

Trading update – the pandemic clouds disperse

27th May 2022

RUA Life Sciences' trading update illustrated both a recovery from the challenges of the pandemic faced by medical device companies which translated into increased revenues at RUA Medical Devices and increased investment in its vascular and heart valve products.

Preliminary FY 2022 Results

RUA's preliminary group revenues for FY 2022 increased by 6% to £1,625K (vs. £1,528k for the year to 31 March 2021). Group revenues were in-line with our £1,675K estimates and provide the clearest evidence yet of the post-pandemic rebound in surgical procedures (see below). The majority of RUA's revenues come from the RUA Medical Devices business acquired in March 2020 and at £1,138K, these were ahead of our £1,061K estimate. R&D expense (which we include in Administration expenses) is expected to have increased by 64% to £887K from £541K in FY 2021 because of the higher headcount, and the investment in the development and manufacture of RUA's products. This increased pace of investment in R&D is expected to widen the FY 2022 operating loss to £2,360k from FY 2021's £1594k, and we await the detailed FY 2022 final results to see if our estimate of higher R&D tax credits of £247k (vs. £143k in FY 2021) provides some offset to the higher FY 2022 R&D expense in net figures. RUA's cash balance has decreased from £6,294k at the end of FY 2021 to £2,963k a year later but this was much higher than our previous FY 2022 estimate and we have aligned with the higher YE 2022 cash position in RUA's trading update.

Supportive environment for medical devices

Sales of medical devices, particularly those associated with elective surgical procedures like hip and knee replacements, were hit hard by the pandemic as hospitals focussed on treating COVID-19 patients, and physicians and patients' contact for other conditions was limited. In 2021, the big US medical device manufacturers and RUA's major US customer started to see a recovery in revenues as the first COVID-19 waves subsided and the vaccines were rolled out. Since the summer of 2021 the Delta and Omicron variant waves brought worries of a further disruption in surgical procedures - but the recent results of the big medical device companies have demonstrated **a more resilient and supportive environment**. Johnson & Johnson's – admittedly with a broad medical device portfolio including orthopaedics and cardiovascular – FY 2021 medical device division reported revenue growth of nearly 18% on FY 2020, above that of its pharmaceutical and consumer divisions. RUA Medical Devices FY 2022 revenues are expected to have grown by 11% compared to those of FY 2021.

Valuation adjusted

Our valuation has been updated for RUA's trading statement with the only change reflecting the cash consumption. This modestly decreased our valuation to £121.0m or 545p per share from £122.9m or 554p per share.

Summary Financials					
£'000s, y/e 31 March	2018A	2019A	2020A	2021A	2022E
Revenues	404	463	489	1528	1675
Reported EBIT	-34	-638	-941	-1551	-2714
Basic EPS (US c / UK p)	-0.61c	-4.72p	-5.55p	-8.20p	-11.12p
Net Assets	1016	3000	2275	8506	5926
Net Cash	422	2412	1976	5924	2963

Source: Company historic data, ED estimates

Company Data

EPIC	RUA
Price	43p
52 weeks Hi/Lo	168p / 39p
Mkt Cap	£9.5m
ED Fair Value, per share	£121.0m / 545p
End FY22 net cash	£2.96m
Avg. daily volume	24,112

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

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A year of pushing medical device boundaries

RUA's interim statement details the 510(k) FDA submission for RUA Vascular's large bore graft and the subsequent disappointing delay (expanded and more iterative process with the FDA) to the revised submission that will now include supplementary clinical data. While the delay to the launch of RUA Vascular's products in the US and EU to 2025 may disappoint some, the generation of data that establishes the safety and efficacy of Elast-Eon as a graft sealant has a number of competitive advantages.

At the very least, the modification of the 510(k) process away from just equivalence to predicate devices that are already on the market, could provide equivalent data to other devices, but without the safety concerns of animal-sourced sealants like gelatin or collagen.

The possibility also exists that an Elast-Eon sealed large bore vascular graft could demonstrate improved benefits in either safety (leakage) or efficacy (graft performance) than the predicate devices: this would give RUA more leverage in the discussions with potential OEM and distribution partners, whose interest RUA mentions in the trading update. In either event, a 510(k) approval based on RUA's clinical data would provide a beachhead and high-water mark for a fully synthetic vascular graft that other devices are unlikely to be able to use as a predicate.

