly those with implantable cardiovascular and neurovascular applications. Elast-Eon has 15 years' worth of data in humans and an FDA Masterfile. Elast-Eon forms the basis of three divisions within Aortech all of which are expected to have significant news flow in the next 12 months.

A medical device company with heritage

AorTech was incorporated in 1996 and IPO-ed on the London Stock Exchange in 1997 initially on AIM, then it moved to the LSE main list and moved back to AIM at the end of 2002. Fifteen years later in 2018, AortTech raised £2.6m before expenses in a placing and open offer in June 2018 at 30p per share and by the start of 2020, the stock price had started to recover to 99p per share. Whatever investors know about AorTech's history should now be put aside as the company has restructured under its new management and refocussed into its three components. With the renaissance already underway, AorTech today retains the intellectual property, clinical heritage and potential of Elast-Eon in a cost-effect holding company that has both royalties and products in development.

Probably the best biocompatible polymer coating

Elast-Eon is a best in class biostable co-polymer of polyurethane and silicon (polyether siloxane). Polyurethane-based medical devices have important applications as the supporting basis for many medical devices including stents, grafts and canulae.

The structural properties that give polyurethane its medical device applications – flexibility on implantation and in use, and the ability to be thermally processed and shaped – are only limited by their stability *in vivo* once implanted. This means that short-term use and the requirement for early removal can limit the use and increase the costs of naked polyurethane-based medical devices.

Elast-Eon is a silicon-polyurethane co-polymer that combines the structural properties and applications of polyurethane, with the biocompatibility of silicon macrodials, thus enabling biostability and biocompatibility. Elast-Eon has been used as a coating in implantable medical devices but also, when formed from the preformed co-polymer base material, as biocompatible medical devices in their own right.

The applications of Elast-Eon to date, and those under development, have focussed on the cardiovascular therapeutic area – heart valves, grafts, membranes and canulae – since these are amongst the most challenging implanted medical devices. When surgical repair and or implantation is undertaken, the medical devices used need not just to restore leak-free function, but to do so in the presence of circulating blood flow that regurgitates, clots or calcifies if non-biocompatible material is exposed to the circulation.

That is why mechanical heart valves require anticoagulation therapy for the remainder of the patients' lives.

Elast-Eon's biocompatible properties give the medical devices it coats, or are comprised of, increased longevity and convenience to the patient (in reducing anticoagulation therapy, for example) and a reduction in the cost of repair or reimplantation for healthcare budget holders.

The commercialisation of medical devices

Medical device commercialisation is different to that of pharmaceutical and biotechnology products. The regulatory, clinical and financial requirements are typically lower than for a drug (and therefore lower risk) and the purchasing and prescribing decision is made partly on surgeon or interventionalist preference, but largely on purchasing group (hospital or health authority) choice.

This means that to be successful, the marketing of individual medical devices is more about a company having **a full spectrum** of orthopaedic or cardiovascular devices, rather than just a single device product.

As AorTech have found over the years, small company's products are better licensed to a big medical device company for sale in their catalogue, rather than by AorTech itself. That said, innovation as a means of differentiating one canula or heart valve from another is highly prized, as long as it can be supported by better outcomes.

Thus, AorTech's Elast-Eon provides medical device companies with a means of differentiating their products. Over time the improved outcomes of better device longevity, lower complications and fewer device failures will also be valued by payers and physicians.

Small- to mid-sized medical device companies with differentiated products that could fit into an existing product catalogue of one of the big medical device marketers (Abbott Inc., Medtronic Inc., Edwards Life Sciences and Boston Scientific), usually either exclusively license their products to one of these bigger companies, or are acquired just before or just after:

- Human safety and efficacy data
- Initial commercialisation
- Litigation on intellectual property infringement

AorTech's heritage is widely recognised

Whilst AorTech's previous management teams did not cost-effectively manage the medical device platform on which, Elast-Eon and its related technologies are based, today's company retains not just the intellectual property that protects the Elast-Eon definitive co-polymer formulation and its manufacture, but the heritage of its use in more than a decade of surgical practice.

