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Direction of travel intact

Ahead of its FY 2021 results in July, RUA Life Sciences' trading update included its first year after the acquisition of RUA Medical and a period where the pandemic brought challenges to its customers. While FY 2021 marked a period of transformation for RUA Life Sciences and the medical device market, some things stayed the same as the progress in RUA's products in RUA Vascular and RUA Structural Heart have continued unabated despite the pandemic.

While the pandemic reduced the number of elective surgical procedures in the year to March 31 2021, the royalty fees earned on Elast-Eon-enabled medical devices by RUA Biomaterials actually increased by c.5%. However, these are billed in US dollars so when translated back into Sterling, RUA saw a 5% decline in royalty revenues. We estimate these to be £416,000 vs. £438,000 in FY 2020. In a year when large medical device customers were not focussed on new product development no new Elast-Eon licenses were granted, although this was a minor component of FY 2020 revenues (£40,000). RUA Medical is the third-party manufacturing business acquired at the start of FY 2021 and has also been subject to pandemic-related pressures. We forecasted RUA Medical revenues of £1.43m for FY 2021 but have now reduced this to RUA's expectations of £1.02m. Based on our interpretation of Q1 results of the major medical device manufacturers (see P.2), we continue to expect the revenue shortfall to be temporary and have not altered our forecasts for FY 2022.

Patches, grafts and heart valve advance

RUA recently updated the progress and timelines for its large bore vascular graft and cardiac/vascular patches, and the timings of their US 510k regulatory submissions. RUA's trading update further notes that the vascular graft has now completed of the 510k-enabling *in vivo* study. With a regulatory submission expected in June 2021, RUA is now within touching distance of commercial sales in FY 2022. RUA plans to sell into the important US market through a combination of OEM sales and distributor partners, we would anticipate announcement of these deals around 510k approval. Discussions are commencing with European partners in anticipation of seeking approval through CE and CA marking., and while we still value the products in RUA Vascular as an acquisition, we would not be surprised to see RUA Vascular revenues in FY 2022, as the trading update suggests that revenues could come sooner than we had expected. The heart valve in development in RUA Structural Heart continues with the investment of additional testing and manufacturing equipment.

Iterative valuation increases reflect progress

We have updated our valuation for the cash balance included in the trading update and have started to reflect tangible progress in the vascular graft. Our valuation has modestly increased to £115.4m or 520p, from £113.2m or 510p per share. With graft and patch product regulatory submissions on the horizon before the end of the second quarter of 2021 and by the end of 2021, respectively, we anticipate making more substantive changes to our valuation at both these time points to reflect the value added by product advancement and the shorter time to a licensing transaction.

Summary Financials

£'000s, y/e 31 March	2018A	2019A	2020A	2021E	2022E
Revenues	404	463	489	1436	2005
Reported EBIT	-34	-638	-941	-1825	-1560
Basic EPS (US c / UK p)	-0.61c	-4.72p	-5.55p	-9.92p	-6.06p
Net Assets	1016	3000	2275	8574	7849
Net Cash	422	2412	1976	6410	4366

Source: Company historic data, ED estimates

Company Data

EPIC	RUA
Price (last close)	138p
52 weeks Hi/Lo	177p / 74p
Mkt Cap	£30.6m
ED Fair Value, per share	£115.4m / 520p
Est. FY21 net cash	£6.41m
Avg. daily volume	45,341

Share Price, p



Source: ADVFN

Description

RUA Life Sciences PLC ('RUA') 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. RUA has four divisions: RUA Biomaterials that receives the licensing and royalty fees from products based on Elast-Eon, RUA Vascular that is commercialising biostable surgical patches and grafts, and RUA Structural Heart, which is developing an artificial aortic heart valve replacement. In early 2020, the predecessor company (AorTech International) announced the acquisition of RUA Medical to retain the Vascular business collaboration and RUA Medical's integrated medical device design and manufacturing capabilities in the combined company.

Andy Smith (Analyst)

0207 065 2690

andy.smith@equitydevelopment.co.uk

Hannah Crowe

0207 065 2692

hannah@equitydevelopment.co.uk

Changes to our financials

The major effect of the pandemic on medical device companies had been the reduction in number of elective surgical procedures as patients were dissuaded from attending hospitals during an active pandemic. This has had the knock-on effect on RUA Life Sciences via its customers that either already sell products on which RUA earns a royalty, or are developing new Elast-Eon-enabled products. The royalty fees earned on Elast-Eon-enabled medical devices by **RUA Biomaterials actually increased by about 5%**. However, since these are billed in US dollars, when translated back into Sterling, RUA have indicated a 5% decline in FY 2021 royalty revenues to what we now estimate will be £416,000 vs. £438,000 in FY 2020. In a year when the medical device industry was not focussed on new product R&D, no new Elast-Eon licenses were granted for new product development at partners. This was a minor component of FY 2020 revenues (£40,000). **RUA Medical** is the third-party manufacturing business acquired at the start of FY 2021 and has also been subject to pandemic-related pressures at its customers. We had forecasted RUA Medical revenues of £1.43m for FY 2021 but have now reduced this to RUA's expectations of £1.02m. Based on our interpretation of the first-quarter results of the major medical device manufacturers (see below), we continue to expect the revenue shortfall to be temporary and have largely maintained our forecasts for FY 2022 onwards.

