

25 June 2021

Minor bump in the road to 510k submission

RUA have released a precautionary announcement noting a minor delay to the 510k submission for its large bore vascular graft. This was almost certainly due to the handling of the batch of un-implanted grafts, and we share RUA's frustration with the resulting delay. Since we had not yet updated our valuation for a June 2021 510k submission, our fair value remains unchanged.

RUA announced a delay to their 510k medical device submission to the FDA for their large bore vascular graft. Surprisingly, a chemical analysis detected cellulose in an early batch of un-implanted grafts. The delay is very much a **precautionary move** as RUA's **Elast-Eon-coated medical devices are completely artificial** – cellulose (an inert, natural, plant-derived material) is NOT used in their manufacture, and none has been detected in the three components (yarn, Elast-Eon and plastic packaging). The grafts **must have been** accidentally contaminated prior to leach testing.

In order to maximise the success of its first 510k submission with the FDA, RUA have proposed the following strategy. The 510k submission will await and include the results of the same leachable extract testing conducted on a different graft production batch at a different lab. In addition, further analysis will be conducted on the grafts where cellulose was detected to confirm no toxic substances present.

Other testing de-risks submission

Despite the chemical analysis, the performance of the Elast-Eon-coated large bore vascular graft in *in vivo* and *in vitro* testing has been positive with sealant and kink resistance confirmed, a normal healing process and no emboli or thrombosis observed in the pathology results. Even with the minor delay for the secondary testing, RUA continues to expect first revenues from its large bore vascular graft by the close of its financial year ending 31 March 2022.

Iterative valuation increases reflect progress

Both our financials and valuation are unchanged after the recent buy back and cancellation of deferred shares, and the announcement of the delay to the vascular graft submission due to the likely ex-manufacturing contamination issue.

Our valuation remains at £115.4m or 520p per share. We had been expecting to alter our valuation after the 510k submission and continue to await this announcement to amend it.

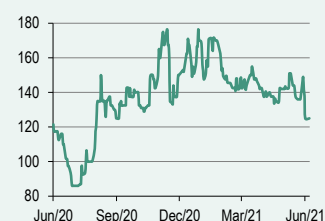
Summary Financials					
£'000s, y/e 31 March	2018A	2019A	2020A	2021E	2022E
Revenues	404	463	489	1436	2005
Reported EBIT	-34	-638	-941	-1825	-1560
Basic EPS (US c / UK p)	-0.61c	-4.72p	-5.55p	-9.92p	-6.06p
Net Assets	1016	3000	2275	8574	7849
Net Cash	422	2412	1976	6410	4366

Source: Company historic data, ED estimates

Company Data

EPIC	RUA
Price	125p
52 weeks Hi/Lo	177p / 84p
Mkt Cap	£28m
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.

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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.



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