Roquefort Therapeutics PLC

Licensing announcement

20 February 2023

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Licencing of Midkine intellectual property to Randox for cancer diagnostics development

Roquefort Therapeutics announced its ten-year exclusive worldwide (excluding Japan) licence and royalty agreement for its Midkine antibody portfolio with Randox Laboratories in diagnostics. Randox and Roquefort will collaborate in research programs to identify new diagnostics for cancers that will be treatable with Roquefort Midkine therapeutics. The partnership focuses on diagnostics to detect the cancers that overexpress Midkine, a heparin-binding protein that prevents tumour cell death and promotes metastasis and resistance to treatment.

Headquartered in the U.K., Randox Laboratories is an international health and toxicology company in the in-vitro diagnostics industry. According to Companies House data, Randox's sales were £548m and net income was £177m for the financial year ended in June 2021.

This licence agreement with Randox validates Roquefort's strategy of targeting Midkine. Roquefort estimates the total transaction value to be in excess of £5m over the life of this agreement. Identifying the patients with cancers that overexpress Midkine is highly synergistic with Roquefort's development of first-in-class cancer medicines. These are the patients most likely to benefit from Roquefort's Midkine therapeutics (antibodies or oligonucleotides) and to be enrolled in pharmaceutical clinical trials.

Hybridan's view: Clinical trials with companion diagnostics have a significantly higher success rate. According to a report by BIO, QSL Advisors and Informa UK 2021, drug development programs with trials employing patient preselection biomarkers have a two-fold higher likelihood of approval (LOA) (15.9%) than those that do not (7.6%).

We note that Roquefort's Midkine programs are first-in-class. To the best of Roquefort's knowledge and as far as we are aware, there are no Midkine related drugs or therapeutics for cancer on the market or in the clinical stage. Roquefort thinks that it is one year ahead of the game in the pre-clinical stage of developing reagents targeting Midkine for treatment of cancer. We believe Roquefort's MDK antibody programs are on track for CTA/IND readiness by the end of 2023.

According to IQVIA Institute (a global life science research firm) and based on data in the U.S. in 2017-2021, first-in-class drugs that use a novel mechanism represent an increasing share of novel active substance (NAS) launches in oncology, with 59% in 2021 and 42% in the last five years. A NAS is a new molecular or biologic entity or combination where at least one element is new.

Key Statistics:

Code	ROQ
Listing	LSE; OTCQB
Sector	Biopharma
Market cap*	£8.7m
Shares in issue*	129.15m
Current price*	6.75p
12-month high/low*	9.85p/6.375p
Free float**	55%

**Closing price on 17 February 2023. High/low based on closing prices. **Free float based on Hybridan estimates.*

Share Price Performance

Year to date	2%
Past 12 months	-32%
2021	75%

Source: Alpha Terminal

Financials Y/E Dec (£)

	Sales	EBIT	Net cash
2021	719	(917,433)	899,721
1H22	-	(762,281)	3,328,573

Source: Company Data

Company Description

Roquefort Therapeutics is a drug and therapy discovery and development company for hard-to-treat cancers focusing on novel targets. All of its development programs are supported with licensed patents and anchored on Roquefort's own knowhow and intellectual property.

Roquefort has four best-in-class oncology drug development programs: (1) Midkine antibodies; (2) Midkine RNA therapeutics with novel anti-cancer gene editing action; (3) Mesodermal Killer (MK) cell therapy with direct and nature-killer-mediated anti-cancer action; and (4) siRNA targeting novel STAT-6 target in solid tumours.

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Midkine antibody programs

ROQ-A1 (humanised N-domain antibody) and ROQ-A2 (humanised C-domain antibody) are the latest patented medicines designed by Roquefort to target the novel Midkine (MDK) target prevalent in hard-to-treat cancers. In laboratory experiments, ROQ-A1 and ROQ-A2 bind highly specifically to the MDK receptors in cancer cells to kill cancers in vitro.

The MDK antibody programs targeting metastatic breast cancer and metastatic lung cancer commenced in Q4-2022 at La Trobe University, Melbourne in the Olivia Newton-John Cancer Research Institute and Hawkins Laboratory respectively and have successfully reached the first pre-clinical drug development milestone. Both MDK antibody programs will now progress into in vivo pre-clinical efficacy studies to assess cancer killing ability in primary and metastatic breast cancer and lung cancer.

Metastatic breast cancer and metastatic lung cancer were chosen because of high patient mortality rates (~70% at five years) and prevalence of resistant MDK subtypes which can reduce effectiveness of existing therapies.

Hybridan's view: We believe ROQ-A1 and ROQ-A2 sit at the sweet spot of monetisation in terms of indications and the demand for antibody therapeutics for cancer.

