

Redx Pharma Update

## Two key Phase II results on track for next 12 months

18 May 2023

Redx Pharma has an impressive portfolio of ROCK programmes, with a clear focus on serious and debilitating fibrotic diseases. The lead compound, RXC007, is a next-generation ROCK2 inhibitor in Phase IIa trials for IPF (idiopathic pulmonary fibrosis). Top-line results, expected in H124, should provide invaluable data on its clinical, and commercial, potential and guide future studies. RXC008, a highly novel GI-targeted ROCK inhibitor, is progressing towards IND/CTA submission by end-2023 for fibrostenotic Crohn's disease. A second clinical asset, RXC004, a porcupine inhibitor for Wnt-ligand dependent solid tumours, is completing Phase IIa studies in combination with a CPI with the results from these important trials expected by end-2023. Cash of £34.6m (end-March 2023) provides a runway into Q1 2024, beyond RXC007 Phase II data. Our updated rNPV-based valuation is £363m, or 109p/share.

Year-end: September 30	2021	2022	2023E	2024E
Revenues (£m)	10.0	18.7	3.9	1.0
Adj. PBT (£m)	(18.8)	(17.3)	(44.1)	(49.7)
Net Income (£m)	(21.6)	(18.0)	(49.6)	(52.9)
Adj.EPS (p)	(7.4)	(5.9)	(12.9)	(11.2)
Cash (£m)	29.6	53.9	11.2	4.1
EBITDA (£m)	(19.1)	(15.4)	(47.2)	(50.2)

Source: Trinity Delta Note: Adjusted numbers exclude share-based payments and exceptionals. \* Our cash forecast assumes receipt of £40m in additional funding during CY23

- RXC007 Phase IIa data will spotlight potential The Phase IIa trial of RXC007 in IPF is progressing well and is on track to deliver results in H124. These should confirm safety and tolerability, with the potential for early efficacy insights and will inform the design of a Phase IIb trial, which could also be expanded to include broader interstitial lung diseases (ILDs). Industry interest in fibrosis is rising and the ROCK programmes have the potential to alter a number of serious and intractable fibrotic diseases. These programmes are becoming a pivotal part of the investment case.
- Key RXC004 combo data due H223 Data from the ongoing PORCUPINE and PORCUPINE2 Phase II trials of RXC004 in combination with a CPI (checkpoint inhibitor) should be available by end-2023. These should provide the first evidence that RXC004 can reverse Wnt-driven immune evasion, turning previously "cold" tumours into "hot" ones that can then be treated with CPI therapy. Monotherapy data (March 2023 Lighthouse) confirmed RXC004's safety profile but, as expected, did not support further development alone.
- Cash runway into H124 End-March 2023 cash of £34.6m is sufficient to fund planned operations through key clinical data points, including the key readouts for RXC007 and RXC004. Management has conducted a detailed review of all assets and expenses to ensure timely delivery of these important clinical goals, and is also exploring all financial and other strategic options to extend the cash runway further.
- rNPV valuation of £363m or 109p/share Our risk-adjusted pipeline NPV model is based on conservative assumptions and has been updated to incorporate H123 financial results and recent news flow. Our revised model results in a valuation for Redx Pharma of £363m (\$436m), equivalent to 109p per share.

Price	32.0p
Market Cap	£107.2m
Enterprise Value	£72.6m
Shares in issue	334.9m
12 month range	26.5-70.0p
Free float	13.6%
Primary exchange	AIM London
Other exchanges	N/A
Sector	Healthcare
Company Code	REDX



Yes

#### **Company description**

Corporate client

Redx Pharma specialises in the discovery and development of small molecule therapeutics, with an emphasis on oncology and fibrotic diseases. It aims to progress them through proof-of-concept studies, before evaluating options for further development and value creation.

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## **Redx Pharma: Key data points in next 12 months**

Redx Pharma is prioritising development of its unique and differentiated ROCK portfolio. The lead asset, RXC007, is progressing through Phase IIa studies in IPF (idiopathic pulmonary fibrosis), with key data on track for Q124. Earlier-stage studies also support expansion into broader immune mediated interstitial lung diseases (ILDs). Redx's innovative GI-targeted ROCK inhibitor, RXC008, is finalising IND-enabling studies for fibrostenotic Crohn's disease with a submission to initiate human trials expected during 2023. Alongside, the Phase IIa modules for RXC004, a porcupine inhibitor for Wnt-dependent tumours, in combination with anti-PD-1 checkpoint inhibitors are expected to report data by end-2023. Cash of £34.6m (end-March 2023), provides funding into Q124 and covers important inflection points (including RXC007 Phase IIa IPF data). Management is considering all financing and strategic options to extend the cash runway to support further development of its lead programmes. Our updated rNPV-based valuation is £363m (\$436m), equivalent to 109p per share.