This includes cardiac pacemaker lead implantations in **over 10 million patients worldwide** and the Getinge's Avalon Elite Bi-Caval Dual Lumen Catheter (see overleaf).

Elast-Eon-enabled devices have been removed after 144 months' implantation and have been found to be **structurally and functionally identical** to those before implantation. Elast-Eon-enabled medical devices also now have a **15-year heritage in humans** and an FDA master file that shortens the time to development of any new Elast-Eon-enabled device compared to a new polymer.

Early batches of Elast-Eon were marred by a batch-to-batch variation in the co-polymer composition and this resulted in instability.

Elast-Eon coated Avalon Elite Bi-Caval dual lumen catheter

Source: Getinge AB

The corrective steps to refine and define the manufacturing process (now conducted under license at AorTech's medical device validated supplier and partner, Biomerics) have all been taken and are retained as a source of AorTech's intellectual property (IP) and trade secrets.

The extended Elast-Eon family of products

While the Elast-Eon biostable co-polymer and raw material form the basis of AorTech's business, and in particular the AorTech Royalty business segment (see below), they have been in clinical use for decades, and a family of new products have been built upon AorTech's original IP. ECSil is carbonate silicon variant of the Elast-Eon co-polymer that retains the biostable longevity of Elast-Eon but extends the range of softness and flexibility to that of silicon rubbers.

An exciting application of the ECSil co-polymer could be in the manufacture of artificial spinal discs (subject to durability studies). E-RIM is the application of reaction injection moulding (RIM) to the Elast-Eon co-polymer. RIM is typically used to manufacture modern car bumpers and would produce medical devices with much higher bond strengths than the native Elast-Eon co-polymer, but still retaining its biostability. The resulting biostable products could include sensitive electronics like neurostimulation devices.

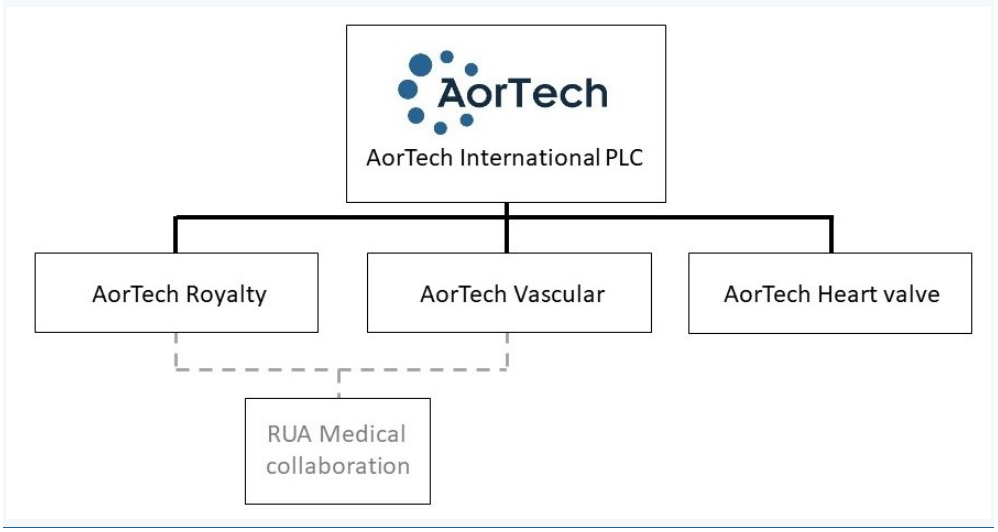
Group Structure

Following the 2018 fundraising and building on the progress noted in the January 2019 corporate update announcement, AorTech can be considered as a number of interrelated businesses:

AortTech Royalty comprises the intellectual property that protects Elast-Eon and its related products, including the trade secrets and relationships with its suppliers and licensees.

Were AorTech Royalty a separate entity, it would be profitable because it shares the gross margin from the manufacture of Elast-Eon and licensing fees from the sales of Elast-Eon-containing products, despite the annual patent maintenance costs.

