

Significant milestone and trading update

4 November 2021

RUA Life Sciences released a well-received announcement on an important milestone in the commercialisation of its large bore vascular graft and its related product, the vascular patches. The release also included a trading update on group businesses. As a result of this positive development on RUA's vascular graft product, we have updated our valuation of the product itself and RUA's cash position at the end of September 2021.

Vascular graft progress

The manufacturing hiccup that had held up the US FDA's medical device Premarket Notification (510k) submission for RUA Vascular's large bore vascular graft earlier in June, and which was resolved before the end of the summer, has now been consigned to the past - **as RUA has announced the 510k submission.**

Unlike drugs, which under the FDAs PDUFA legislation have strict, and near year-long timetables for routine reviews, US medical device product reviews are much shorter in duration and approval can occur within three months if no further interactions or data are required. Along with RUA Life Sciences' manufacturing preparations, this would be in-line with RUA's previously announced timing for a commercial launch of the vascular graft in Q1 2022.

Earlier in the summer we had been discussing a change to our valuation to reflect RUA's progress made on the vascular products, and so this announcement has helped us start to incorporate the progress that RUA has made into our valuation of its products.

RUA's announcement also discussed the regulatory separation, for submission purposes, of the vascular graft and patch products which we explore further in the body of the note.

Trading update

RUA Life Sciences' trading update included many moving parts in its revenue- and royalty- generating divisions, and its cash position. We have reviewed these updates and noted how they either largely net each other off. We have prudently deferred our estimates of vascular graft sales in Q1 2022 until RUA's FY 2023 to reflect the timing of the 510k submission. This changes our forecasts of FY 2022 revenues, and the subsequent YE 2022 cash position which are detailed in the note.

Valuation now incorporating the first step-up

Our valuation has increased to £122.9m or 554p per share (from £116.5m or 525p per share) as a result of changing our discount rate on the vascular products to reflect the progress made, RUA's revised cash balance at the end of H1 2022, and the deferred (from our previous forecasts) Vascular graft sales.

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	166p
52 weeks Hi/Lo	180p / 113p
Mkt Cap	£37m
ED Fair Value, per share	£122.9m / 554p
End HY21 net cash	£4.8m
Avg. daily volume	32,876

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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The product portfolio progresses

The recent delay to RUA Life Sciences' large bore vascular graft product, was later identified and rectified as cellulose contamination (for a product that does not contain cellulose) from cleaning materials. By September, the product was back on-track for a Q1 2022 commercial launch and that same timing was repeated in RUA's recent announcement of the regulatory submission to the FDA. RUA's R&D team are now validating the production equipment, ready for the commercial manufacture and launch.

Earlier this year, our notes had included a discussion on changing our valuation to reflect RUA's progress made on the vascular products, and the announcement has helped us start that process. For RUA Vascular's products – the large bore vascular graft and patches – we have decreased our discount rate from 12.5% (which is used for early-stage products) **to 9%** to reflect near-term regulatory approval. We have also incorporated RUA's cash position disclosed in the trading update, into this valuation.

These changes have **increased our valuation** of RUA Life Sciences from £116.5m or 525p per share, to **£122.9m or 554p per share**. Our deferral of RUA Vascular revenues from Q1 2022 to RUA's FY 2023 has also had a minor impact on our valuation since it includes a 1.5X multiple on RUA's revenues. It is important to note that this is just the first step in a valuation process that tracks RUA's transition to a more commercial entity.

There are other dynamics in our valuation, even just for the Vascular products, such as the risk-adjustment and the time to a commercial transaction, that can be levered in the coming year to more appropriately value RUA's products as they progress.

RUA's announcement also discussed the regulatory separation, for submission purposes, of the vascular graft and patch products. While the Elast-Eon-coated patches are simpler medical devices than the large-bore vascular graft, they have the same composition. As such, the regulatory submissions of the two devices are likely to be similar and RUA have been advised to run the submissions sequentially. There are good precedents for this in drug submissions where it is convention not to submit two indications for the same drug at the FDA at the same time.

There are other advantages, as any learnings from the first submission can be applied to the second and in addition in RUA's case, it allows the team to focus on the development of the new devices for peripheral artery disease and critical limb ischemia disease, that were the subject of a recently received grant.

RUA Structural Heart's polymeric aortic heart valve continues in-house testing and the recent low-stress design changes have been incorporated to potentially extend the durability of this product when implanted.

Trading update

Along with the product update announcements, RUA's release included the recent trading performance of its other divisions. RUA Biomaterials – the division that collects royalties on Elast-Eon-enabled devices – performance was ahead of the Board's expectations.

Royalties from RUA's licensee Biomerics grew 22% in US dollar terms in RUA's first half year while those to other licensees also continued to demonstrate growth over the previous period. Royalty and revenues have been affected by the strength of Sterling and were £156k (£216k in 2020) in the six months to the end of September 2021 but are expected to be positively weighted towards the second half of RUA's year.

RUA Medical Devices – the division which receives the majority of its revenues from one US medical device manufacturer – has seen revenues increase 33% to £552k (£416k in 2020) as elective US surgical procedures returned to pre-pandemic levels.

The investment in plant and equipment, which we had included in our financials, and the final element of the consideration payable for the acquisition of RUA Medical in April 2020, which was also in our forecasts, have resulted in a cash balance of £4,763k at the end of September (£6,293k at the end of March 2021).

Considering that the trading update of revenues at RUA's divisions largely net each other off against our expectations at the end of the half year, and we had assumed the payment of the final part of the consideration for the RUA Medical acquisition, the **only change** we have made to our financial forecasts was to defer our previous estimate of a full quarter of vascular graft sales to RUA's FY 2023 to reflect the approval of the vascular graft within Q1 2022.

This changes in our full-year estimates of total revenues from £2,255 to £1,675k and results in cash of £906k at the end of March 2022.

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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