Value inflection points for lead wholly-owned clinical assets expected over next 12 months

H123 results provide confirmation that Redx Pharma's investment case remains intact. Following the lapse of the Jounce Therapeutics deal (April 2023 Lighthouse), management focus is on driving pipeline momentum, delivering important data from its clinical assets over the next 12 months. The key value inflection points include results for: (1) the lead asset RXC007, a ROCK2 inhibitor under evaluation in IPF, with top-line data from the Phase IIa study expected Q124 and (2) the oncology programme RXC004, with Phase II combination data plus anti-PD-1 inhibitors in Wnt-ligand dependent solid tumours expected by end-2023. Submission of the clinical trial authorisation (CTA) for RXC008, GI-targeted pan-ROCK inhibitor for fibrostenotic Crohn's disease, is expected by end-2023. A summary of Redx Pharma's pipeline is shown in Exhibit 1.

**Exhibit 1: Redx Pharma pipeline** 

	Target/ Product	Indication(s)	Research	Preclinical	Phase 1	Phase 2	Upcoming Milestones	
Fibrosis	Potential best-in-class ROCK2 Selective Inhibitor (RXC007)	Lead: Idiopathic pulmonary fibrosis (IPF) Potential: ILD, cancer associated fibrosis					Phase 2a topline data – <b>Q1 2024</b>	
	Potential first-in-class Gl-targeted ROCK Inhibitor (RXC008)	Fibrostenotic Crohn's disease					CTA submission - end 2023	
ogy	Potential best-in-class <b>Porcupine Inhibitor</b> (RXC004)	Genetically selected MSS mCRC	PORCUPINE				Topline data in combination with anti-PD-1-	
Oncology		Biliary tract cancer and pancreatic cancer	PORCUPINE2				H2 2023	
DDR Inhibitor (Discoidin Domain Receptor)  Research Targets (Multiple Programmes)	Fibrosis, cancer-associated fibrosis					Progress programmes - target of 2 INDs by 2025		
		Oncology & fibrosis						
Partnered	Porcupine Inhibitor (RXC006/AZD5055)	Idiopathic pulmonary fibrosis (IPF)					Licensed to AstraZeneca	
	Pan-RAF Inhibitor (JZP815)	Oncology					Sold to Jazz Pharmaceuticals	
	MAPK Pathway Target	Oncology					Progress Jazz collaboration	

Source: Redx Pharma Note: GI = gastrointestinal; IND = investigational new drug application; IPF = idiopathic pulmonary fibrosis; MAPK = mitogen-activated protein kinase; MSS mCRC = microsatellite stable metastatic colorectal cancer; RAF = rapidly accelerated fibrosarcoma.



## **RXC007 Phase IIa trial in IPF is**

# progressing well

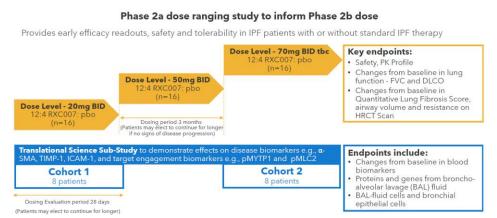
Initial top-line IPF data are expected during Q124

## RXC007: Top-line results from IPF Phase IIa trial in Q124

RXC007 (zelasudil) is a novel and highly specific small molecule that selectively targets the ROCK2 (Rho Associated Coiled-Coil Containing Protein Kinase 2) enzyme. RXC007 is the lead programme in a unique portfolio of diverse and distinct assets addressing ROCK, a well-recognised nodal point for pro-fibrotic signalling that is pivotal in a broad range of fibrotic conditions. We have covered RXC007's attractive mechanism, encouraging preclinical data (which suggest the potential to be disease modifying), and prior supportive Phase I results, most recently in our October 2022 Update.

