RNS Number : 6485Z Redx Pharma plc 17 May 2023

THIS ANNOUNCEMENT CONTAINS INSIDE INFORMATION FOR THE PURPOSES OF ARTICLE 7 OF EU REGULATION 596/2014 AS IT FORMS PART OF DOMESTIC LAW IN THE UNITED KINGDOM BY VIRTUE OF THE EUROPEAN UNION (WITHDRAWAL) ACT 2018.

REDX PHARMA PLC ("Redx" or the "Company")

Interim Results for the Six Months Ended 31 March 2023

Focus on progressing industry-leading ROCK portfolio with RXC007 Phase 2a trial on track to deliver topline data Q1

2024 and RXC008 CTA submission expected H2 2023

RXC004 combination modules open for enrolment with topline data expected H2 2023

Redx funded through significant value inflection points; evaluating all options to extend cash runway beyond Q1 2024

Alderley Park, UK, 17 May 2023 Redx (AIM:REDX), the clinical-stage biotechnology company focused on discovering and developing novel, small molecule, targeted therapeutics for the treatment of fibrotic disease and cancer announces its unaudited financial results for the six month period ended 31 March 2023.

Lisa Anson, Chief Executive Officer, Redx Pharma commented: "During the six months to 31 March 2023 the Company has prioritised our industry-leading ROCK portfolio where we have made very significant progress. Our lead asset RXC007, a next-generation selective ROCK2 inhibitor, is progressing well through a Phase 2a clinical trial in idiopathic pulmonary fibrosis (IPF), with topline data expected in Q1 2024. Our first-in-class GI-targeted ROCK inhibitor, RXC008, is on track for a CTA submission in H2 2023 to become our second ROCK programme in clinical development. We also look forward to the important RXC004 Phase 2 combination data due at the end of 2023 and remain well positioned to deliver multiple near-term value inflection points."

Operational Highlights:

Advanced RXC007, a next-generation selective ROCK2 inhibitor, with the commencement of the Phase 2a dose escalation study in IPF:

- On 11 October 2022, the first patient was dosed in Phase 2a IPF study. The study has been approved in 6 European
 countries with 14 sites open and patient recruitment is progressing well and on track to deliver topline data Q1
 2024;
- Recruitment into the translational science sub-study opened in the UK and under an IND in US, with additional nonclinical work ongoing to support longer dosing durations in the US;
- On 2 October and 10 November 2022, encouraging preclinical data were presented at ICLAF and AFDD respectively, supporting expansion into additional interstitial lung diseases;
- Post period, an initial safety review in the first eight patients dosed at 20mg BID confirmed no safety signals to date, supporting the planned dose escalation;

 Post period, on 10 May 2023, preclinical data highlighting potential in cancer-associated-fibrosis were presented at the Resistant Tumour Microenvironment, Keystone Symposia.

Progressed RXC008, a GI-targeted ROCK inhibitor being developed as a potential first-in-class treatment for fibrostenotic Crohn's disease, through IND-enabling studies with a CTA submission planned in 2023:

On 23 November 2022, preclinical data were presented at the IBD Nordic Conference showing RXC008 can suppress
fibrosis in animal models of GI fibrosis.

Commenced patient recruitment into the combination programme for RXC004, a small molecule Porcupine inhibitor being developed for the treatment of Wnt-ligand dependent cancers, which is investigating the primary efficacy hypothesis to overcome immune evasion in combination with anti-PD-1:

- On 10 November 2022, Phase 1 combination data presented at the Society for Immunotherapy of Cancer
 Conference (SITC) showed an acceptable tolerability and PK profile in this patient population supporting a dose of
 1.5mg in combination with an anti-PD-1 in the Phase 2 trial. The Phase 2 modules of RXC004 in combination with
 anti-PD-1 in both PORCUPINE and PORCUPINE2 continue to recruit, with data expected to report at the end of 2023;
- On 16 December 2022, a clinical trial collaboration and supply agreement was announced with MSD (Merck & Co., Inc.) for the supply of Keytruda®[1] (pembrolizumab) for the PORCUPINE2 biliary tract cancer combination module;
- On 8 March 2023, initial Phase 2 data were reported from the monotherapy biliary tract cancer (BTC) module, with some patients experiencing durable clinical benefit. The overall safety and efficacy profile was in line with the Phase 1 study;
- All monotherapy modules have now been closed for further recruitment enabling the single agent profile of RXC004
 to be characterised for future partnership and regulatory discussions, whilst streamlining the study design to
 prioritise resources and patients to combination arms.

