

13 December 2021

Regulatory hiccup

RUA Life Sciences have announced a regulatory update on the 510(k) submission for its vascular graft products that was filed on November 3rd, 2021. The FDA appears to have questions about the products that will almost certainly take longer to resolve than the normal review window. RUA and the FDA have converted the application into a pre-notification process and RUA does not now expect its first commercial sales in the first quarter of 2022.

Vascular graft delay

In medical device premarket notifications to the FDA, or 510(k) applications, companies can often test the waters by opening a dialogue with the FDA using so-called pre-submissions or Q-submissions. For novel medical devices, even with predicate comparators, this early interaction can iron-out any questions that the FDA may have and help the agency to become comfortable with the new device. RUA Life Sciences RNS announcement on its 510(k) submission for its Elast-Eon-coated vascular graft products, that occurred in early November, has stated that the normal 510(k) process has converted to the pre-submission stage.

As a result, RUA does not expect any commercial sales for its vascular products in Q1 2022. However, we had not included any new revenues for RUA Vascular in our recent valuation update on RUA Life Sciences, and while we had reduced our discount rate to reflect the progress made on the vascular grafts, RUA are still in a regulatory process with the FDA. We shall therefore await more information before changing our valuation and forecasts as a result of this news.

While the transition back to a pre-submission is clearly not ideal, and the timing of the first vascular revenues will be delayed, a normal 510(k) process can take between 60 to 90 days, or even longer if the FDA has questions that need to be answered. While addressing the FDA's questions in a pre-submission process may take the whole regulatory process outside the original 90-day time frame, there is still hope that this pre-submission familiarity will help take the subsequent (normal) 510(k) re-submission and review timings towards the lower end of 60 to 90-day timeframe.

Valuation unchanged ahead or interims

We are leaving our valuation unchanged at **£122.9m or 554p per share** despite the delay to the 510(k) process for the vascular graft products since RUA are still in an, albeit longer regulatory process with the FDA, which should result in the approval of those products.

We are making no changes to our financial forecasts ahead of RUA's interim results.

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	5785
Net Cash	422	2412	1976	5924	906

Source: Company historic data, ED estimate

Company Data

EPIC	RUA
Price (last close)	136p
52 weeks Hi/Lo	180p / 113p
Mkt Cap	£30m
ED Fair Value, per share	£122.9m / 554p
End HY21 net cash	£4.8m
Avg. daily volume	43,747

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

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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	100
Trade and other receivables	134	238	258	949	1079
Cash and equivalents	422	2412	1976	6294	906
Total current assets	556	2650	2234	7328	2085
Total assets	1083	3099	2494	10155	7412
Equity and liabilities					
Equity					
Ordinary shares	12118	12575	12574	12949	12949
Share Premium	2500	4550	4550	11729	11857
Retained earnings	-11599	-12208	-13024	-14475	-17600
Foreign exchange reserve					
Other reserve	-2003	-1916	-1825	-1697	-1697
Equity attributable to the company	1016	3000	2275	8506	5785
Total equity	1016	3000	2275	8506	5785
Current liabilities					
Trade and other payables	67	99	219	1016	1016
Total current liabilities	67	99	219	1099	1076
Total non-current liabilities				550	550
Total equity and liabilities	1083	3099	2494	10155	7411

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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