Both metastatic breast and metastatic lung cancer are sizeable markets with poor survival rates from existing therapies. A study from the UNC Centre for Health Promotion and Disease Prevention forecasts the number of metastatic breast cancer patients to be c. 246k in the U.S. by 2030, up 55% from approximately 159k patients in 2015. The global metastatic breast cancer treatment market was US$17bn in 2021 and is expected to expand at a CAGR of 10.4% to US$42bn by 2030 according to Strategic Market Research. In the U.S., 56% of lung cancer patients are diagnosed when the cancer has already metastasized, according to the National Cancer Institute. The global lung cancer therapeutics market was US$25bn in 2021 and is expected to reach US$54bn by 2029, registering a CAGR of 10.4% for 2022-2029, according to Data Bridge Market Research.

Meanwhile, monoclonal antibody-based immunotherapy is a major element of cancer therapy. According to Grand View Research in 2022, the global cancer monoclonal antibodies market was valued at US$62bn in 2021 and is expected to grow to US$160bn at a CAGR of 11.2% from 2022 to 2030. By type, the humanised segment held the highest market share of 39.5% in 2021, owing to low cost, availability and quick production time for mouse monoclonal antibodies.

Roquefort has established a good understanding of COGS (the cost of goods sold) for its antibody candidates and believes that it would be easy to scale up.

Updates on other programs

Roquefort's other three novel patent-protected development programs are:

- Midkine RNA therapeutics with novel anti-cancer gene editing action;
- Mesodermal Killer (MK) cells activate NK cells and kill cancer cells; and
- Novel siRNAs inhibit STAT-6, targeting solid cancers.

The siRNA, MK cell therapy and MDK oligonucleotide programs are also progressing well and are expected to complete development milestones in Q1 2023.

Financial Statements

Income Statement (£) Y/E December	2021	1H21	1H22
Revenue	719	-	-
Other income	130	-	-
Cost of goods	(10,069)	-	-
Administrative expenses	(907,515)	(301,232)	(543,041)
Research and development expenditure	(698)	-	(69,288)
Amortisation of Intangible assets	-	-	(149,952)
Operating loss	(917,433)	(301,232)	(762,281)
Finance income	-	-	-
Profit (loss) before tax	(917,433)	(301,232)	(762,281)
Taxation	-	-	-
Other comprehensive loss	-	-	-
Total comprehensive income (loss)	(917,433)	(301,232)	(762,281)
Earnings (loss) per share	(3.71)	(1.79)	(2.05)
Balance Sheet (£) Y/E December	**2021**	**1H21**	**1H22**
Intangible assets	1,481,530	-	1,331,578
TOTAL NON-CURRENT ASSETS	1,481,530	-	1,331,578
Trade and other receivables	2,178,783	13,241	98,520
Cash and cash equivalents	899,721	880,445	3,328,573
TOTAL CURRENT ASSETS	3,078,504	893,686	3,427,093
TOTAL ASSETS	4,560,034	893,686	4,758,671
Deferred tax liabilities	281,911	-	281,911
TOTAL NON-CURRENT LIABILITIES	281,911	-	281,911
Trade and other payables	195,517	14,331	1,094,389
TOTAL CURRENT LIABILITIES	195,517	14,331	1,094,389
TOTAL LIABILITIES	477,428	14,331	1,376,300
NET ASSETS	4,082,606	879,355	3,382,371
Share capital	719,000	339,000	719,000
Share premium	3,910,595	774,300	3,910,595
Share based payments reserve	366,708	74,911	424,219
Retained deficit	(914,321)	(308,856)	(1,676,602)
Currency translation reserve	624	-	5,159
TOTAL EQUITY	4,082,606	879,355	3,382,371

Note: The increase in trade and other payables in 1H22 reflects the placing for £1.015m announced on 23 June 2022. This amount is shown in the cash flow statement in fundraise during the period.

Source: Company Data

Cash Flow Statement (£) Y/E December	**2021**	**1H21**	**1H22**
Profit (loss) before tax	(996,068)	(301,232)	(762,281)
Adjustment for:			
Foreign exchange	765	-	(5,160)
Non-cash adjustment	(2,602)	-	-
Share based payment	366,708	74,911	57,511
Amortisation of intangible asset	-	-	149,952
Changes in working capital:			
Change in trade and other receivables	(2,130,636)	(11,798)	2,083,286
Change in trade and other payables	129,525	14,331	(121,325)
Change in inventory	9,273	-	-
CASHFLOWS FROM OPERATING ACTIVITIES	(2,623,035)	(223,788)	1,401,983
Acquisition of subsidiary, net of cash acquired	(1,106,225)	-	-
CASHFLOWS FROM INVESTING ACTIVITIES	(1,106,225)	-	-
Proceeds from issue of ordinary shares	4,789,000	1,015,000	-
Share issuance costs	(159,405)	(25,700)	-
Proceeds from fundraise	-	-	1,015,000
CASHFLOWS FROM FINANCING ACTIVITIES	4,669,502	989,300	1,015,000
Net change in cash & cash equivalents	900,335	765,511	2,416,983
FX translation difference	(614)	-	899,721
Cash at the beginning of the period	-	114,933	11,869
Cash at the end of the period	899,721	880,445	3,328,573

Source: Company Data

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