Financial Highlights:

- Cash balance at 31 March 2023 of £34.6 million (31 March 2022: £31.6 million), sufficient to fund the Company into Q1 2024. The Company is financed to deliver key project milestones including RXC007 Phase 2a data, RXC008 CTA submission and RXC004 combination data readout;
- R&D expenses for the period of £16.1 million (31 March 2022 £12.9 million);
- Loss for the period of £20.8 million (31 March 2022 £9.8 million), driven by lower revenue, higher R&D expense and reverse merger transaction expenses;
- Post period on 3 April, a recommended all-share business combination with Jounce Therapeutics, Inc. ("Jounce"),
 announced on 23 February, was terminated following the withdrawal by the board of directors of Jounce of its
 recommendation for the combination, in favour of an unsolicited all-cash offer from another party, which the board
 of directors of Jounce felt to be in the best interest of Jounce's shareholders;
- The Company continues to evaluate alternative options to extend cash runway beyond Q1 2024.

As previously announced, the Company will hold a live webcast of the 2023 interim results presentation at 12pm GMT (7am EST) today. Attendees can register via the following link: https://webcast.openbriefing.com/redxpharma-may23/ and the presentation will be available for replay on the Company's website at: https://www.redxpharma.com/investor-centre/presentations-analyst-reports-documents-and-videos/.

The person responsible for the release of this announcement on behalf of the Company is Claire Solk, Company Secretary.

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About Redx Pharma Plc

Redx Pharma (AIM: REDX) is a clinical-stage biotechnology company focused on the discovery and development of novel, small molecule, targeted therapeutics for the treatment of fibrotic disease, cancer and the emerging area of cancer-associated fibrosis, aiming initially to progress them to clinical proof of concept before evaluating options for further development and potential value creation. The Company's lead fibrosis product candidate, the selective ROCK2 inhibitor RXC007, is in development for interstitial lung disease and commenced a Phase 2a trial for idiopathic pulmonary fibrosis (IPF) in October 2022, with topline data expected in Q1 2024. Redx's lead oncology product candidate, the Porcupine inhibitor RXC004, being developed as a targeted treatment for Wnt-ligand dependent cancers, is expected to report combination with anti-PD-1 Phase 2 data during 2023. Redx's third drug candidate, RXC008, a GI-targeted ROCK inhibitor for the treatment of fibrostenotic Crohn's disease, is progressing towards a CTA application at the end of 2023.

The Company has a strong track record of discovering new drug candidates through its core strengths in medicinal chemistry and translational science, enabling the Company to discover and develop differentiated therapeutics against biologically or clinically validated targets. The Company's accomplishments are evidenced not only by its two wholly-owned clinical-stage product candidates and rapidly expanding pipeline, but also by its strategic transactions, including the sale of pirtobrutinib (RXC005, LOXO-305), a non-covalent (reversible) BTK inhibitor now approved by the US FDA for adult patients with mantle cell lymphoma previously treated with a covalent BTK inhibitor, and AZD5055/RXC006, a Porcupine inhibitor targeting fibrotic diseases including IPF, which AstraZeneca is progressing in a Phase 1 clinical study. In addition, Redx has forged collaborations with Jazz Pharmaceuticals, which includes JZP815, a pan-RAF inhibitor developed by Redx which Jazz is now progressing through Phase 1 clinical studies, and an early stage oncology research collaboration.

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Chief Executive's Statement

During the six months ended 31 March 2023, we have continued to execute our core strategy to develop potential best-in-class or first-in-class therapeutics in areas of high unmet medical need.

We have prioritised the development of our industry-leading ROCK portfolio and are particularly excited by the potential of the lead programme, RXC007, a next-generation selective ROCK2 inhibitor which is progressing through a Phase 2a clinical trial in IPF. The ROCK portfolio also includes a potential first-inclass programme, RXC008, a GI-targeted ROCK1/2 inhibitor which is advancing towards the clinic as a potential treatment for fibrostenotic Crohn's disease. RXC004, the Company's lead oncology asset, continues to recruit patients to the combination modules of the Phase 2 programme and we expect initial topline data by the end of 2023. Additionally, our discovery pipeline has continued to advance key research programmes towards our goal of two further INDs by the end of 2025.

