

30 May 2022

RUA Life Sciences Plc

Trading update

RUA Life Sciences has released a trading update for the 12-months to March 2022, noting revenues are expected to be £1.6m, up 6% YoY (Cenkos est £1.8m), loss before tax of £2.4m (Cenkos est £2.8m) and year-end cash of £3.0m (Cenkos est £1.8m). The company has provided an update on its four business divisions, with a discussion on the progress of the vascular graft programme which was delayed towards the end of 2021. RUA are targeting vascular graft approval in late 2024 with a market launch in 2025. While requirement to undertake clinical studies for the vascular graft and the associated extension of approval timelines was disappointing, we remain confident that RUA's core technology can disrupt the cardiovascular market and maintain our Buy rating.

- Results** – Revenues from the RUA Biomaterials and RUA Medical Devices divisions are expected to be c£1.1m, up 11% YoY and £0.5m, respectively, for a combined £1.625m for the year, up 6%. These results are marginally (£150k) down versus our forecast. Loss before tax of £2.4m was ahead of our estimate, while RUA closed FY22A with cash of £2.96m strongly up on our estimated £1.8m. We maintain our forecast and await the audited final results in July.
- RUA Vascular** – The requirement for human clinical data has delayed the commercial plans for RUA's vascular graft programme, with approval now expected in late 2024. Significantly, RUA notes 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. As part of the overall programme review process, RUA has implemented a number of changes to support future commercialisation.
- RUA Biomaterials / RUA Medical Devices** – RUA notes its Biomaterials partner, Biomerics, has expanded manufacturing capacity which we expect will support future growth and that the Medical Devices division were not significantly affected by the pandemic during FY22 and supply chain disruption was managed.
- 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.
- Investment thesis** – 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 produces enter the c\$1bn market for these products, while the heart valves could disrupt the \$8bn heart valve market. We maintain our Buy recommendation.

Forecast and Ratios

Y/E March (£m)	2018A	2019A	2020A	2021A	2022E
Revenues	0.4	0.5	0.5	1.5	1.8
EBITDA	(0.1)	(0.4)	(0.7)	(1.2)	(2.2)
Net Income	(0.0)	(0.6)	(0.8)	(1.5)	(2.8)
EPS (GBp)	(0.6)	(4.7)	(5.6)	(8.2)	(13.4)
Net cash	0.4	2.4	2.0	6.3	1.8

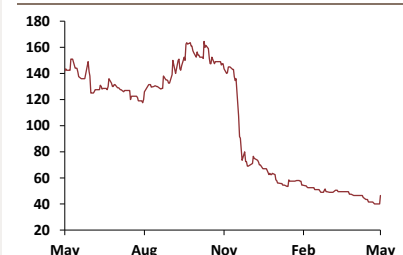
Source: Cenkos Securities estimates, Company data

Brokership Company

BUY

Price at COB 27 May 22 42.5p
 52-week range 40.0-164.5p
 Ticker RUA LN

Share Price Performance



Source: Morningstar

Performance	1m	3m	12m
Absolute	0.0	(19.1)	(67.6)

Stock Data

Market cap (£m)	10.3
Shares outstanding (m)	22.2

Activities

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

Directors

Bill Brown	Chairman
Caroline Stretton	Group MD
Lachlan Smith	CFO

Significant Shareholders

A J Bell Stockbrokers	7.2%
Walker Crips Stockbrokers	7.1%
Mr DM Richmond	6.9%
Hargreaves Lansdown AM	6.5%
Interactive Investors	6.5%

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RUA Life Sciences

RUA Vascular

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.

RUA has provided preliminary guidance for the human trials and subsequent submission, approval and commercialisation of the vascular graft products, which we expect will result in the following timings though 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.

Clearly, while the delay to commercialisation was disappointing, RUA expects that the availability of human clinical data at product launch will support faster clinical adoption of the product. Additionally, the data developed to support US FDA clearance is expected to support the approval in Europe and additional markets where access can be achieved following US/EU clearance.

RUA notes continued interest from third-party medical device companies for the OEM use of the Elast-Eon vascular graft and that these opportunities are being advanced alongside RUA's internal commercialisation plans.

The delay in the vascular graft programme has allowed RUA to review the division in detail and has made the following advances:

- Transformed business processes to transition from an OEM supplier to full-scale medical device manufacturer.
- Developed high-throughput manufacturing.
- Accelerated the development of the extended range of vascular grafts including aortic arch and descending aorta products.
- Revitalised the vascular graft team to maximise the potential of the programme.

Financials

We are leaving our forecasts unchanged at this time and await the audited final results in July.