A Phase IIa trial (Exhibit 2) in IPF started in October 2022. This is a randomised, dose escalation study with and without standard of care (SoC) in IPF (nintedanib or pirfenidone) over 12 weeks, and assesses early efficacy signals, safety, and tolerability. The key endpoints, other than safety and PK profile, are changes in lung function (Forced Vital Capacity and Carbon Dioxide Diffusion Coefficient), changes in Quantitative Lung Fibrosis Score and airway volume and resistance on high resolution computerised tomography (HRCT) scan. Patients may continue on the study for longer if there are no signs of disease progression or toxicity.

#### Exhibit 2: RXC007 Phase IIa study design



Source: Redx Pharma Note: DLCO = carbon monoxide diffusion coefficient; FVC = forced vital capacity; HRCT = high resolution computerised tomography; Pbo = placebo

#### Phase IIa trial results will inform the format of Phase IIb studies

Three cohorts, each consisting of 16 patients with 12 receiving RXC007, are planned. The first eight patients in Cohort 1, dosed at 20mg twice daily, have completed successfully with no adverse safety signals seen. The study is approved in six European countries with 14 active study sites open; further sites are expected to be active by mid-year 2023. Recruitment is progressing as expected, with top-line data on track to report during Q1 2024. If positive, these results will inform dosing and the design of a larger 12-month Phase IIb trial, which will likely explore RXC007 plus SoC over 12 months in IPF with lung function (FVC) as a primary endpoint. A parallel 28-day translational science sub-study, evaluating target engagement and fibrosis modification in 16 patients is also underway.

**RXC007** development could be expanded to broader indications Assuming positive outcomes, the future Phase IIb trial could also expand RXC007 development to include interstitial lung diseases (ILD), which is a much broader indication, with IPF representing only around 20-50% of ILDs. This is supported by preclinical data in models of GVHD (Graft vs Host disease) that suggest RXC007 could have an impact on immune-mediated fibrotic diseases such as ILD,

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as well as systemic sclerosis. Additionally, preclinical data <u>presented</u> at the Resistant Tumour Microenvironment, Keystone Symposia suggest RXC007 could have utility in cancer-associated fibrosis (<u>May 2023 Lighthouse</u>). Specifically, RXC007 showed dose-dependent survival improvements in highly fibrotic models of pancreatic cancer when used in combination with gemcitabine/abraxane (a standard of care in treating advanced pancreatic cancer) compared to gemcitabine/abraxane alone.

## RXC008: approaching the clinic in Crohn's disease fibrosis

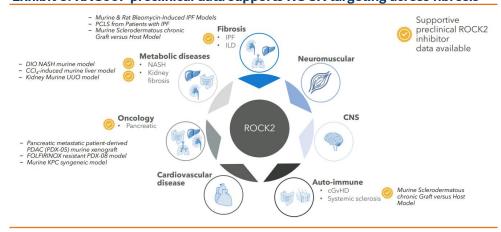
A highly innovative approach that could be disease modifying

RXC008 is a potent, oral, small molecule ROCK1/2 inhibitor designed to only act locally in the GI tract at the site of fibrosis in Crohn's disease. As it is quickly degraded by metabolic enzymes it has a short systemic half-life once absorbed, thus minimising the unwanted effects (ie hypotension) seen with ROCK1. The preclinical data have been particularly impressive, suggesting a disease modifying potential. Again, more detail is available in our October 2022 Update. IND enabling studies are being finalised, with plans to submit a Clinical Trial Authorisation (CTA) during H2 2023, which would allow a first-in-man Phase I study to start in 2024 subject to funding.

Fibrosis is gaining increasing industry attention and ROCK pathway has been de-risked

We view these innovative ROCK programmes as particularly promising in the treatment of a variety of fibrosis conditions. In previous notes we have described how RXC007's clinical profile has the potential to become a major element in a broad range of fibrosis indications (Exhibit 3), including IPF and ILDs, and how it is increasingly seen as a key component of Redx Pharma's investment case. We believe Sanofi's Rezurock effectively de-risks the ROCK pathway in general and Pliant Therapeutics' share price attests to investor interest in fibrosis indications.