The cash balance at the end of the period of £34.6 million funds our programmes into Q1 2024 and through multiple near-term value inflection points. During the period, we have rigorously reviewed our expenses and portfolio to prioritise resources towards the areas where we see the highest impact on clinical benefit, commercial returns and value creation for shareholders.

An industry-leading ROCK portfolio

Redx has developed a unique portfolio of multiple distinct assets targeting Rho-associated protein kinase (ROCK), a known nodal point for pro-fibrotic signalling central to fibrosis in a range of fibrotic conditions. Our medicinal chemistry expertise and deep understanding of the ROCK target has allowed successful development of these programs through optimising molecular properties in areas such as exposure, drug-drug interaction and selectivity.

With RXC007, we have used our medicinal chemistry expertise to selectively target ROCK2, historically known to be a very challenging target, for the treatment of interstitial lung disease (ILD), with an initial focus on IPF where ROCK2 is upregulated. Taking a different approach with RXC008, we have developed a GI-targeted ROCK1/2 inhibitor which is in preclinical development for the treatment of fibrostenotic Crohn's disease. RXC008 is specifically designed to avoid the potential cardiovascular side-effects of systemic ROCK1/2 inhibition by being restricted to the GI tract with any breakthrough rapidly degraded in plasma.

RXC007 - Currently in Phase 2a for IPF, with potential in a number of other fibrotic conditions

RXC007, a next-generation selective inhibitor of ROCK2 commenced a Phase 2a trial in IPF in October 2022.

The Phase 2a trial is a randomised, dose escalation study with and without standard of care agents. Three cohorts, each consisting of 16 patients with 12 receiving RXC007, will be dosed with an escalating dose of RXC007, with the key endpoints being safety, PK profile, changes from baseline in lung function - Forced Vital Capacity (FVC) and Carbon Dioxide Diffusion Coefficient (DLCO), changes from baseline in Quantitative Lung Fibrosis Score and airway volume and resistance on high resolution computerised tomography (HRCT) scan. The initial dosing period will last for 12 weeks; however, patients may continue for longer if there are no signs of disease progression or toxicity. The data collected will inform the potential dose we take forward into a larger Phase 2b study, which will be powered to detect an efficacy signal based on the current regulatory endpoint of FVC change over 12 months.

Recruitment into the Phase 2a study is on track with the initial safety review for the first eight patients, dosed at 20mg BID, completed with no safety signals to date, enabling recruitment and dose escalation to continue. The study is currently approved in 6 countries across Europe with 14 active study sites open and with further sites expected to be active by the end of H1 2023. Based on current recruitment rates, we expect to report topline data during Q1 2024, as previously communicated.

In parallel with the main study, a translational science sub-study is ongoing to demonstrate the effect on disease biomarkers. In total, 16 patients will be recruited into this study and dosed with RXC007 for 28 days, with endpoints including changes from baseline in blood biomarkers, proteins and genes from broncho-alveolar lavage (BAL) fluid and BAL-fluid cells and bronchial epithelial cells. An open IND in the US is allowing enrolment into the 28-day translational science sub-study with longer dosing currently under an FDA partial clinical hold pending the data readout from an ongoing nonclinical study. The requested data, at clinically relevant doses, is expected later this year.

Treatments for IPF have remained largely stagnant since the 2014 approval of pirfenidone and nintedanib, both of which have been shown to slow but not halt or reverse the effect of fibrosis, and which have significant tolerability issues for a large percentage of patients, limiting their use.

Based on current biological knowledge, targeting downstream pathways is most likely to be effective in treating clinically overt disease^[2]. ROCK sits downstream of a number of competitor targets including the TGF- β , CTGF and LPA pathways, all of which signal, or partially signal, through ROCK. As a known nodal point in these signalling cascades, by selectively targeting ROCK2, RXC007 can act pleiotropically, an important characteristic of approved antifibrotic compounds.

ROCK2 inhibition is now a commercially validated target with potential in multiple disease areas, following the FDA approval and launch of the first drug with this mechanism of action for the treatment of chronic graft versus host disease (cGvHD).