Comparisons with the cardiovascular device sector

The pandemic brought significant commercial challenges to the life science sector. When hospitals, clinics and primary care contracted to handle mostly coronavirus patients, or moved to telehealth consultations, respectively, elective surgical procedures and even cancer therapy and diagnoses were severely curtailed. After the acquisition of RUA Medical, the combined company was exposed to these pressures via the cardiovascular medical device customer that accounted for the majority of RUA Medical Devices' revenues. At the time of the FY2020 results, much of the revenue shortfall had been quantified and remedial action in terms of grant funding had been taken.

RUA's trading update was a further reminder of last year's pandemic pressures on the medical device sector, but in this, RUA and its customers are by no means alone. Other, bigger medical device companies that have cardiovascular franchises (and are ironically, potential licensors or acquirors of RUA's products), have reported larger revenue impacts as a result of the pandemic, than RUA. While most big medical device companies with cardiovascular franchises include a broad range of products outside of grafts, patches and heart valves that are applicable to RUA Life Sciences, their commercial pressures under the pandemic are illustrative. The world's largest healthcare company, Johnson & Johnson (J&J), reported FY calendar 2020 medical device revenues that fell by 11.4%. A large part of J&J's medical devices division comprises orthopaedic products (hip and knee replacements) and ophthalmic surgical devices but as a guide to the cardiovascular space, general surgical revenues fell by 18.8% whereas interventional revenues (which include cardiac electrophysiology) recovered in H2 2020 and rose by 1.6% for the year. As the first medical device company to report Q1 2021 financials, and indicating a positive trend for RUA in FY 2022, J&J reported medical device and general surgical revenues that rose 10.9% and 17.3%, respectively, over Q1 2020.

Medical device companies with a less diverse product offering and therefore a higher cardiovascular device component of revenues than J&J include Medtronic, Boston Scientific and Edwards Life Sciences.

Medtronic has a cardiac and vascular group which includes products to treat cardiac rhythm disorders and heart failure as well as structural heart and endovascular stents and grafts. While Medtronic's net sales fell by 5% in FY 2020, its cardiac rhythm & heart failure, coronary & structural heart and aortic, peripheral & venous business unit sales fell by 12%, 5% and 7%, respectively. Boston Scientific's total medical device revenues declined by 9.0% in FY 2020 although like J&J and Medtronic, these included divisions like cardiac rhythm management (pacemakers), neuromodulation (deep brain stimulation) and peripheral interventions that are less relevant comparators to RUA. More specifically, Boston Scientific's interventional

cardiology revenues fell by 18.4% in 2020. In the three months ending March 31 2021, Boston Scientific's interventional cardiology revenues rose by 9.9% compared to the same quarter of 2020.

The much more focussed cardiovascular medical device company Edwards Life Sciences have the vast majority of its revenues from transcatheter aortic valve replacements – which may eventually become a competitor, licensor or acquiror of RUA Structural Heart products – saw total revenues rise by 1.5% in 2020 although in the more relevant to RUA, surgical structural heart division, revenues fell by 9.5% last year. In the quarter ending March 31 2021, Edwards Life Sciences surgical structural heart division's sales were up 10% compared to first quarter of 2020.

RUA Life Sciences' products continue to advance

RUA Life Sciences had recently announced progress in its sealed vascular grafts and cardiac/vascular patches that are developed in its RUA Vascular division. These products have a much simpler path to approval than its heart valve, for example, and the US 510k regulatory path is made easier if the new product can demonstrate "Substantial Equivalence" to another product already on the market for the same indication, with only animal implantations. Indeed, RUA Vascular's large bore vascular graft was designed with the FDA's 510k process in mind to perform the same function as vascular grafts already approved, but with better longevity and biocompatible properties. 12 RUA vascular grafts were implanted together with three control grafts in the summer of 2020, were subsequently explanted for analysis. All performed to their design expectations. As a reminder, large bore vascular grafts are not an unusual medical device although the use of animal sourced material to seal the material and prevent leakage is typical. This is eliminated in RUA's product by the use of its biostable polymer Elast-Eon. It was interesting to note the Company commenting on the grafts being described as disruptive and plays to a growing trend of eliminating animal by products.

