

RUA Life Sciences Plc

FY22 Prelims

RUA Life Sciences has announced preliminary results for the year to March 22, in line with the May 22 Trading Update. Revenues grew 6% to £1.6m with an operating loss of £2.4m. Fiscal year-end cash was £3.0m. At the division level, the company continues to make progress with its vascular graft programme, targeting regulatory approvals in late 2024 and market entry during 2025. Both RUA Biomaterials and RUA Medical Devices division had strong years with underlying volumes up for Biomaterials and YoY revenue growth of 11% for the medical devices division. We believe RUA Life Sciences is making strong progress and we remain confident that RUA's core technology can disrupt the cardiovascular market. However, given near-term uncertainties, largely related to the vascular graft development programme, we are unable to provide a financial forecast and therefore move to a Hold rating.

- **Prelims** – Group revenues were up 6% to £1.6m for FY22A, based upon £0.5m generated by RUA Biomaterials and £1.1m from RUA Medical Devices. Group gross margin was 84%, up from 82% in FY21A. Increased investment in R&D (largely in RUA Vascular and RUA Structural Heart) drove the increase in loss for the year to £2.1m. After CAPEX of £0.9m, group year-end cash was £3.0m.
- **RUA Vascular** – RUA now anticipate approval of its vascular graft in late 2024. Significantly, the FDA will still allow a 510(k) application with human data and a clinical trial has now been designed and submitted with first patient enrolment expected during 2022.
- **RUA Structural Heart** – RUA continued to progress two heart valve programmes in parallel, a 100% polymer leaflet valve and a composite textile leaflet valve. Through the year, RUA aims to optimise both heart valve designs and subsequently prioritise one to take forward into in vivo trials during 2023, with clinical trials to follow.
- **RUA Biomaterials/RUA Medical Devices** – Supporting future growth in the current revenue generating divisions, RUA Biomaterials partner, Biomerics, has expanded manufacturing capacity for Elast-Eon and RUA Medical Devices is in the final stage of a new manufacturing and supply contract with a global medtech company.
- **Investment overview** – Building on an established and growing revenue base, RUA is developing two cardiovascular programmes targeting billion-dollar markets, enabled by its proprietary Elast-Eon technology. The expected shift from animal sourced graft sealants should support the vascular graft and patch products enter the c\$1bn market for these products, while the heart valves could disrupt the \$8bn heart valve market.

Forecast and Ratios

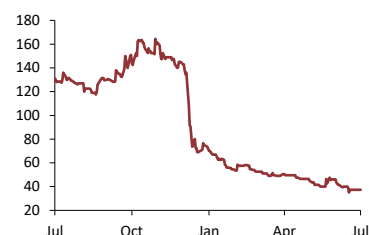
Y/E March (£m)	2018A	2019A	2020A	2021A	2022A
Revenues	0.4	0.5	0.5	1.5	1.6
EBITDA	(0.1)	(0.4)	(0.7)	(1.2)	(1.9)
Net Income	(0.0)	(0.6)	(0.8)	(1.5)	(2.1)
EPS (GBp)	(0.6)	(4.7)	(5.6)	(8.2)	(9.3)
Y/E cash	0.4	2.4	2.0	6.3	3.0

Source: Cenkos Securities estimates, Company data

Brokership Company HOLD

Price at COB 8 Jul 22 37.3p
52-week range 35-164.5p
Ticker RUA LN

Share Price Performance



Source: Morningstar

Stock Data

Market cap (£m) 8.3
Shares outstanding (m) 22.2

Activities

RUA Life Sciences Plc is a holding company, which engages in the commercialisation of biomedical polymer technology, components, and medical devices.

Directors

Bill Brown	Chairman
Caroline Stretton	Group MD
Lachlan Smith	CFO

Significant Shareholders

AJ Bell	7.2%
Walker Crips Stockbrokers	7.0%
Mr DM Richmond	6.9%
Hargreaves Lansdown	6.5%
Interactive Investors	6.5%

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RUA Life Sciences

Results

RUA Life Sciences generated £1.6m of revenues in FY22A, up 6% YoY with the gross margin improving to 84% from 82% in FY21A. The loss for the year was £2.1m reflecting the anticipated increase in R&D investment into the RUA Vascular and RUA Structural Heart business divisions. Group R&D expense was £0.9m for FY22A up from £0.5m in FY21A.