In addition to the ongoing clinical development plan in IPF, which accounts for around one third of patients with a significant lung pathology, we have also generated consistently supportive preclinical data that highlights the broad potential of next-generation ROCK2 inhibitors across a number of fibrotic indications where there remains a significant unmet need.

We presented proof-of-concept data at the International Colloquium on Lung and Airway Fibrosis (ICLAF) on 2 October 2022 that detailed development work in immune mediated models of cGvHD, where the underlying disease mechanisms that drive pathology in the model show similarities to those observed in the lung pathology of auto-immune driven fibrotic diseases such as systemic sclerosis and ILD. The data presented showed the pleiotropic, anti-fibrotic effects of RXC007, which when dosed orally and therapeutically, was able to significantly reduce skin thickness, fibrosis and collagen deposition in the skin and lungs.

Beyond lung fibrosis, encouraging data from an ongoing collaboration with the Garvan Institute of Medical Research (the "Garvan"), presented at the Antifibrotic Drug Development Summit (AFDD) on 10 November 2022, showed the potential of Redx's ROCK2 inhibitors in cancer-associated fibrosis, such as that seen in pancreatic cancer. Post period, on 10 May 2023, preclinical data showing the effect of RXC007 in an aggressive patient derived xenograft model of pancreatic ductal adenocarcinoma in combination with standard of care (SoC) chemotherapy, were presented at the Resistant Tumour Microenvironment, Keystone Symposia. The data observed showed a striking increase in survival when RXC007 was combined with SoC chemotherapy, compared to SoC chemotherapy alone.

These data add to an extensive preclinical data package which supports opportunities in multiple fibrotic indications, including the wider ILD indications being planned for in the future Phase 2b study. They also support the exploration of RXC007 in cancer-associated fibrosis, such as that seen in advanced pancreatic cancer, thereby presenting a novel opportunity in a disease area with both a high unmet need and the potential for accelerated development in combination with standard first line chemotherapy regimens, which we aim to commence early in 2024.

As our RXC007 clinical activities continue to mature, we have also filed a proposed International Non-proprietary Name (INN), zelasudil, which we expect to become active in June 2023.

RXC008 - On track for a CTA submission during H2 2023

RXC008 is a potent, oral, small molecule non-systemic GI-targeted ROCK inhibitor designed to act exclusively in the GI tract at the site of fibrosis in Crohn's disease. RXC008 is currently undergoing IND enabling studies to allow the submission of a Clinical Trial Authorisation (CTA) during H2 2023, which would allow the commencement of a first-in-man Phase 1 study in 2024.

RXC008 is a potential first-in-class treatment for fibrostenotic Crohn's disease, for which no therapeutic treatment is currently available, meaning patients must endure invasive, and often multiple, surgeries. RXC008 has shown *in vivo* efficacy in animal fibrosis models and *ex vivo* efficacy in human tissue from Crohn's disease patients.

During the period, results from adoptive transfer and chronic dextran sulphate sodium (DSS) studies were presented at the Inflammatory Bowel Disease Nordic (IBD Nordic) Conference in November 2022.

These studies, undertaken in collaboration with Ghent University, also incorporated the use of non-invasive magnetic resonance imaging (MRI) texture analysis and histology to assess reduction in tissue injury and fibrosis, and is something that we aim to use translationally in our clinical studies moving forward. Of note, the most compelling preclinical data were seen in a therapeutic 12-week DSS model with a closely related GI-targeted ROCK inhibitor, REDX08087, which was able to fully reverse fibrosis back to baseline levels when the compound was administered orally once a day from weeks 6 to 12, once fibrosis was established. We were able to show complete reversal of preformed GI fibrosis as measured by trichome collagen staining, with this level of anti-fibrotic effect the strongest we have seen in any of Redx's fibrosis models and modes of action to date.

RXC004 - primary efficacy hypothesis in combination with anti-PD-1 expected to read out at the end of 2023 with a view to partnering for future development

RXC004 is an orally active, once daily, Porcupine inhibitor in Phase 2 development as a targeted treatment for Wnt-ligand dependent cancers.