Table 1: RUA Life Sciences Profit & Loss statement

Year-end March (£000)	2018A	2019A	2020A	2021A	2022E
Revenues	404	463	489	1,528	1,775
<i>growth</i>	<i>0.0%</i>	<i>14.6%</i>	<i>5.6%</i>	<i>212.5%</i>	<i>16.2%</i>
COGS	0	0	0	(276)	(313)
<i>% of revs</i>	<i>0.0%</i>	<i>0.0%</i>	<i>0.0%</i>	<i>18.1%</i>	<i>17.6%</i>
Gross profit	404	463	489	1,252	1,463
<i>gross margin</i>	<i>100.0%</i>	<i>100.0%</i>	<i>100.0%</i>	<i>81.9%</i>	<i>82.4%</i>
Operating expenses	(474)	(816)	(1,123)	(2,690)	(3,700)
<i>% of revs</i>	<i>117.3%</i>	<i>176.2%</i>	<i>229.7%</i>	<i>176.0%</i>	<i>123.9%</i>
Other income	0	0	14	279	0
Other expense	0	(19)	(37)	8	0
EBITDA, adj	(70)	(372)	(657)	(1,151)	(2,238)
Depr & Amort	(219)	(218)	(193)	(272)	(500)
Share based payments	0	(42)	(91)	(128)	(100)
Operating profit, adj	(289)	(632)	(941)	(1,551)	(2,838)
exceptionals	255	(6)	0	0	0
Operating profit	(34)	(638)	(941)	(1,551)	(2,838)
Finance, net	0	29	44	(43)	0
Pre-tax profit	(34)	(609)	(897)	(1,594)	(2,838)
Tax	0	0	81	143	0
<i>tax rate</i>	<i>0.0%</i>	<i>0.0%</i>	<i>9.0%</i>	<i>9.0%</i>	<i>0.0%</i>
Net income	(34)	(609)	(816)	(1,451)	(2,838)
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	21,187
EPS (GBp)	(0.6)	(4.7)	(5.6)	(8.2)	(13.4)

Source: Company data. Cenkos Securities estimates

Table 2: RUA Life Sciences Balance Sheet

Year-end March (£000)	2018A	2019A	2020A	2021A	2022E
Goodwill	0	0	0	301	301
Intangible assets	527	448	255	574	424
PP&E	0	1	5	1,952	3,652
Total non-current asset	527	449	260	2,827	4,377
Inventory	0	0	0	85	105
Trade receivables	134	238	258	949	1,122
Cash and equivs	422	2,412	1,976	6,294	1,800
Total current asset	556	2,650	2,234	7,328	3,027
Total assets	1,083	3,099	2,494	10,155	7,404
Trade payables	67	99	219	1,016	1,002
Borrowings	0	0	0	23	23
Lease liabilities	0	0	0	40	40
Other	0	0	0	20	20
Total current liabilities	67	99	219	1,099	1,085
Borrowings	0	0	0	223	223
Lease liabilities	0	0	0	124	124
Deferred tax	0	0	0	163	163
Other non-current liabilities	0	0	0	40	40
Total non-current liabilities	0	0	0	550	550
Total liabilities	67	99	219	1,649	1,635
Issued capital	12,118	12,574	12,574	12,949	12,949
Share premium	2,500	4,550	4,550	11,729	11,729
Other reserve	(2,003)	(1,916)	(1,825)	(1,697)	(1,597)
Accumulated profit	(11,599)	(12,208)	(13,024)	(14,475)	(17,313)
Total equity	1,016	3,000	2,275	8,506	5,769
Total equity & liabilities	1,083	3,099	2,494	10,155	7,404

Source: Company data. Cenkos Securities estimates

Table 3: RUA Life Sciences Cash Flow statement

Year-end March (£000)	2018A	2019A	2020A	2021A	2022E
Net income	(34)	(609)	(816)	(1,451)	(2,838)
Amortisation	219	218	193	68	200
Depreciation	0	0	1	204	300
Share based payments	0	42	91	128	100
Interest income	0	(7)	(7)	9	0
Tax income	0	0	(81)	(143)	0
Change in inventory	0	0	0	7	(20)
Change in receivables	176	(104)	(20)	(589)	(173)
Change in payables	(14)	31	120	231	(14)
Tax received	0	0	81	122	0
Net cash from operations	347	(429)	(438)	(1,414)	(2,444)
CAPEX PP&E	0	(1)	(5)	(620)	(2,000)
CAPEX intangibles	(16)	0	0	0	(50)
Acquisition	0	(139)	0	(323)	0
Interest received	0	7	7	(9)	0
Cash flow from investing	(16)	(133)	2	(952)	(2,050)
Share issue, net	0	2,552	0	6,462	0
Change in borrowings	0	0	0	222	0
Cash flow from financing	0	2,552	0	6,684	0
Change in cash	331	1,990	(436)	4,318	(4,494)
Opening cash	91	422	2,412	1,976	6,294
Closing cash	422	2,412	1,976	6,294	1,800

Source: Company data. Cenkos Securities estimates

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- HOLD is an expected return -10% - +10%; and
- SELL is an expected return less than -10%.
- UNDER REVIEW: recommendation and/or forecasts are under review pending further clarity as to the company's financial and/or operational position.

For Sales recommendation please refer to <http://cenkos.com/bottom-menu/legal-and-regulatory/conflicts-of-interests-disclosures>

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	Corporate No.	Corporate %	No.	%
Buy	68	93	83	92
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	2,6,7,8,9,10	10 May 21	Buy	137.5p

Source: Cenkos Securities

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