The company notes that RUA Medical Devices saw a strong recovery from the impact of COVID, generating revenues of £1.14m, up 11% YoY at a margin of c50%. The company notes it is at the final stages of negotiating a new manufacturing and supply agreement with a global medtech company, which we believe will support continued growth in the division.

RUA Biomaterials generated revenues of £0.5m for the year, which largely represents royalty income and license fees and therefore delivers high gross margins. Volumes of Elast-Eon polymer delivered to the licensees showing strong growth; however, a one-off payment in FY21A has resulted in RUA Biomaterials revenues being down year on year. RUA's partner Biomerics, has expanded manufacturing capacity which we expect will support future growth for this division.

Cash at the end of March 22 was £2.96m.

RUA Vascular

As previously announced and discussed following the submission of its 510(k) regulatory application to the FDA for its vascular grafts in November 2021, RUA Life Sciences agreed with the agency to convert the application to a pre-submission, allowing further discussion on the regulatory pathway. The FDA sees the incorporation of Elast-Eon on the outside of the grafts as introducing novel technology to the products and therefore requires human clinical data to support the application.

As per the May 22 trading update, we anticipate the following timings for the vascular grafts through to commercialisation:

- H1/22A – the human clinical trial has now been designed and submitted to the FDA as a further pre-submission to ensure the design meets FDA expectations.
- H2/22E – completion of any discussions with the FDA on the trial design.
- H2/22E – first patient recruited into the clinical trial.
- 2023/24E – trial completion and data analysis.
- 2024E – submission of the revised 510(k) application, which could see clearance within 90-days, depending upon potential FDA questions.
- Late 2024E – FDA clearance for the vascular graft products.
- 2025E – commercial launch in the US and Europe.

RUA has estimated that the global market for its range of vascular graft and patch products for the cardio-thoracic market is c\$1bn, with the company targeting a market share of at least 10% based upon the improved technology it has developed.

RUA Structural Heart

RUA Structural Heart is developing heart valves utilising the group's Elast-Eon technology to overcome key issues faced by the current heart valves, such as noise and risk of thrombosis for mechanical valves and limited lifespan for biological valves.

RUA continues to progress two heart valve programmes in parallel, a 100% polymer leaflet valve and a composite textile leaflet valve. Through the year, RUA aims to further advance the testing of the heart valves and subsequently move forward into in vivo trials during 2023. Clinical trials are expected to follow assuming positive outcomes.

Financials

Table 1: RUA Life Sciences Profit & Loss statement

Year-end March (£000)	2018A	2019A	2020A	2021A	2022A
Revenues	404	463	489	1,528	1,625
<i>growth</i>	<i>0.0%</i>	<i>14.6%</i>	<i>5.6%</i>	<i>212.5%</i>	<i>6.3%</i>
COGS	0	0	0	(276)	(267)
<i>% of revs</i>	<i>0.0%</i>	<i>0.0%</i>	<i>0.0%</i>	<i>18.1%</i>	<i>16.4%</i>
Gross profit	404	463	489	1,252	1,358
<i>gross margin</i>	<i>100.0%</i>	<i>100.0%</i>	<i>100.0%</i>	<i>81.9%</i>	<i>83.6%</i>
Operating expenses	(474)	(816)	(1,123)	(2,690)	(3,315)
<i>% of revs</i>	<i>117.3%</i>	<i>176.2%</i>	<i>229.7%</i>	<i>176.0%</i>	<i>204.0%</i>
Other income	0	0	14	279	66
Other expense	0	(19)	(37)	8	(3)
EBITDA, adj	(70)	(372)	(657)	(1,151)	(1,894)
Depr & Amort	(219)	(218)	(193)	(272)	(313)
Share based payments	0	(42)	(91)	(128)	(145)
Operating profit, adj	(289)	(632)	(941)	(1,551)	(2,352)
exceptionals	255	(6)	0	0	0
Operating profit	(34)	(638)	(941)	(1,551)	(2,352)
Finance, net	0	29	44	(43)	(8)
Pre-tax profit	(34)	(609)	(897)	(1,594)	(2,360)
Tax	0	0	81	143	293
<i>tax rate</i>	<i>0.0%</i>	<i>0.0%</i>	<i>9.0%</i>	<i>9.0%</i>	<i>12.4%</i>
Net income	(34)	(609)	(816)	(1,451)	(2,067)
No. shares, period end	5,558	14,687	14,687	21,187	21,187
No. shares, average	5,558	12,911	14,687	17,697	22,185
EPS (GBp)	(0.6)	(4.7)	(5.6)	(8.2)	(9.3)

Source: Company data.