The primary efficacy hypothesis for RXC004 is in combination, which we are initially exploring clinically with anti-PD-1 therapy, where it is believed to overcome immune evasion and anti-PD-1 resistance in late-stage hard-to-treat tumour types. However, due to its mechanism of action, there is further potential to combine with MAPK pathway inhibitors given the significant co-occurrence of both BRAF and KRAS mutations in Wnt-ligand dependent tumours, as well as with chemotherapy.

The Phase 2 development programme consists of two studies, PORCUPINE, evaluating RXC004 as both monotherapy and in combination with an anti-PD-1 checkpoint therapy, nivolumab (OPDIVO $^{\circ}[3]$ - Bristol Myers Squibb), in genetically selected MSS mCRC; and PORCUPINE2, as monotherapy in genetically selected pancreatic cancer and as monotherapy and in combination with anti-PD-1 therapy, pembrolizumab (KEYTRUDA $^{\circ}[4]$) in unselected Biliary Tract Cancer (BTC). The objective of the Phase 2 programme is to provide an initial assessment of the efficacy and safety of RXC004.

During the period, we presented enabling Phase 1 combination data at the Society for Immunotherapy of Cancer (SITC) Conference in November 2022, which confirmed the selection of 1.5mg as the dose to take forward and duly supported the decision to open enrolment into the Phase 2 combination modules. Recruitment into the Phase 2 combination modules of the RXC004 programme is ongoing and we expect to report topline data at the end of 2023. Given the highest potential opportunity to develop RXC004 is in combination, following these data read outs Redx aims to seek a partner to develop RXC004 more broadly in combination with other agents.

On 8 March 2023, the first data from the Phase 2 programme were announced from 16 previously treated patients enrolled in the advanced unselected BTC monotherapy arm of the PORCUPINE2 study, the primary endpoint of which was progression free survival at six months. The initial data showed some patients received durable clinical benefit from RXC004, consistent with clinical activity seen in the earlier Phase 1 trial, which Redx believes is notable given few drugs have received regulatory approval as single agents in this treatment setting. The data also showed that the safety profile of RXC004 in this module was consistent with that reported in Phase 1. Whilst an encouraging demonstration of potential for RXC004's contribution to efficacy in a combination therapy, the overall results were not sufficient to support the further development by Redx of RXC004 as a monotherapy in BTC.

The emerging single agent profile of RXC004 with the BTC monotherapy data reported to date is showing modest clinical benefit and supportive of the primary efficacy hypothesis in the combination setting. In light of this, and the fact that it has taken longer than initially anticipated to identify patients in the genetically selected pancreatic and MSS mCRC monotherapy modules, a trend that has been evidenced across the industry landscape, we have made the decision to close further patient recruitment for all monotherapy. This will enable us to prioritise both patient recruitment and resources into the combination modules which we expect to report at the end of 2023 as planned.

Discovery Engine - Progressing towards two further INDs by end of 2025

Our approach to discovery has historically been to select biologically or clinically validated targets where we believe our capabilities can solve historical challenges, including those associated with resistance, dosing and pharmacokinetics, tolerability or drug-drug interactions. This approach is evidenced both

with RXC007 which we believe has the potential to be a best-in-class molecule, as well as the recent US FDA approval of Jaypirca™ (pirtobrutinib), during the period. Pirtobrutinib, a non-covalent (reversible) BTK inhibitor, was originally discovered and developed by Redx^[5] and is the first Redx-discovered molecule to receive a marketing authorisation.

We continue to progress towards our goal of two further INDs by the end of 2025 and have a pipeline of undisclosed research programmes ongoing. The most advanced of these is the Discodin Domain Receptor (DDR) programme. DDRs are receptor tyrosine kinases containing a discoidin homology domain in their extracellular region and which act as non-integrin collagen receptors. There are two DDR receptors, DDR1 and DDR2, and DDR expression is increased in many fibrotic diseases. DDRs have recently gained traction as new druggable targets with the potential to treat multiple fibrotic conditions, including kidney fibrosis. Redx has generated compelling preclinical data on REDX12271, a novel, potent, selective and orally active DDR1 inhibitor, in chronic kidney disease models, which were presented at the American Society of Nephrology Kidney Week (ASN) in November 2022. The data presented showed that selective inhibition of DDR1 with REDX12271 reduces inflammation and fibrosis in prophylactic Murine Unilateral Ureteral Obstruction (UUO) models, and to our knowledge this is the first example of selective inhibition of DDR1 with a small molecule giving rise to efficacy in mouse UUO models.