The implantation studies required for the 510k regulation submission have been largely unaffected by the pandemic and while delays from RUA's packaging and device sterilization suppliers have been observed, RUA now remains on target to submit the 510k application towards the end of the second quarter. For now, and to reflect the imminent regulatory submission, we have started to adjust the risk-adjustment of the valuation of RUA Vascular to reflect the progress that has been made. As we expect that the regulatory submission will be a notifiable event, we will update our valuation of RUA Life Sciences further on its announcement. A potentially shorter time to a licensing transaction than the four years we currently have estimated, and another iterative risk-adjustment are the two valuation drivers we will be reviewing after a regulatory submission.

The large bore vascular graft is a related, but more complicated medical device in RUA Vascular than the cardiac/vascular patches. Both devices are comprised of an Elast-Eon coated and sealed medical-grade woven fabric which in the case of the graft, is further manipulated into a sealed cylindrical tube-like structure. Both devices were to be included in the same 510k application however, proof of concept studies on the patches have suggested greater compliance on surgical implantation as well as the potential for automated manufacturing. As the Elast-Eon-coated surgical patches could have additional applications and claims than were originally anticipated, a separate 510k submission is expected to be made before the end of 2021. We have not made any changes to our valuation yet, with respect to the cardiac/vascular patch regulatory submissions.

Consolidated Income Statement & Forecasts

£'000s, y/e 31 March	2018A	2019A	2020A	2021E	2022E
IFRS Income Statement					
Total revenue	404	463	489	1436	2005
Administration expenses	-474	-822	-1123	-2345	-2936
Other income (expense)	255	7	14	14	14
Depreciation & amortisation	-219	-218	-193	-200	-200
Reported EBIT	-34	-638	-941	-1823	-1560
Reported profit before tax	-34	-609	-897	-2301	-1560
Taxation			81	100	215
Basic EPS (c before 2019, p after 2019)	-0.61	-4.72	-5.55	-9.92	-6.06
Dil'd EPS (c before 2019, p after 2019)	-0.61	-4.72	-5.55	-9.92	-6.06
Share count at end of period (basic)	5,557,659	14,686,608	14,686,608	22,184,797	22,184,797

Source: Company historic data, ED estimates

NB From 2020 onwards, pro forma numbers of the combined AorTech and RUA Medical business are shown

Consolidated Balance Sheet & Forecasts

£'000s, at y/e 31 March	2017A	2019A	2020A	2021E	2022E
Assets					
Non-current assets					
Tangible assets			5	1481	1481
Goodwill				1352	1352
Intangible assets	527	448	255	55	955
Total non-current assets	527	449	260	2888	3788
Current assets					
Trade and other receivables	134	238	258	483	513
Cash and equivalents	422	2412	1976	6410	4366
Total current assets	556	2650	2234	6893	4879
Total assets	1083	3099	2494	9781	8667
Equity and liabilities					
Equity					
Ordinary shares	12118	12575	12574	19649	19649
Share Premium	2500	4550	4550	5975	5975
Retained earnings	-11599	-12208	-13024	-15225	-16226
Foreign exchange reserve					
Other reserve	-2003	-1916	-1825	-1825	-1825
Equity attributable to the company	1016	3000	2275	8574	7849
Total equity	1016	3000	2275	8574	7849
Current liabilities					
Trade and other payables	67	99	219	818	818
Total current liabilities	67	99	219	818	818
Total non-current liabilities				389	
Total equity and liabilities	1083	3099	2494	9781	8667

Source: Company historic, ED estimates. From 2020 onwards, pro forma numbers of the combined businesses are shown.

Consolidated Cash Flow Statements & Forecasts					
£'000s, y/e 31 March	2018A	2019A	2020A	2021E	2022E
Profit before taxation	-34	-609	-897	-2301	-1560
Adjustment for:					
Depreciation & amortisation	219	218	193	200	200
Movements in working capital	162	-73	100	425	425
Net cash generated by operating activities	347	-429	-438	-1676	-719
Investing activities					
Capital expenditure on tangibles		-1	-5	-290	-900
Capital expenditure on intangibles	-16				
Acquisition of subsidiary		-139		-600	
Net cash used in investing activities	-16	-133	2	-890	-900
Financing activities					
Net proceeds from issue of shares		2552		7000	
Net cash from financing activities		2552		7000	-425
Net cash from discontinued operations					
Cash & equivalents at beginning of year	91	422	2412	1976	6410
Cash & equivalents at end of year	422	2412	1976	6410	4366

Source: Company historic data, ED estimates. From 2020 onwards, pro forma numbers of the combined business are shown.



Contacts

Andy Edmond

Direct: 020 7065 2691

Tel: 020 7065 2690

andy@equitydevelopment.co.uk

Hannah Crowe

Direct: 0207 065 2692

Tel: 0207 065 2690

hannah@equitydevelopment.co.uk

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More information is available on our website www.equitydevelopment.co.uk

Equity Development, 15 Eldon Street, London, EC2M 7LD

Contact: info@equitydevelopment.co.uk | 020 7065 2690