Group constituents



Source: Company

In terms of product development, **AorTech Vascular** represents the development of AorTech's graft and surgical film products that are part of the collaboration with RUA Medical (and hence require a license from AorTech Royalty). The **AorTech Heart valve** division represents the latest generation of AorTech's replacement aortic heart valve. We examine these separate parts of AorTech, and the collaboration with RUA Medical below.

AorTech Royalty: the base, enabling business

AorTech Royalty is a profitable polymer business in its own right. AorTech Royalty receives the royalties and manufacturing margin, and holds the licenses from, AorTech's partners (with revenues that increased 27% to £299,000 in the six months to the end of September 2019). AorTech Royalty also secures and protects the Elast-Eon intellectual property, knowhow and trade secrets.

The Elast-Eon co-polymer raw material is manufactured under license by AorTech's partner Biomerics, with gross margin shared on any Elast-Eon raw material sold. In addition, medical device manufacturers who incorporate Elast-Eon into their products pay license fees and royalties to AorTech.

The products include Abbott's cardiac rhythm leads, Avalon's Elite catheters and the recently announced collaboration with Medibrane that includes neurovascular stent products. This part of AorTech should be considered an established business, although not as exciting as the development of its own products.

Based on the historical run rate we have assumed a growth rate for these revenues at 8% annually. We will keep this growth rate under review because while the latest financial statements reported a higher rate in the six months to the end of September 2019, the historical ramp to that point has been slower in some periods.

AorTech Vascular: lower risk device development

AorTech Vascular includes the development of Class II medical devices that require approved by the FDA in the 510(k) medical device pathway. These are defined by the FDA and EU to be those that support or sustain human life, are of substantial importance in preventing the impairment of human health and require regulatory approval. In AorTech's case, the medical devices that are included in AorTech Vascular are those that can be manufactured from an Elast-Eon coated yarn.

Medical grade textiles are comprised of surgical grade (in this case, Elast-Eon) coated textiles. Class II medical devices carry a moderate level of risk to the user but do not require as much testing as Class III medical devices that require the more extensive premarket approval (PMA). The AorTech heart valve is a Class III medical device.

This fabric can be used to manufacture either a flat membrane patch that can be surgically implanted to prevent lesions from adhering to other tissues or organs in the recovery period after surgery. Alternatively, they can be manufactured as a cylinder or large bore blood vessel graft repair that is heat formed, sealed and coated. These devices already exist, although the Elast-Eon technology has only recently been applied to make them biostable in the collaboration with RUA Medical.

In June 2018, AorTech announced a development and supply agreement with RUA Medical for the development of its soft tissue pericardial patch and large bore vascular graft. RUA Medical is a profitable implantable fabric and medical device developer and manufacturer. AorTech appointed RUA Medical as its development and manufacturing partner to accelerate the application of Elast-Eon in medical devices that are constructed from implantable medical grade yarn.

More recently in January 2020, the agreement was extended to allow RUA Medical to develop third-party devices that incorporate Elast-Eon. RUA Medical had the design and manufacturing facility, and now has the ability to differentiate their implantable devices with the biocompatible and biostable properties of Elast-Eon.

Large diameter vascular grafts are typically 10-40mm in diameter and are constructed of a woven or knitted polyester polymer construction. These are used to repair tears or weaknesses in higher pressure blood vessels that can have fatal consequences (in acute aortic aneurysms, for example). AorTech's aortic heart valve has been in development for many years but it is a complicated medical device that requires multiple testing and design cycles in order to ensure safety, durability and efficacy.

The Elast-Eon-enabled large diameter vascular grafts and pericardial patches have not been development for long, but because the devices themselves have less-demanding performance requirements and no moving parts compared to a cardiac valve for example, they are easier and quicker to develop. More so on the timeline to a commercially available product since RUA Medical have been working on this type of non-Elast-Eon-enabled products for many years.