Exhibit 3: RXC007 preclinical data supports ROCK targeting across fibrosis



Source: Redx Pharma Note: IPF: idiopathic pulmonary fibrosis, NASH: non-alcoholic steatohepatitis

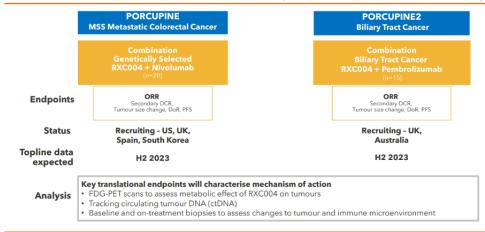
## RXC004: key combination data due in H223

RXC004 is in a Phase II programme in solid tumours with data expected during H223

RXC004 is an innovative porcupine inhibitor for Wnt-ligand dependent cancers. Two Phase II trials are ongoing (Exhibit 4): <a href="PORCUPINE">PORCUPINE</a> in genetically selected microsatellite stable metastatic colorectal cancer (MSS mCRC) and <a href="PORCUPINE2">PORCUPINE2</a> in genetically selected pancreatic and unselected biliary cancer. A detailed overview of RXC004, including the role of Wnt signalling and the Phase I data, is available in our <a href="February 2022 Outlook">February 2022 Outlook</a>.



Exhibit 4: RXC004 Phase II combination programme and top-line data timing



Source: Redx Pharma Note: DCR = disease control rate; DoR = duration of response; ORR = overall response rate; OS = overall survival; PFS = progression free survival

RXC004 monotherapy data, as expected, did not justify further development effort...

In March 2023, top-line data from the monotherapy advanced biliary tract cancer (BTC) arm of the Phase II PORCUPINE2 study was presented and confirmed that RXC004's safety profile is consistent with prior Phase I safety data. Of the 16 treated BTC patients, who had not been genetically selected, some experienced a durable clinical benefit, albeit this is not sufficient to support further development of RX004 as monotherapy in this indication. This was not unexpected (March 2023 Lighthouse) as very few monotherapy agents are effective or have been approved in advanced second-line BTC (the patients population included in this trial). Analysis of results from this cohort, including efficacy and biomarker data, will be used to characterise and understand combination activity. We note that Redx has closed further patient recruitment in the monotherapy cohorts due to a combination of factors including: the modest benefit as monotherapy, industry-wide challenges in identifying appropriate genetically selected patients (relevant for the pancreatic and MSS mCRC modules), and the decision to prioritise patients and resources into the combination modules.

...the treatment rationale is in combination with checkpoint inhibitors

The evidence of some durable clinical benefit is consistent with RXC004's dual mechanism of action. RXC004 is an innovative porcupine inhibitor for Wnt-ligand dependent cancers and, as we have previously highlighted, RXC004 on its own is cytostatic (slows cell growth) rather than cytotoxic (kills tumours). RXC004 also has an immune-enhancing effect, and the primary efficacy hypothesis is that RXC004 could reverse Wnt-driven immune evasion and act synergistically with anti-PD-1 checkpoint inhibitors (CPIs), turning non-responsive "cold" tumours "hot". Hence, a better indication of RXC004's potential efficacy, and commercial potential, should arise from the combination studies with CPIs Keytruda and Opdivo. Some tumours fail to respond to CPIs and it is RXC004's immune-enhancing mechanism that could overcome this resistance. Hence, the RXC004 combination data, expected in H223, will be eagerly anticipated.

Partner sought post-Phase II data

Redx aims to partner RXC004 post-Phase II data for further development as part of a combination, initially with CPIs. However, there is a wider opportunity as preclinical data has indicated that there is strong rational for RXC004 combination with other agents, including chemotherapies and MAPK inhibitors. A partnership would facilitate further evaluation of this broader RXC004 potential.



### **Valuation**

rNPV valuation of £363m, or 109p per share

We value Redx Pharma as a classic drug discovery and development play, using a sum of the parts rNPV-based model that includes a pipeline rNPV (risk-adjusted net present value) and a discovery platform valuation based on Redx's output/track record and benchmarked against discovery peers. Updating our model post-H123 results and revisiting our assumptions for RXC007 and RXC004 to align these with recent disclosures generates a company valuation of £363m (\$436m), equivalent to 109p per share, vs £461m (\$553m), or 138p per share previously. Exhibit 5 summarises the outputs and underlying assumptions of our valuation model, with a more detailed overview of our methodology provided in our February 2022 Outlook.