Finance

Our cash balance at the end of the period of £34.6 million provides funding into Q1 2024 and enables the delivery of several significant value inflection points, including Phase 2a data in IPF. The increase in our R&D expenditure to £16.1 million (31 March 2022: £12.9 million) results from the expansion of our clinical trial activities. Although no milestones from partnerships were received during the period, the revenue reported of £2.3 million is as a result of the revenue recognition from our ongoing collaboration with Jazz Pharmaceuticals. Driven by higher R&D expenses and lower revenue for the period, in addition to one-time reverse merger transaction expenses, the Loss from Operations of £20.8 million was higher than the comparative period (31 March 2022: £9.8 million).

Management remain highly focused on efficiently allocating resources, including conducting a detailed prioritisation review of all programmes and expenses, to ensure delivery of important value inflection points. The Board and management continue to explore all financing and other strategic options to extend the cash runway in the best interests of all our shareholders.

Outlook

During the period under review, we continued to advance our clinical and preclinical programmes towards significant value inflection points, with a focus on our industry-leading ROCK portfolio. We remain very enthused by the data to date from our clinical portfolio, and the overall momentum within our pipeline. Whilst disappointed that the announced merger with Jounce did not complete, we remain well positioned to deliver multiple near-term value inflection points. Redx retains the foundations for longer term success and shareholder value creation and our Board will continue to explore all options to secure the funding required to further enable this. I look forward to reporting our progress in due course.

I would like to take this opportunity to thank our employees who continue to drive the success of the Company through their talent and commitment, as well as our partners and collaborators who augment our ability to deliver these potential drugs to patients, and our shareholders who have continued to show strong support for the Company.

Lisa Anson

Chief Executive Officer

		Unaudited	Unaudited	Audited
	Note	Half Year to 31 March 2023 £000	Half Year to 31 March 2022 £000	Year to 30 September 2022 £000
Revenue	2	2,311	8,353	18,690
Research and Development expenses		(16,097)	(12,913)	(28,563)
General and Administrative expenses		(4,747)	(5,314)	(10,229)
Reverse merger expenses	3	(2,395)	-	-
Exchange (losses)/gains on translation		(441)	409	2,297
Other operating income	_	915	625	1,539
Loss from operations		(20,454)	(8,840)	(16,266)
Finance income	5	704	8	187
Finance expense	5_	(897)	(850)	(1,725)
Loss before taxation		(20,647)	(9,682)	(17,804)
Income tax	6	(119)	(81)	(201)
Loss attributable to owners of Redx Pharma Plc Other comprehensive (loss) / income Items that may subsequently be reclassified to profit or loss		(20,766)	(9,763)	(18,005)
Exchange difference from translation of foreign operations	_	(5)	8	31
Total comprehensive loss for the period attributable to owners of Redx Pharma Plc	=	(20,771)	(9,755)	(17,974)
		Pence	Pence	Pence
Loss per share From continuing operations - basic & diluted	7	(6.2)	(3.5)	(6.1)

Consolidated Statement of Financial Position

		Unaudited	Unaudited	Audited
		31 March 2023	31 March 2022	30 September 2022
	Note	£000	£000	£000
Assets				
Property, plant and equipment		2,370	3,047	2,699
Intangible assets		397	403	400
Total non-current assets	_	2,767	3,450	3,099
Trade and other receivables	8	5,445	4,881	5,498
Current tax		26	26	26
Cash and cash equivalents		34,610	31,583	53,854
Total current assets	<u></u>	40,081	36,490	59,378
Total assets	_	42,848	39,940	62,477
Liabilities				
Current liabilities				
Trade and other payables	9	6,546	5,678	5,958
Contract liabilities	10	2,582	11,044	4,893
Borrowings Lease liabilities	11	16,526 649	- 599	15,731
	_			623
Total current liabilities		26,303	17,321	27,205
Non-current liabilities				
Borrowings	11	-	14,971	-
Lease liabilities		1,619	2,268	1,951
Total liabilities	_	27,922	34,560	29,156
Net assets		14,926	5,380	33,321
Equity	=			
Share capital	12	3,349	2,753	3,349
Share premium		99,501	66,299	99,501
Share-based payment		10,431	6,746	8,199
Capital redemption reserve		1	1	1
Exchange translation reserve		55	37	60
Convertible note reserve		3,524	3,524	3,524
Retained deficit		(101,935)	(73,980)	(81,313)
Equity attributable to shareholders	_	14,926	5,380	33,321