Indeed, RUA Medical was involved in the development of Lombard Medical's Aorfix approved and commercially-available endovascular stent graft. AorTech's vascular business should therefore be considered as a lower-risk part of its product portfolio compared to the more demanding heart valve.

Early prototype designs of the aortic grafts have shown that the Elast-Eon coating of medical-grade textiles is functional and the devices are expected to progress through *in vitro* (ISO standard) testing, a 21-day animal study and then the design freeze in 2020. We would then expect a 6-month animal implant study for the patch to be completed in 2021 that would enable US 510(k) approval.

We have assumed that the Elast-Eon-enabled large diameter vascular graft will be the first product to come out of the collaboration with RUA Medical. This is because it is more complex and of a higher value than the patch. To achieve a functional graft prototype for testing would effectively validate the production methodology for the patch which is a component of the graft.

In fact, the completion of the Elast-Eon-enabled graft would go beyond any of the technical or development challenges of developing the Elast-Eon-enabled patch such as the complexity and extent of surgical testing. The time, cost and US 510(k) regulatory process required for the development of the Elast-Eon-enabled patch is lower than that for the graft so we assume that the Elast-Eon surgical patch would have a similar launch date to the graft.

AorTech Heart Valve

The AorTech replacement mechanical aortic valve has been in development for many years. While other surgically replaced aortic valves have been developed and commercialised quicker than AorTech's valve, a gap in the market remains. There are four valves in the heart, the one most frequently replaced after disease damage (which could be from an infection or an immune response), or narrowing (stenosis), is the aortic valve.

There are two types of aortic valve – mechanical and animal tissue-based – and, there are two ways to replace a valve – by open heart cardiovascular surgery (which is AorTech's current focus), or by a minimally invasive procedure (which will be a later version of AorTech's valve).

The archetypal mechanical aortic valve replacement has been developed from the old ball and cage valve to the bi-leaflet type in the LHS picture overleaf, whilst the typical tissue-based valve is constructed from bovine pericardium, see the RHS of the picture overleaf.

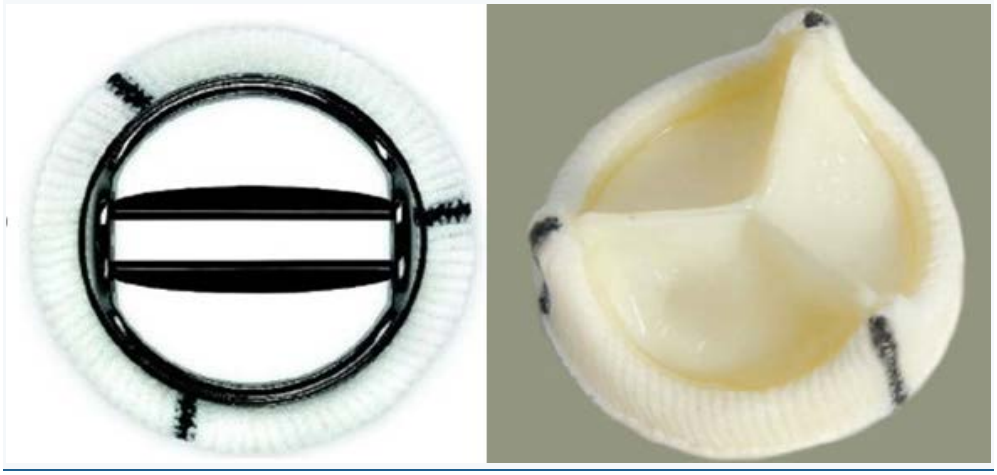
AorTech's heart valve should be seen as a hybrid (or bio-prosthesis) of these two extremes that combines the biostable, flexible and tri-leaflet design of nature (made from Elast-Eon soft material), with the durability of a man-made artificial valve, that reduces or eliminates the need for anticoagulation therapy.

Patients who have had a mechanical valve replacement need constant lifetime anticoagulation therapy. The Elast-Eon coating on AortTech's aortic valve reduces or eliminates this requirement for life-long anticoagulation therapy.