**Exhibit 5: rNPV-based valuation of Redx Pharma** 

Programme	Total NPV (\$m)	Total NPV (£m)	Approval likelihood	rNPV (\$m)	rNPV (£m)	rNPV/ share (p)	Notes
RXC007 (ROCK2 inhibitor - IPF/NASH/oncology)	1,528.6	1,273.8	15%	160.4	133.7	39.9	Peak sales: \$4.13bn
RXC004 (porcupine inhibitor - oncology)	505.8	421.5	30%	103.1	86.0	25.7	Peak sales: \$1.95bn
<b>AZD5055</b> (AstraZeneca: porcupine inhibitor - IPF)	337.1	280.9	15%	43.7	36.4	10.9	Peak sales: \$1.66bn
JZP815 (Jazz Pharma: pan-RAF - oncology)	151.8	126.5	10%	12.8	10.7	3.2	Peak sales: \$707m
RX008 (ROCK1/2 - Crohn's disease)	173.9	144.9	5%	40.3	33.6	10.0	Peak sales: \$1.61bn
Discovery engine				101.3	84.4	25.2	
Operating costs	(39.1)	(32.5)		(39.1)	(32.5)	(9.7)	
Net cash	13.5	11.2		13.5	11.2	3.4	FY23e cash
Total	2,671.5	2,226.3		436.1	363.4	108.5	
Total (fully diluted)				455.1	379.3	77.9	Based on all options and CLNs

Source: Trinity Delta Note: The rNPV of RXC004 and RXC007 includes a deal success factor of 80%, and of 75% for GI-targeted ROCK; other valuation assumptions include a 12.5% discount factor, £/\$ FX rate of 1.20, and 10% taxation from 2028 (UK patent box).

Clinical progress, clarity on timelines and patient sizes will refine our valuation We continue to employ conservative assumptions throughout our modelling, particularly regarding market sizes and growth rates, net pricing, adoption curves, and peak market penetration. Valuation upside should be unlocked by the clinical progress of the various pipeline assets, as further data would prompt us to adjust the respective success probabilities that reflect the inherent clinical, commercial, and execution risks that each programme carries. Additionally, as these assets progress, there should be more insight into the specific oncology or fibrosis patient populations that will be addressed, and this in turn would mean that peak sales (pricing, penetration) and timeline assumptions could be revisited.



### **Financials**

R&D spend rises as programmes progress, plus £2.4m exceptional cost in H123 for Jounce deal

Redx Pharma's H123 revenues of £2.3m (H122: £8.4m) were solely derived from research collaboration income while the comparative period included a \$9m milestone receipt from AstraZeneca. Continued pipeline progress and advancement, with three Phase II studies ongoing for two candidates, underpin higher R&D investment of £16.1m (H122: £12.9m); whereas ongoing tight cost control reduced G&A to £4.7m (H122: £5.3m). An additional £2.4m in exceptional expenses were incurred in H123 in relation to the reverse merger transaction with Jounce Therapeutics which formally lapsed in April 2023: no further associated costs are expected. This translated into a H123 operating loss of £20.5m (H122: £8.8m loss) and a net loss of £20.8m (H122: £9.8m loss).

Forecasts do not include any unknown/uncertain milestones given limited visibility

Our future revenue forecasts do not include any unknown and/or uncertain milestones, hence we only include remaining deferred revenue recognition of previously received milestones of £3.9m in FY23e and £973k in FY24e, which relate to the Jazz Pharmaceuticals collaboration. While future potential milestone receipts are significant (c \$750m in aggregate) there is limited visibility on timings as they are linked to the clinical development progress of AZD5055 and JZP815 which are under the control of their respective licensors. Given the ongoing Phase II studies and plans for pipeline expansion/progression (including RXC008 Phase I start in 2024), we continue to forecast R&D spend of £40.0m in FY23e and £42m in FY24e. with core G&A of £11-12m.

Cash of £34.6m should be sufficient beyond key value inflection points

At end-March 2023, Redx had cash resources of £34.6m (30 September 2022: £53.9m) which provides funding through significant value inflection points, most notably RXC007 Phase IIa IPF data and RXC004 Phase II CPI combination data. Management has indicated that options to extend the cash runway beyond Q1 2024 are under evaluation.