Consolidated Statement of Changes in Equity

	Unaudited	Unaudited	Unaudited	Unaudited	Unaudited	Unaudited	Unaudited	Unaudited
	Share capital £000	Share premium £000	Share- based payment £000		Exchange translation reserve £000	Convertible note reserve £000	Retained deficit £000	Total equity £000
Movements by half year	1000	1000	1000	1000	1000	1000	1000	1000
At 30 September 2021	2,753	66,299	4,752	1	29	3,524	(64,226)	13,132
Loss for the period	-	-	-	-	-	-	(9,763)	(9,763)
Other comprehensive income	-	-	-	-	8	-	=	8
Total comprehensive loss for the period Transactions with owners in	-	-	-	-	8	-	(9,763)	(9,755)
their capacity as owners								
Share-based compensation	-	-	2,003	-	-	-	-	2,003
Release of share options lapsed in the period	-	-	(9)	-	-	-	9	
At 31 March 2022	2,753	66,299	6,746	1	37	3,524	(73,980)	5,380
Loss for the period	-	-	-	-	-	-	(8,242)	(8,242)
Other comprehensive income	-	-	-	-	23	-	-	23
Total comprehensive loss for the period Transactions with owners in their capacity as owners	-	-	-	-	23	-	(8,242)	(8,219)
Issue of ordinary shares	596	33,972	-	-	-	-	-	34,568
Transaction costs on issue of ordinary shares	-	(770)	-	-	-	-	-	(770)
Share-based compensation	-	-	2,362	-	-	-	-	2,362
Release of share options lapsed in the period	-	-	(909)	-	-	-	909	
At 30 September 2022	3,349	99,501	8,199	1	60	3,524	(81,313)	33,321
Loss for the period	-	-	-	-	-	-	(20,766)	(20,766)
Other comprehensive loss	-	-	-	-	(5)	-	-	(5)
Total comprehensive loss for the period	-	-	-	-	(5)	-	(20,766)	(20,771)
Transactions with owners in their capacity as owners								
Share-based compensation	-	-	2,376	-	-	-	-	2,376
Release of share options lapsed in period	-	-	(144)	-	-	-	144	
At 31 March 2023	3,349	99,501	10,431	1	55	3,524	(101,935)	14,926

Consolidated Statement of Cash Flows			
	Unaudited	Unaudited	Audited
	Half Year to 31 March 2023	Half Year to 31 March 2022	Year to 30 September 2022
	£000	£000	£000
Net cash flow from operating activities			
Loss for the period	(20,766)	(9,763)	(18,005)
Adjustments for:			
Income tax Finance costs (net) Depreciation and amortisation Share based compensation Profit on disposal of assets	119 193 496 2,376	81 842 438 2,003	201 1,538 886 4,365 (13)
Movements in working capital			
(Increase) / decrease in trade and other receivables and contract assets	(545)	8,694	7,631
(Decrease) / increase in trade and other payables and contract liabilities	(1,723)	278	(5,593)
Cash (used in) / generated by operations	(19,850)	2,573	(8,990)
Tax credit received Interest received	582 601	8 8	333 187
Net cash (used in) / generated by operations	(18,667)	2,589	(8,470)
Cash flows from investing activities			
Sale of property, plant and equipment	-	-	21
Purchase of property, plant and equipment	(164)	(158)	(262)
Net cash used in investing activities	(164)	(158)	(241)
Cash flows from financing activities			
Proceeds of share issues	-	-	34,568
Share issue costs Payment of lease liabilities	- (408)	(408)	(770) (816)
Net cash (used in) / generated by financing activities	(408)	(408)	32,982
Net (decrease) / increase in cash and equivalents	(19,239)	2,023	24,271
Cash and cash equivalents at the beginning of the period	53,854	29,552	29,552
Foreign exchange difference	(5)	8	31
Cash and cash equivalents at the end of the period	34,610	31,583	53,854