One of the factors that limits the life of animal tissue-derived valves is that the tissue calcifies over time. Elast-Eon does not calcify.

The ***disadvantages*** of mechanical valves that also applied to AorTech's earlier tri-leaflet designs is that leaflets in blood flow can cause turbulence that damages the cells in the blood. These unnatural blood flow pattens and shear stresses can lead to thrombosis (clotting) and haemolysis (broken red cells), respectively. The latest version of AorTech's heart valve has been designed to minimise this with the tri-leaflet design that is similar to a native valve.

Bi-leaflet mechanical valve / Bioprosthetic valve



Source: Left image - St Jude 2009, Right – www.researchgate.net

One of the ***main advantages*** of mechanical heart valves is that they are sterilised by ethylene oxide or other aggressive sterilising agents that render non-functional, a tissue-derived valve. Elast-Eon is compatible with ethylene oxide sterilisation. In summary, the Elast-Eon-enabled heart valve uses nature's design to restrict and then allow blood flow in the harsh environment of the heart (in normal health), without forming coagulation, scarring, calcification, membranes (pannus) or regurgitation.

This is a tall order, even for biological tissue-derived replacement heart valve even though, like AorTech's valve, their tri-leaflet design emulates nature, because the biostability of the bovine pericardium that comprises the leaflets is lower than that of a vital human tissue valve. This is because bovine pericardium treated and fixed, similar to a tanning process in its preparation and this limits its durability in man and increases the potential for calcification. The Elast-Eon coating of the tri-leaflets of AorTech's valve restores this biostability to a tri-leaflet heart valve.

Unlike AorTech's other products in development – the graft and patch – that require approval under the US 510(k) pathway, the surgically replaced aortic valve also requires *in vitro* and animal implantation, but then more human implantations before applying for regulatory approval in the PMA pathway. Unlike the Elast-Eon-enabled patches and grafts, the functional testing is more extensive requiring many millions of cycles (heartbeats). Early design series of the AorTech valve (going back to 2002) encountered inconsistent polymer quality and poor leaflet quality.

Furthermore, the leaflet design was not optimised which resulted in the torsional stress encountered being close to the tensile strength of the leaflet material. In addition, the most recent work on the valve has employed the latest fluid flow analysis software to optimise the leaflet design. The manufacturing method now used to produce the Elast-Eon of the leaflets has also been refined and the frame profile that holds the leaflets to the heart, redesigned.

Finally, a different Elast-Eon grade than was used in earlier prototypes is now used for the latest heart valve design. All these learnings form part of AorTech's IP and trade secrets.

In terms of timelines and costs for AorTech's heart valve, we have assumed that, like the patches and grafts, AorTech will be a licensee to a big medical device manufacturer who typically want some clinical data before licensing the Elast-Eon-enabled valve.

This would imply that if the manufacturing of the latest prototypes is completed in mid-2020, the long-term *in vitro* durability, 180 days sheep implantation study and a small number of successful implants in humans could then result in either the licensing or the acquisition transaction for AorTech's heart valve business in 2.5 to 3 years. We have conservatively estimated 5 years for a heart valve transaction in our valuation.

We have estimated that AorTech has the cash resources to complete the steps in the development of the heart valve up to human testing (see financials below) and that human testing would require a further fund-raising.

In 10-20% of aortic valve replacements, the disease extends up from the aortic valve into the ascending aorta weakening the vessel which itself has a circulatory function and holds blood under high pressure. The weakness in the ascending aorta results in a bulging in the vessel that, if ruptured, has a very high mortality. Stenosis within the ascending aorta can also require a more extensive repair than just the replacement of the aortic valve.

For these surgical cases, aortic valve conduits, also known as apicoaortic conduits (AAC) or aortic graft valve (AGV), and repair are needed at the same time as the aortic valve replacement. Currently the best-selling AAC is the Terumo Aortic Valsalva Graft aortic valve conduit where biocompatibility is mediated by a gelatine coating. The Valsalva Graft is used as a component into which an aortic valve is sewn to make the multicomponent valve and graft conduit.

