

## Positive trading and regulatory update

14th November 2022

RUA Life Sciences' trading update was accompanied by a regulatory update on its vascular graft products. Investors look for companies to do three things – achieve clinical, regulatory, and commercial success. While the first of these is awaiting all the clinical trial components to be in place, which the trading update notes that the company is now much closer to, we note RUA's achievement of the second and third of these tasks.

### Strong trading ahead of expectations

The revenues from RUA's two cash-generative businesses – Elast-Eon royalties and contract manufacturing – were 20% and 66% ahead, respectively, on the same six-month period of last year. Moreover, total sales of £1,104k in H1 2023 puts RUA ahead of the Board's, and our, expectations for FY 2023. We have forecasted total revenues of £1,625k for FY 2023. At this point last year RUA noted that the second half of its year would not be as strong as the first but have not added this caveat in its H1 2023 trading update.

This aligns with the recovery of elective surgical procedures after the pandemic as other medical device companies like Boston Scientific reported more than 10% sales growth in its cardiology segment during its recent third-quarter 2022 announcement. The increased sales volume noted in RUA's trading update also supports this trend.

RUA's cash and equivalents at the end of H1 2023 were £2,500k (vs. £2,963k end FY2022) and this represents the combination of outstanding cost control, the 56% year-on-year sales growth, and increased R&D Tax Credit expectations which together trounced our expectations for a c.£300k cash position at this point. Cost control also helped the reduction in H1 2023 Group loss by 15% to £1,100k (vs £1,300k end H12022).

### Regulatory progress

RUA continues to have a constructive relationship with the US FDA on aligning and agreeing the important facets of the 510(k) pre-submission of the RUA's range of Elast-Eon sealed vascular grafts. The trading update notes FDA's agreement on the clinical endpoints and duration (of patient follow-up) of the clinical study – which is more than half the usual battle – with only the statistical analysis plan (SAP) left to be agreed. Investors should not underestimate the task of achieving, or the regulatory weight, of an agreed SAP since this is what regulators hold companies to during and after a clinical study. RUA appears to be maximising the chances for the FDA's agreement on its SAP by using the FDA's statisticians' preferred methodology.

Not all companies are as fastidious as RUA with their interactions with the FDA. UK Biotech company Summit Therapeutics changed the primary endpoint (and therefore the SAP) half-way through a Phase 3 study of its antibiotic ridinilazole without consultation with the FDA. Summit subsequently announced the discontinuation of its ridinilazole clinical studies and a shift to oncology drug development.

### Valuation unchanged

The valiant efforts that RUA has made on cost control and sales growth suggest that changes are needed to our revenue and YE 2023 cash estimates, but we are holding off making changes to our financials until the detail of RUA's interim results expected on December 12.

**Our financial estimates and forecasts remain unchanged for the moment with Fair Value seen at £121.0m or 545p per share.**

#### Company Data

EPIC	RUA
Price (last close)	34.5p
52 weeks Hi/Lo	155p / 31p
Mkt Cap	£7.7m
ED Fair Value, per share	£121.0m / 545p
End FY22 net cash	£2.96m
Avg. daily volume	19,610

#### 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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Summary estimates					
£'000s, y/e 31 March	2019A	2020A	2021A	2022A	2023E
<b>Revenues</b>	463	489	1528	1625	1767
<b>Reported EBIT</b>	-638	-941	-1551	-2352	-2296
<b>Basic EPS (GBp)</b>	-4.72	-5.55	-8.20	-9.32	-8.80
<b>Net Assets</b>	3000	2275	8506	6584	3725
<b>Net Cash</b>	2412	1976	5924	2963	123

Source: Company historic data, ED estimates

## Financials

Consolidated Income Statement & Forecasts					
£'000s, y/e 31 March	2019A	2020A	2021A	2022A	2023E
<b>IFRS Income Statement</b>					
Total revenue	463	480	1528	1625	1767
Administration expenses	-822	-1123	-2690	-3315	-3398
Other income (expense)	7	14	279	66	66
Depreciation & amortisation	-218	-193	-272	-313	-400
<b>Reported EBIT</b>	<b>-638</b>	<b>-941</b>	<b>-1551</b>	<b>-2352</b>	<b>-2296</b>
<b>Reported profit before tax</b>	<b>-609</b>	<b>-941</b>	<b>-1551</b>	<b>-2360</b>	<b>-2296</b>
Taxation		81	143	293	343
Basic EPS (p)	-4.72	-5.55	-8.20	-9.32	-8.80
Diluted EPS (p)	-4.72	-5.55	-8.20	-9.32	-8.80
Share count at end of period (basic) m	14.7	17.6	22.2	22.2	22.2

Source: Company historic data, ED estimates

NB From 2020 onwards, pro forma numbers of the combined AorTech and RUA Medical business are shown

<b>Consolidated Balance Sheet &amp; Forecasts</b>					
£'000s, at y/e 31 March	2019A	2020A	2021A	2022A	2023E
<b>Assets</b>					
<b>Non-current assets</b>					
Tangible assets	1	5	1952	2597	2197
Goodwill			301	301	301
Intangible assets	448	255	574	521	521
Total non-current assets	449	260	2827	3419	3019
<b>Current assets</b>					
Trade and other receivables	238	258	949	1120	1150
Cash and equivalents	2412	1976	6294	2963	123
Total current assets	2650	2234	7328	4207	1397
<b>Total assets</b>	<b>3099</b>	<b>2494</b>	<b>10155</b>	<b>7626</b>	<b>4416</b>
<b>Equity and liabilities</b>					
<b>Equity</b>					
Ordinary shares	12574	12574	12949	1109	1109
Share Premium	4550	4550	11727	11727	12741
Retained earnings	-12208	-13024	-14475	-16542	-20385
Foreign exchange reserve					
Other reserve	-1916	-1825	-1697	-1552	-1552
Equity attributable to the company	1016	3000	2275	8506	7207
Total equity	3000	2275	8506	6584	3725
<b>Current liabilities</b>					
Trade and other payables	99	219	1016	410	410
Total current liabilities	99	219	1099	511	410
Total non-current liabilities			550	531	282
<b>Total equity and liabilities</b>	<b>3099</b>	<b>2494</b>	<b>10155</b>	<b>7626</b>	<b>4417</b>

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

<b>Consolidated Cash Flow Statements &amp; Forecasts</b>					
<b>£'000s, y/e 31 March</b>	<b>2019A</b>	<b>2020A</b>	<b>2021A</b>	<b>2022A</b>	<b>2023E</b>
Profit before taxation	-609	-897	-1594	-2360	-2296
Adjustment for:					
Depreciation & amortisation	218	194	272	312	400
Movements in working capital	-73	100	820	-400	-400
Net cash generated by operating activities	-429	-438	-1414	-2353	-2840
<b>Investing activities</b>					
Capital expenditure on tangibles	-1	-5	-620	-904	
Capital expenditure on intangibles					
Acquisition of subsidiary	-139		-341		
Net cash used in investing activities	-133	2	-952	-912	
<b>Financing activities</b>					
Net proceeds from issue of shares	2552		6462		
Net cash from financing activities	2552		6684	66	
Net cash from discontinued operations					
Cash & equivalents at beginning of year	422	2412	1976	6294	2963
<b>Cash &amp; equivalents at end of year</b>	<b>2412</b>	<b>1976</b>	<b>6284</b>	<b>2963</b>	<b>123</b>

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



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