

16 December 2021

Interim results

RUA Life Sciences interim results demonstrated the continued investment in the business and its new products. The highlight of the interims was the 33% increase in third-party contract revenues that were a result of a recovery in elective surgical procedures, particularly in the US. Clouding the interims were the implications of the regulatory delay to the 510(k) review of RUA's large-bore vascular graft medical device, which we explore more in this note.

Financials reflect increased investment

Revenues for the six months to 30 September 2021 were £708,000. These comprised of £552,000 and £156,000 from RUA Medical, and polymer licensing fees, respectively. This compared to £631,000, split £416,000 and £215,000, respectively, in the same period of 2020. While the third-party contract manufacturing fees from the acquired RUA Medical Devices business increased 33% in H1 2022, polymer license and royalty fees fell as a result of exchange rate movements and the timing of payments. The latter of these, should reverse in H2 2022. We have not changed our FY 2022 revenue estimate of £1,675,000, partly because we had not previously included any RUA Vascular revenues until FY 2023.

H1 2022 expenses reflected the investments in the business that were highlighted in previous announcements and the headcount expansion as a result of the RUA Medical acquisition. Administration expenses – which include R&D – increased to £1,658,000 (£1,181,000 in H1 2021) to reflect this investment and we have maintained our FY 2022 administration expense estimate of £3,733,000. As a result, RUA's loss before tax increased to £1,315,000 (£622,000 H1 2021) and the end of September's cash position was £4,763,000 (£1,009,000 end-H1 2020).

510(k) Regulatory update

RUA's recent regulatory update announcing a delay to the approval of its Elast-Eon sealed vascular grafts was a knock to investors' confidence as it reflected a delay to the product's approval and therefore early sales. We had not included revenues from these products before RUA's YE 2023 in our forecasts but bearing in mind the Chairman's statement on an expectation for human clinical trial data, we have now deferred vascular graft sales until FY 2024. Despite this, it should not be forgotten that RUA remains in a regulatory process with the FDA which should result in the products' approval.

Valuation and financials largely unchanged

Our valuation remains at **£122.9m or 554p per share** since regulatory progress continues to be made on the vascular products even if revenues are delayed. There are however, the emerging variables of the additional clinical costs for the vascular graft products, and time until approval. We have made minor updates to our FY 2022 forecasts of working capital and liabilities from the interim balance sheet but will revisit our forecasts and valuation once these variables are known.

Company Data

EPIC	RUA
Price	91.5p
52 weeks Hi/Lo	180p / 90p
Mkt Cap	£20.3m
ED Fair Value, per share	£122.9m / 554p
H1 22 net cash	£4.8m
Avg. daily volume	51,087

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

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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	906

Source: Company historic data, ED estimate

Interims overshadowed by a regulatory delay

Despite RUA's rapid progress and investment in its Elast-Eon-sealed large bore vascular graft product in the last 18 months, the interim results were overshadowed by the recent announcement of a delay to the approval and first revenues from this product. As a result of the interim results discussion that human clinical trial data is likely to be required for a 510(k) approval, and that the approval is based much less on a predicate device, we have now deferred our forecasts of vascular product sales until FY 2024 to reflect the time needed to complete these studies and the regulatory process.

If anyone was under the impression that the regulatory approval of a ground-breaking medical device that frees manufacturers, surgeons and patients from the burden of animal-derived products was easy, then they now know why such a biocompatible product has not been approved before. As RUA pointed out in its recent trading update, the industry momentum for animal sealant-free biocompatible medical devices is moving its way and the eventual approval of these devices would represent a significant barrier to entry for medical device companies with products that still contain animal sealants. In order to obtain regulatory approval for RUA's Elast-Eon-coated vascular grafts, and ironically, provide a higher barrier for any other competitor to enter, human clinical trial data is required.

The deferral of RUA Vascular product revenues raises the spectre that bigger medical device companies, and even its potential OEM partners for the products, might sense an opportunity. The pressures that a delay to revenues could bring, and the extent of the investment cost already spent on the product's development, means they could attempt a licensing transaction at a fraction of our £74m valuation of RUA's Vascular products, or acquire the whole portfolio today for about half the price of RUA's market capitalisation a year ago.

It is unfortunate that RUA's requirement for the cash flows from a licensing transaction in FY 2023, coincides with the deferral of its new vascular revenues that same year. On the other hand, RUA have always controlled its costs, and investment still to be incurred may be deferred beyond YE 2022 to make our YE 2022 cash estimate look anaemic. Included in the Chairman's statement is the anticipation of regulatory clarity, and as such, the costs of the clinical studies required for approval are not yet known. Once they are, investors will be able to recognise how close RUA are to approval, and the resources that are needed, for this last lap of this product's development.

FINANCIALS

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	-3773
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 (basic)	5,557,659	14,686,608	17,609,120	17,967,120	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	4452
Goodwill				301	301
Intangible assets	527	448	255	574	574
Total non-current assets	527	449	260	2827	5327
Current assets					
Inventories				85	177
Trade and other receivables	134	238	258	949	1079
Cash and equivalents	422	2412	1976	6294	906
Total current assets	556	2650	2234	7328	2162
Total assets	1083	3099	2494	10155	7489
Equity and liabilities					
Equity					
Ordinary shares	12118	12575	12574	12949	1109
Share Premium	2500	4550	4550	11729	11727
Capital redemption reserve					11840
Retained earnings	-11599	-12208	-13024	-14475	-17399
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				550	673
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	2021A	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	-2500
Capital expenditure on intangibles	-16				
Acquisition of subsidiary		-139		-341	
Net cash used in investing activities	-16	-133	2	-952	-2500
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	906

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



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