Group benefits

Having the AorTech Vascular and AorTech Heart Valve businesses developing products under the same roof, and the collaboration with RUA Medical, gives AorTech the potential to develop a single piece aortic valve conduit with the biostable properties of Elast-Eon.

This avoids the manufacturing, supply and moisture control difficulties that are inherent with either gelatine or collagen.

Competitors

There are few obvious competitors for the collective portfolio of assets that today sit within AorTech.

The individual components are, however, easier to compare – since many of the various differentiated heart valves that are sold by the biggest medical device companies were acquired from smaller companies. For a heart valve that offers differentiated technology and improved outcomes, the acquisitions of ATS Medical and 3F Therapeutics are good precedents that we have used in our valuation section below.

While it may be tempting to think of the existing aortic replacement valves as competitors to AorTech's aortic valve, it is important to realise that large medical suppliers are always looking for improvements to their product lines. On the one hand, this makes an existing marketeer of replacement heart valves a likely licensor or acquirer of AorTech's heart valve. On the other, such differentiation and potential for improved outcomes needs to be demonstrated to them.

We understand that AorTech has been in dialogue with potential licensors of its heart valve in order to use trial providers, designs and models that large medical device companies regard as validation for this type of product.

There is another polymer heart valve in development with, what appears to be an earlier-generation polymer coating and leaflet design than AorTech's aortic valve. The US private company **Foldax** was founded in 2013 and recently started human implantations for its Tria heart valve with the LifePolymer coating. As the Tria valve is between two to three years ahead of AorTech's valve, the design would have been too late to have benefitted from the latest fluid flow design software. Foldax would also not have included the improvements that AorTech have made in the Elast-Eon formulation and coating.

Nevertheless, at the end of 2018, Foldax completed a Series C private round raising $10.3m in a post-money valuation rumoured to be around $60m (£46m) to fund their pre-registration studies that are now in progress. AorTech had previously engaged in a legal dispute against Foldax and its CEO, (who was a former CEO of AorTech). This included the alleged misappropriation of trade secrets, and the action was resolved amicably, according to AorTech, at the end of 2017.

A potential competitor to AorTech Vascular was the former **Vascutek** business that is part of **Terumo** before it became Terumo Aortic. This business was at a later stage than AorTech Vascular is today since it already had a range of endovascular, surgical woven and hybrid graft products on the market. Vacuteck was acquired in 2002 for €172m (£146m) and along with the recent funding round for Foldax, provides some validation that these slightly more advanced medical devices than those at AorTech, are both fundable and acquirable.

Financials

AorTech finished the six months to 30 September 2019 with £2.3m in cash. The AorTech Royalty business revenues increased 27% to £299,000 (*vs.* £236,000 for the six months to September 2018). Administration costs, which included R&D in the AorTech Vascular and AorTech Heart Valve businesses and patent maintenance costs, increased 29% to £451,000.

These costs represented the increased investment in the products being developed in the AorTech Vascular and AorTech Hearth Valve divisions. As development continues in these two divisions, we anticipate annual 20% increases in R&D spend to 2022.

This resulted in our forecast of Administration costs for FY 2020 of £1.01m (*vs.* £0.84m for FY 2019) and £1.21m for FY 2021. The increased R&D expenditure has started to be alleviated by the recognition of R&D Tax credits. This was £81,000 in the six months to 30 September 2019 (relating to FY 2018) and we have linked to the increase in AorTech's Administration costs. AorTech's net loss for the six months to 30 September 2019 was £158,000 against £225,000 at the end of H1 2018 as the increased investment was balanced by the increase in AorTech Royalty revenues and the R&D Tax credit.

While we expect licensing, royalty and R&D Tax credit inflows to increase, the investment in AorTech's products will also increase as they reach the later stages of development. We forecast AorTech's cash runway to extend into 2023 and would anticipate a fund-raising before then.

