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## FY 2022 Final Results

RUA Life Sciences' FY 2022 results included total revenues that increased by 6% on the previous year highlighting the movement beyond the pandemic of the medical device sector. After the dust has settled on the revised requirements for the 510(k) vascular graft re-submission, the way forward is now clear which we explore in the body of this note. Our forecasts have only needed modest and non-material updates for RUA's YE 2022 financials and our valuation remains unchanged.

## RUA Bounces back

RUA's final FY 2022 results were aligned with its recent trading update. Group revenues for FY 2022 were £1,625K (vs. £1,528k for the year to 31 March 2021). While there were moving parts within the group's revenues like the 11% growth in third party contract manufacturing revenues that were above our estimates, and polymer license and royalty revenues that were slightly below, together with a lower cost of goods than we had estimated, gross profit was modestly above our forecast. Administration expenses that included additional regulatory and medical device manufacturing expertise, the investment in R&D and also manufacturing capacity, increased from £2,690k to £3,315k in FY 2022. These additional investments resulted in a higher FY 2022 pre-tax loss of £2,360k compared to FY 2021's £1,594k. Finance expense was lower at £8k (compared to FY 2021's £43k) and R&D tax credits of £293k (vs. £143k in FY 2021) were higher. The increased pace of R&D investment should result in a further rise in R&D tax credits, delayed by about 18 months, and we have estimated a £343k R&D tax credit for FY 2023. RUA's FY 2022 net loss increased to £2,067k from £1,451k in FY 2021, while the cash balance has decreased from £6,294k at the end of FY 2021 to £2,963k a year later. We forecast a cash runway beyond FY 2023.

## Medical devices beyond the pandemic

While the effects of the pandemic continue in the waves brought about by new sub-variants and waning immunity, this is different to the shock to the sector in 2020 where medical device sales faltered as many elective surgical procedures were postponed. This has evolved with the number of surgical procedures recovering, and the backlog being addressed as the hospitals learn to work with the virus. Despite Delta and Omicron waves, **RUA Life Sciences' group revenues have been increasing since before the pandemic and after the acquisition of RUA Medical Devices, reinforcing this sector-wide rebound.**

## Valuation unchanged

Our financial estimates and forecasts have barely changed since RUA's FY 2022 trading update while **our valuation remains unchanged at £121.0m or 545p per share.**

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

Source: Company historic data, ED estimates

### Company Data

EPIC	RUA
Price	37.5p
52 weeks Hi/Lo	168p / 34.1p
Mkt Cap	£8.1m
ED Fair Value, per share	£121.0m / 545p
End FY22 net cash	£2.96m
Avg. daily volume	26,126

### 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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## Investments Applied to Products and Manufacturing

RUA Life Sciences FY 2022 results extended its transition from a medical device developer that had royalties from products containing the synthetic and biocompatible Elast-Eon™ polymer, and its own vascular and heart valve products through the integration of RUA Medical Devices' third-party manufacturing, to a period of investment that should enhance all its capabilities.

As the FY 2022 announcement makes clear, investments have been made in acquiring the expertise in medical device regulatory affairs, with the appointment of Director of Clinical and Regulatory Affairs Iain Anthony, product development and manufacturing as well as financial management with appointment of CFO Lachlan Smith. In addition, at some point before the anticipated 510(k) FDA approval of the large bore vascular graft in 2024, RUA's new high output cleanroom facility will have to be commissioned, currently planned during 2023.

## Products Still Front and Centre

RUA Life Sciences revenues derive from contract manufacturing (the RUA Medical Devices business) and the licensing and royalties from Elast-Eon-containing medical devices (the RUA Biomaterials business). These are a useful offset for the research and product development activities of the group. RUA's results announcement notes that its own product developments in vascular grafts (RUA Vascular) and heart valves (RUA Structural Heart) **remain a major attraction for investors** and indeed, in our valuation, **RUA's own products comprise about 90% of our fair value**. This further justifies the investments RUA has made in its products and capacity in FY 2022.

RUA has moved beyond the disappointment of the delay to the 510(k) submission for its large bore vascular graft to focus on (as we put it in [our previous note](#)) making omelettes from cracked eggs. This is because while the submission is delayed until clinical trial data can be provided to the FDA (and scheduled for late 2024), **the data was requested in part because an Elast-Eon-enabled vascular graft could have additional clinical advantages beyond any predicate vascular graft comparator**. Aside from RUA's product not containing animal-derived products like gelatine or collagen, an upside for RUA's vascular graft could be a lower rate of sticking or adhesion by the tissue surrounding or in contact with the external surfaces of the graft. Surgical adhesion is known to complicate some surgical procedures. In addition to the properties of Elast-Eon coated devices preventing this post-surgical adhesion, it is also logical to believe that Elast-Eon-coated devices may result in less inflammation than uncoated or animal-derived coated or sealed devices. While both properties are advantageous from a marketing perspective if proven in the clinical trial, the latter also is easily and cheaply demonstrated by tests on peripheral blood for non-specific inflammatory markers.

RUA's FY 2022 announcement also provided detail on the development of its Elast-Eon enabled replacement aortic heart valve. As noted previously, there are two heart valve programs running simultaneously, one with a 100% polymer leaflet (the flexible segments within a valve that open and close as the heart pumps blood through the valve in one direction, but prevent back flow or regurgitation in the wrong direction), and a textile polymer composite leaflet. While it is too early to pick a winner from these two technologies, it is important to note that only RUA – with its heritage in the Elast-Eon technology, and with the medical textile expertise from the RUA Medical Devices acquisition – has the option of evaluating both these technologies.

## Imminent Clinical Trial

RUA's FY 2022 announcement has set out a timeline for the large bore vascular graft clinical study that follows alignment and agreement with the FDA on the study size and endpoints, for example, in August 2022. **The clinical study start is then anticipated before the end of RUA's FY 2023, regulatory approval would follow in late 2024 and then market launches in 2025.**

We have published our financial estimates out to YE 2023 and have reduced the investment included in administration expense (now that those facilities and expertise are now largely in place) compared to that of FY 2022 (£3,315k), but have balanced this with some additional R&D expense because of the recruitment and conduct of the small clinical trial for the large bore vascular graft. Our FY 2023 administration expense estimate is now £3,398k.

**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)	14,686,608	17,609,120	22,184,798	22,184,798	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	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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