Kinarus Therapeutics Holding AG

Receptive environment for KIN001

11 April 2023

Three years after the start of the pandemic investors might be forgiven for thinking that new product approvals for drugs to treat COVID-19 have come to an end. Running against this perception is Kinarus' lead drug – the oral p38 MAP kinase inhibitor combination – which remains in a Phase 2 study for the treatment of COVID patients. Moreover, the FDA has just approved a new anti-inflammatory drug to treat COVID-19 patients: indicating that the era of pandemic preparedness remains as an attractive environment for new drug developments.

COVID-19 drug approvals continue

German biotech company InflaRx's anti-inflammatory drug **Gohibic** (vilobelimab) was recently approved by the US FDA under an emergency use authorization (EUA) to treat COVID-19 in a limited hospitalised patient population undergoing invasive mechanical ventilation or extracorporeal membrane oxygenation. The EUA was granted *despite* Gohibic failing a Phase 3 study. This suggests firstly that the unmet medical need to treat COVID-19 patients remains (the US CDC reports about 2,000 COVID-19-related deaths each week) and secondly, that for drugs that show signs of efficacy in this indication, the bar to FDA approval may not be high.

In addition, with the significant sensitivities of governments and regulators to potential future pandemics mediated by respiratory pathogens that may not yet be identified, broad-spectrum anti-inflammatory activity like p38 MAP kinase inhibition mediated by KIN001 could be a therapeutic intervention in future pandemics. In the past, with for example smallpox vaccines, this has given rise to stockpiling contracts.

Kinarus is currently conducting the Phase 2 KINFAST study in the less severe and mild to moderate ambulatory COVID-19 patients, but unlike Gohibic which is a monoclonal antibody, Kinaris' KIN001 is an oral drug with **a much easier administration** and **lower cost of goods**. In addition, Kinarus has demonstrated that KIN001 has **both** anti-inflammatory and preclinical antiviral activity against SARS-CoV-2 whereas as an antibody directed against complement factor c5a, Gohibic has only anti-inflammatory activity.

Should Kinarus demonstrate efficacy in the KINFAST study, a whole range of discussions would start on a potential EUA for KIN001 in the treatment of COVID-19 patients, where full approval may be contingent on a Phase 3 study, but also raises the profile of KIN001 in another indication **– idiopathic pulmonary fibrosis (IPF)**. This is because should KIN001 demonstrate anti-inflammatory activity in the KINFAST study, this would almost certainly imply systemic **but also local** activity in the lung, where most of the pathology in IPF occurs.

No change to our valuation

Our fair valuation of Kinarus remains at CHF96.0m, or CHF0.09 per share.

Summary Financials

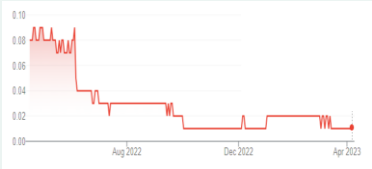
CHF '000s, y/e 31 Dec	2019A	2020A	2021A	2022E
Revenues				
EBIT	(2,267)	(1,522)	(4,720)	(4,236)
Basic EPS, (CHF)	(0.608)	(0.312)	(0.900)	(0.004)
Net Assets	2,555	1,287	(1,371)	37,049
Net Cash	1,019	319	5,225	(1,845)

Source: Company historic data, ED estimates

Company Data

EPIC	**KNRS.SW**
Share Price (last close)	CHF0.011
Market cap	CHF12.0m
ED Fair Value per share	CHF96.0m CHF0.09
Proforma net cash 30 Jun '22	CHF4.58m

Share Price, CHF



Source: Google

Company Description

Kinarus is a Swiss clinical-stage biopharmaceutical company that focusses on small molecule drugs with a history of clinical use in human patients. Much of the early-stage risk is eliminated from Kinarus' projects as the dose range, mechanism of therapeutic benefit and manufacturing and regulatory considerations have already been addressed.

With the benefit of much of this work already undertaken, the cost and duration of Kinarus' clinical programs should be shorter than is the norm. Kinarus' lead drug KIN001 was originally developed by Roche for RA and after addressing its PD liability, Kinarus is developing KIN001 for the treatment of COVID-19, wAMD and IPF in Phase 2 clinical trials.

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Historic financials and forecasts

Consolidated Income Statement & Forecasts

CHF'000s, y/e 31 December	2019A	2020A	2021A	2022E
IFRS Income Statement				
Total revenue				
General & Administration expenses	(903)	(851)	(1,402)	(1,615)
R&D	(1,322)	(633)	(2,939)	(727)
Depreciation & amortisation	(1)	(1)	(4)	(1,520)
Reported EBIT	**(2,267)**	**(1,522)**	**(4,720)**	**(4,236)**
Reported profit before tax	**(2,280)**	**(1,522)**	**(4,724)**	**(4,231)**
Taxation				56
Basic EPS CHF	(0.6085)	(0.3117)	(0.9003)	(0.0037)
Diluted EPS CHF	(0.6085)	(0.3117)	(0.9003)	(0.0037)
Share count at end of period (basic) '000	3,747	4,883	5,247	1,143,603

Source: Company historic data, ED estimates

Consolidated Balance Sheet & Forecasts

CHF'000s, at y/e 31 March	2019A	2020A	2021A	2022E
Assets				
Non-current assets				
Tangible assets	3	2	7	9
Intangible assets	1,800	1,800	1,800	51,880
Total non-current assets	1,803	1,802	1,807	51,889
Current assets				
Trade and other receivables				
Cash and equivalents	1,019	419	5,032	1,490
Other current assets	22	49	49	174
Total current assets	1,041	468	5,352	1,664
Total assets	**2,844**	**2,270**	**7,158**	**53,553**
Equity and liabilities				
Equity				
Share capital	488	491	536	11,133
Share Premium	7,748	7,747	9,222	42,993
Retained earnings (loss)	(5,680)	(6,949)	(11,128)	(17,076)
Equity attributable to the company	2,555	1,287	(1,371)	37,049
Current liabilities				
Trade and other payables	64	100	77	335
Current provisions				1,140
Other current liabilities	226	182	1,052	869
Total current liabilities	289	983	4,129	2,594
Total non-current liabilities			4,400	13,910
Total liabilities	289	983	8,529	16,504
Total equity and liabilities	**2,844**	**2,270**	**7,158**	**53,553**

Source: Company historic, ED estimates

Consolidated Cash Flow Statements & Forecasts				
CHF'000s, y/e 31 March	**2019A**	**2020A**	**2021A**	**2022E**
Profit before taxation	(2,280)	(1,522)	(4,724)	(4,175)
Adjustment for:				
Depreciation & amortisation	1	1	4	1,520
Movements in working capital	(385)	(34)	5,245	(5,791)
Net cash generated by operating activities	(2,394)	(1,302)	(1,072)	(8,604)
Investing activities				
Capital expenditure on tangibles	(3)		(10)	
Proceeds from disposal of tangibles	(1,500)			
Acquisitions				5,483
Net cash used in investing activities	(1,503)		(10)	5,483
Financing activities				
Net proceeds from issue of shares			1,170	
Proceeds from share option exercise	10	2	4	
Transaction costs	(127)	(1)	(123)	(620)
Proceeds from subordinated loans			3,000	179
Movements in convertible debt	2,880	700	(230)	(250)
Net cash from financing activities	2,767	701	3,821	(691)
Cash & equivalents at beginning of year	2,154	1,019	419	5,302
Cash & equivalents at end of year	**1,019**	**419**	**5,302**	**1,490**

Source: Company historic data, ED estimates.

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