**Exhibit 6: Summary of financials** 

Year-end: Sept 30	£'000s	2020	2021	2022	2023E	2024E
INCOME STATEMENT						
Revenues		5,685	10,035	18,690	3,920	973
Cost of goods sold		0	0	0	0	0
Gross Profit		5,685	10,035	18,690	3,920	973
R&D expenses		(10,460)	(24,445)	(28,563)	(39,988)	(41,988)
G&A expenses		(4,238)	(6,492)	(10,229)	(11,087)	(11,657)
Underlying operating profit		(8,445)	(17,117)	(15,737)	(42,703)	(48,130)
Share-based payments		(568)	(3,785)	(4,365)	(4,452)	(4,541)
Exceptionals		0	0	0	(2,395)	0
Other revenue/expenses		812	1,157	3,836	1,534	1,565
EBITDA		(7,536) (8,201)	(19,112)	(15,380)	(47,202) (48,016)	(50,237)
Operating Profit		(967)	<b>(19,745)</b> (1,698)	<b>(16,266)</b> (1,538)	(46,016)	( <b>51,106</b> ) (1,616)
Financing costs/income  Profit Before Taxes		(9,168)	(21,443)	(1,336)	(49,427)	(52,723)
Adj. PBT		(8,844)	(18,815)	(17,304)	(44,114)	(49,747)
Current tax income		(45)	(133)	(201)	(200)	(210)
Net Income		(9,213)	(21,576)	(18,005)	(49,627)	(52,933)
Net income		(7,210)	(21,570)	(10,003)	(47,027)	(32,700)
EPS (p)		(5.4)	(8.4)	(6.1)	(14.4)	(11.9)
Adj. EPS		(5.2)	(7.4)	(5.9)	(12.9)	(11.2)
DPS (p)		0.0	0.0	0.0	0.0	0.0
Average no. of shares (m)		170.1	256.4	294.2	344.1	445.2
BALANCE SHEET						
Current assets		29,468	35,815	59,378	12,861	4,480
Cash and cash equivalents		27,513	29,552	53,854	11,224	4,054
Accounts receivable		1,923	6,231	5,498	1,611	400
Other current assets		32	32	26	26	26
Non-current assets		3,459	3,730	3,099	987	(1,244)
Property, plant & equipment		3,048	3,325	2,699	2,164	1,587
Intangible assets		411	405	400	396	392
Other non-current assets		0	0	0	(1,573)	(3,223)
Current liabilities		(10,934)	(9,592)	(27,205)	(9,593)	(49,023)
Short-term debt		0	0	(15,731)	0	(40,000)
Accounts payable		(3,362)	(4,699)	(5,958)	(7,998)	(8,398)
Other current liabilities		(7,572)	(4,893)	(5,516)	(1,596)	(625)
Non-current liabilities		(19,967)	(16,821)	(1,951)	(378)	1,272
Long-term debt		(16,758)	(14,247)	(4.054)	(270)	1 272
Other non-current liabilities		(3,209) <b>2,026</b>	(2,574) <b>13,132</b>	(1,951)	(378) <b>3,877</b>	1,272 (44,514)
Equity		2,020	13,132	33,321	3,077	(44,514)
CASH FLOW STATEMENTS						
Operating cash flow		395	(21,379)	(8,470)	(42,355)	(46,881)
Profit before tax		(9,168)	(21,443)	(17,804)	(49,427)	(52,723)
Non-cash adjustments		2,123	6,116	6,776	6,678	7,027
Change in working capital		6,425	(6,065)	2,038	2,007	638
Interest paid		7	13	187	(1,412)	(1,616)
Taxes paid		1,008	(754)	333	(200)	(207)
Investing cash flow		(55) (50)	( <b>754)</b>	(241)	(2 <b>75</b> )	(289)
CAPEX on tangible assets		(59) 4	(754) 0	(262) 21	(275) 0	(289) 0
Acquisitions/disposals Other investing cash flows		0	0	0	0	0
Financing cash flow		23,469	24,143	32,982	0	40,000
Proceeds from equity		1,876	24,929	33,798	0	40,000
Increase in loans		22,563	0	0	0	40,000
Other financing cash flow		(970)	(786)	(816)	0	0,000
Net increase in cash		23,809	2,010	24,271	(42,630)	(7,170)
Cash at start of year		3,704	27,513	29,552	53,854	11,224
·		27,513	29,552	53,854	11,224	4,054
Cash at end of year		27,313	_,,			.,

Source: Company, Trinity Delta Note: Short-term debt in CY23/FY24e is indicative of our view of Redx Pharma's funding requirement. Redmile/Sofinnova Convertible Loan Note has August 2023 conversion date, with a 15.5p conversion price, equating to a potential 110.3m of new shares. Revenue forecasts do not include any contribution from milestone payments yet to be received.



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