Table 2: RUA Life Sciences Balance Sheet

Year-end March (£000)	2018A	2019A	2020A	2021A	2022A
Goodwill	0	0	0	301	301
Intangible assets	527	448	255	574	521
PP&E	0	1	5	1,952	2,597
Total non-current asset	527	449	260	2,827	3,419
Inventory	0	0	0	85	124
Trade receivables	134	238	258	949	1,120
Cash and equivs	422	2,412	1,976	6,294	2,963
Total current asset	556	2,650	2,234	7,328	4,207
Total assets	1,083	3,099	2,494	10,155	7,626
Trade payables	67	99	219	1,016	410
Borrowings	0	0	0	23	23
Lease liabilities	0	0	0	40	39
Other	0	0	0	20	39
Total current liabilities	67	99	219	1,099	511
Borrowings	0	0	0	223	199
Lease liabilities	0	0	0	124	83
Deferred tax	0	0	0	163	75
Other non-current liabilities	0	0	0	40	174
Total non-current liabilities	0	0	0	550	531
Total liabilities	67	99	219	1,649	1,042
Issued capital	12,118	12,574	12,574	12,949	1,109
Share premium	2,500	4,550	4,550	11,729	11,729
Capital redemption reserve	0	0	0	0	11,840
Other reserve	(2,003)	(1,916)	(1,825)	(1,697)	(1,552)
Accumulated profit	(11,599)	(12,208)	(13,024)	(14,475)	(16,542)
Total equity	1,016	3,000	2,275	8,506	6,584
Total equity & liabilities	1,083	3,099	2,494	10,155	7,626

Source: Company data.

Table 3: RUA Life Sciences Cash Flow statement

Year-end March (£000)	2018A	2019A	2020A	2021A	2022A
Net income	(34)	(609)	(816)	(1,451)	(2,067)
Amortisation	219	218	193	68	53
Depreciation	0	0	1	204	259
Share based payments	0	42	91	128	145
Interest income	0	(7)	(7)	9	8
Tax income	0	0	(81)	(143)	(293)
Change in inventory	0	0	0	7	(39)
Change in receivables	176	(104)	(20)	(589)	(53)
Change in payables	(14)	31	120	231	(453)
Tax received	0	0	81	122	87
Net cash from operations	347	(429)	(438)	(1,414)	(2,353)
CAPEX PP&E	0	(1)	(5)	(620)	(904)
CAPEX intangibles	(16)	0	0	0	0
Acquisition	0	(139)	0	(323)	0
Interest received	0	7	7	(9)	(8)
Cash flow from investing	(16)	(133)	2	(952)	(912)
Share issue, net	0	2,552	0	6,462	0
Change in borrowings	0	0	0	222	(66)
Cash flow from financing	0	2,552	0	6,684	(66)
Change in cash	331	1,990	(436)	4,318	(3,331)
Opening cash	91	422	2,412	1,976	6,294
Closing cash	422	2,412	1,976	6,294	2,963

Source: Company data.

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- HOLD is an expected return -10% - +10%; and
- SELL is an expected return less than -10%.
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	Corporate No.	Corporate %	No.	%
Buy	67	93	80	91
Hold	4	5	6	6
Sell	0	0	0	0
Under review	1	1	1	1

Temporary movements by stocks across the boundaries of these categories due to share price volatility will not necessarily trigger a recommendation change. All recommendations are based on 12 month time horizon unless otherwise stated.

Recommendation History

Company	Disclosures	Date	Rec	Price
RUA Life Sciences Plc	2,6,8,9,10	25 Jun 21	Buy	138p

Source: Cenkos Securities

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