Valuation

For a portfolio of medical device assets, with products at an early stage of development and a cash-generative licensing and royalty business (on which the product business depends), we have used a sum of the parts valuation method to value AorTech. We have searched for medical technology companies that have a licensing and royalty business and have not found any good comparators on which to derive a sales multiple. In this respect, AorTech appears unique.

We have focussed on biotech platform and service companies where chemical synthesis, screening and research antibodies are provided as a fee for service business. We have derived a 9.8X estimated FY 2019 sales multiple from the fee for service business models of Evotec and AbCam (9.1 and 10.4, respectively). This implies a £4.5m valuation of AorTech Royalty which may be an underestimate since the comparators are larger businesses that are growing more slowly than we expect AorTech's licensing and royalty revenues to grow over the medium term.

To value AorTech's product divisions, we have used a comparative transaction method discounted using Lerner's VC method[1] to take into account our estimate of how many years AorTech's heart valve, patches and grafts are away from licensing to a medical device marketing partner. Lerner's VC methodology uses fewer inputs than a NPV analysis but is more applicable to early-stage (preclinical companies) where the sensitivity of the key valuation drivers in an NPV analysis would be very wide. The three inputs to Lerner's VC method are a discount rate (where we have use 12.5% to recognise that neither the heart valve, graft nor patch are yet in clinical studies), the time to the transaction (in years) and the exit valuation.

There is an argument for using a lower discount rate than is typically applied to preclinical companies since the time for a medical device to progress to the market is typically shorter than that for a drug. In addition, RUA Medical has already developed these types of products, just not yet with an Elast-Eon coat. The other two inputs in Lerner's VC valuation method are termed the time to exit and the terminal valuation. In both cases, this terminology represented a VC making an early-stage investment and estimating the time to the exit (in years) and the valuation at exit, respectively.

These fit well with small and mid-sized medical device companies since they are typically acquired either just after clinical data has been released or after regulatory approval, and we can estimate how long it will take AorTech to reach that stage. In that respect, there have been a large number of comparative transactions for heart valves and a smaller number of acquisitions of companies that have developed surgical patches or grafts.

Since February 2006, there have been **eleven medical device companies developing heart valves acquired** by either Edwards Life Sciences (five acquisitions), Abbott and Boston Scientific (two acquisitions each), and ATS Medical and Medtronic (one each with Medtronic acquiring ATS Medical in 2010. The average value of these transactions is £251m, although many of them were for mitral valves and already had clinical data. Four of the transactions involved an aortic heart valve with an average value of £214m. This was the value used in the valuation table below.

[1] A Note on Valuation in Private Equity Settings. Josh Lerner & John Willinge, Harvard Business Review, March 2011.

There are far fewer comparative acquisitions for the AorTech Vascular business and although there have been five transactions since 2002, three of them have been by the Japanese company Terumo Aortic and the value has not been disclosed. Terumo did disclose the value of the acquisition of Vascutek in 2002 for £146m and Johnson and Johnson acquired the TachoSil Fibrin sealant business in 2019 for £308m. The average of these is £227m which is the value used in the valuation table below. We have used the time (in years) for AorTech to get the same stages as the exit transactions of the typical Vascular and Heart Valve businesses to be 4 and 5, respectively.

Valuation components (£m)		Valuation Summary (£m)	
Comparable exit valuation heart valve	214	Risk-adjusted heart valve valuation	35.6
Time to heart valve transaction (years)	5	Risk-adjusted vascular valuation	56.7
Target rate of return (preclinical)	12.5%		
Lerner's VC heart valve valuation	118.8	Intrinsic valuation	92.4
Risk adjustment	30%		
Risk-adjusted heart valve valuation	35.6	Implied AorTech Royalty valuation	4.5
Comparable exit valuation vascular	227	Cash at end of September 2019	2.3
Time to exit vascular (years)	4		
Target rate of return (preclinical)	12.5%		
Lerner's VC vascular valuation	141.8		
Risk-adjustment	40%	Total valuation £m	99.2
Risk-adjusted vascular valuation	56.7	Per share valuation p	676

Source: Company historic data, ED estimates, press reports on exits

In addition to the discounting and time aspects that reduce the value of the transactions more towards the stage of those businesses in AorTech, we have also applied a risk-adjustment to both transactions. This is to reflect the uncertainty of the transaction occurring and also some product-specific risk. That is why the risk adjustment is higher for the heart valve than the graft and patches since the heart valve is a more complicated medical device requiring more testing and a more stringent regulatory review (hence also, the greater time to exit).