Valuation virtually unchanged

We await RUA Life Sciences' final results to change any of our financial forecasts and, bar adjusting for the cash and revenue numbers in the trading update, we have largely maintained our valuation despite RUA's clarity on its expectations for the first approval (of potentially an expanded vascular graft pipeline) of a large bore vascular graft in 2024. Our valuation currently expects a transaction for a vascular product in four years.

This timing in our model may have to be reduced as further progress on the clinical study is announced. With the first RUA Structural Heart product entering *in vivo* studies in 2023, we have also left our estimate for a RUA Structural Heart transaction in five years, unchanged.

Omelettes from eggs

RUA's trading update details not just the actions it intends to take from the disappointing regulatory hiccup on its large bore vascular graft and the investment in staff and facilities to streamline development, but the underlying narrative of the update includes a greater role in using these in-house resources to transform the business into a fully-fledged medical device manufacturer and pivoting to sustainable and profitable growth.

In the short term, we interpret this as using RUA's capacity and facilities to leverage revenues in RUA Medical Devices.

In the longer term, this joined-up-thinking across RUA's businesses has the potential to generate new products as the trading update mentions a heart valve containing a textile (as well as polymer) leaflet. The textile leaflet development can only have come about as a result of the RUA Medical acquisition in March 2020.

Consolidated Income Statement & Forecasts

£'000s, y/e 31 March	2018A	2019A	2020A	2021A	2022E
IFRS Income Statement					
Total revenue	404	463	489	1528	1675
Administration expenses	-474	-822	-1123	-2690	-3733
Other income (expense)	255	7	14	279	279
Depreciation & amortisation	-219	-218	-193	-272	-490
Reported EBIT	-34	-638	-941	-1551	-2714
Reported profit before tax	-34	-609	-941	-1551	-2714
Taxation			81	143	247
Basic EPS (c before 2019, p after 2019)	-0.61	-4.72	-5.55	-8.20	-11.12
Dil'd EPS (c before 2019, p after 2019)	-0.61	-4.72	-5.55	-8.20	-11.12
Share count at end of period (basic)	5,557,659	14,686,608	17,609,120	22,184,798	22,184,798

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	2021A	2022E
Assets					
Non-current assets					
Tangible assets			5	1952	2395
Goodwill				301	301
Intangible assets	527	448	255	574	574
Total non-current assets	527	449	260	2827	3270
Current assets					
Trade and other receivables	134	238	258	949	1079
Cash and equivalents	422	2412	1976	6294	2963
Total current assets	556	2650	2234	7328	4219
Total assets	1083	3099	2494	10155	7489
Equity and liabilities					
Equity					
Ordinary shares	12118	12575	12574	12949	1109
Share Premium	2500	4550	4550	11727	11729
Retained earnings	-11599	-12208	-13024	-14475	-17339
Foreign exchange reserve					
Other reserve	-2003	-1916	-1825	-1697	-1629
Equity attributable to the company	1016	3000	2275	8506	5926
Total equity	1016	3000	2275	8506	5926
Current liabilities					
Trade and other payables	67	99	219	1016	847
Total current liabilities	67	99	219	1099	889
Total non-current liabilities				40	
Total equity and liabilities	1083	3099	2494	10155	7488

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	-1594	-2714
Adjustment for:					
Depreciation & amortisation	219	218	193	68	490
Movements in working capital	162	-73	100	820	820
Net cash generated by operating activities	347	-429	-438	-1414	-2469
Investing activities					
Capital expenditure on tangibles		-1	-5	-620	-443
Capital expenditure on intangibles	-16				
Acquisition of subsidiary		-139		-341	
Net cash used in investing activities	-16	-133	2	-952	-443
Financing activities					
Net proceeds from issue of shares		2552		6462	
Net cash from financing activities		2552		6684	-420
Net cash from discontinued operations					
Cash & equivalents at beginning of year	91	422	2412	1976	6294
Cash & equivalents at end of year	422	2412	1976	6294	2963

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



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