The existence of a similar, earlier-generation of polymeric heart valve from Foldax at the clinical implantation stage, may even suggest that this risk-adjustment is too high.

Conclusion

When we combine the implied sales multiple valuation of AorTech Royalty, the intrinsic risk-adjusted valuations of AorTech Vascular and AorTech Heart Valve to AorTech's cash at the end of September 2019, we determine a valuation for the whole business of £99.2m or 676 pence per share.

Forecasts

Consolidated Income Statement & Forecasts

£'000s, y/e 31 March	2017A	2018A	2019A	2020E	2021E
IFRS Income Statement					
Total revenue	614	404	463	500	580
Administration expenses	-559	-474	-841	-994	-1500
Other income (expense)		255	7	7	7
Depreciation & amortisation	-292	-219	-218	-92	-5
Reported EBIT	**-237**	**-34**	**-631**	**-579**	**-918**
Reported profit before tax	**-237**	**-34**	**-609**	**-579**	**-918**
Taxation					81
Reported Net income	**-237**	**-34**	**-609**	**-597**	**-837**
Basic EPS (c before 2019, p after 2019)	-4.26	-0.61	-4.72	-3.94	-5.70
Diluted EPS (c before 2019, p after 2019)	-4.26	-0.61	-4.72	-3.94	-5.70

Source: Company historic data, ED estimates

Consolidated Balance sheet & Forecasts

£'000s, at y/e 31 March	2017A	2018A	2019A	2020E	2021E
Assets					
Non-current assets					
Tangible assets			1	2	2
Intangible assets	914	527	448	355	355
Total non-current assets	914	527	449	357	357
Current assets					
Trade and other receivables	392	134	238	234	264
Cash and equivalents	114	422	2412	1895	1028
Total current assets	506	556	2650	2128	1292
Total assets	1420	1083	3099	2486	1649
Equity and liabilities					
Equity					
Ordinary shares	15189	12118	12574	12574	12574
Share Premium	3133	2500	4550	4550	4550
Retained earnings	-2511	-11599	-12208	-12787	-13624
Foreign exchange reserve	8752				
Other reserve	-23245	-2003	-1916	-1916	-1916
Equity attributable to the company	1318	1016	3000	2421	1584
Total equity	1318	1016	3000	2421	1584
Current liabilities					
Trade and other payables	-102	-67	-99	-65	-65
Total current liabilities	-102	-67	-99	-65	-65
Total non-current liabilities					
Total equity and liabilities	1216	949	2901	2356	1519

Source: Company historic data, ED estimates

Consolidated Cash flow Statement & Forecasts

£'000s, y/e 31 March	2017A	2018A	2019A	2020E	2021E
Profit before taxation	-237	-34	-609	-915	-868
Adjustment for:					
Depreciation & amortisation	292	219	218	92	5
Movements in working capital	-212	162	-73	-30	-30
Net cash generated by operating activities	-200	347	-422	-518	-867
Investing activities					
Capital expenditure on tangibles					
Capital expenditure on intangibles		-16			
Acquisition of subsidiary			-139		
Net cash used in investing activities		-16	-139		
Financing activities					
Net proceeds from issue of shares			2552		
Net cash from financing activities			2552		
Net cash from discontinued operations					
Cash & equivalents at beginning of year	314	91	422	2413	1895
Cash & equivalents at end of year	**114**	**422**	**2413**	**1985**	**1028**

Source: Company historic data, ED estimates

Investor Access

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