Reconciliation of changes in liabilities arising from financing activities

	Unaudited	Unaudited	Audited
	Half Year to 31	Half Year	Year to 30
	March 2023	to 31 March	September
		2022	2022
	£000	£000	£000
IFRS16 Lease liability			
Balance b/fwd	2,574	3,149	3,149
Payment of lease liabilities	(408)	(408)	(816)
Interest on lease liabilities	102	126	241
Balance c/fwd (disclosed as current and non-current lease liabilities)	2,268	2,867	2,574
Convertible loan notes			
Balance b/fwd	15,731	14,247	14,247
Interest	795	724	1,484
	-		

Notes to the Interim Results

1. Basis of preparation and accounting policies

1.01 Description of Group and approval of the consolidated interim financial statements

Redx Pharma Plc ("Redx" or the "Company") is a limited liability company incorporated and domiciled in the UK. Its shares are quoted on AIM, a market operated by The London Stock Exchange. The principal activity of the Group is drug discovery, preclinical development and licensing.

The Group's consolidated interim financial statements are presented in pounds sterling, which is the Group's presentational currency, and all values are rounded to the nearest thousand (£000) except where indicated otherwise.

The consolidated interim financial statements were approved by the Board of Directors on 16 May 2023.

1.02 Basis of preparation

The Group's consolidated interim financial statements, which are unaudited, consolidate the results of Redx Pharma Plc and its subsidiary undertakings made up to 31 March 2023. The Group's accounting reference date is 30 September.

The financial information contained in these interim financial statements does not constitute statutory accounts as defined in section 434 of the Companies Act 2006. It does not therefore include all of the information and disclosures required in the annual financial statements. The financial information for the six months ended 31 March 2023 and 31 March 2022 is unaudited.

The information for the period ended 30 September 2022 has been extracted from the statutory accounts for the year ended 30 September 2022, prepared in accordance with UK adopted International Accounting Standards in conformity with the requirements of the Companies Act 2006. The statutory accounts were approved by the Board on 19 December 2022 and delivered to the Registrar of Companies. The audited financial statements of the Group in respect of the year ended 30 September 2022 received an unqualified audit opinion and did not contain a statement under section 498(2) or (3) of the Companies Act 2006. The audit report included a reference to a material uncertainty that might cast significant doubt over the Group's ability to continue as a going concern, to which the auditors drew attention by way of emphasis without qualifying their report.

1.03 Significant accounting policies

The accounting policies used in the preparation of the financial information for the six months ended 31 March 2023 are in accordance with the recognition and measurement criteria of UK adopted International Accounting Standards ("IAS") in conformity with the requirements of the Companies Act 2006 and are consistent with those adopted in the annual statutory financial statements for the year ended 30 September 2022.

While the interim financial information included has been prepared in accordance with the recognition and measurement criteria of UK adopted International Financial Reporting Standards ("IFRS"), the interim financial statements do not include sufficient information to comply with IFRS.

1.04 Segmental information

Operating segments are reported in a manner consistent with the internal reporting provided to the chief operating decision-maker. The Board of Directors and the Chief Financial Officer are together considered the chief operating decision-maker and as such are responsible for allocating resources and assessing performance of operating segments.

The Directors consider that there are no identifiable business segments that are subject to risks and returns different to the core business. The information reported to the Directors for the purposes of resource allocation and assessment of performance is based wholly on the overall activities of the Group.

The Group has therefore determined that it has only one reportable segment.

1.05 Going concern

As part of their going concern review the Directors have followed the guidelines published by the Financial Reporting Council entitled "Guidance on the Going Concern Basis of Accounting and Reporting on Solvency Risks - Guidance for directors of companies that do not apply the UK Corporate Governance Code". The Directors have also taken into account recent FRC guidance for companies in relation to going concern and Covid-19.

The Group is subject to a number of risks similar to those of other development stage pharmaceutical companies. These risks include, amongst others, generation of revenues in due course from the development portfolio and risks associated with research, development, testing and obtaining related regulatory approvals of its pipeline products. Ultimately, the attainment of profitable operations is dependent on future uncertain events which include obtaining adequate financing to fulfil the Group's

commercial and development activities and generating a level of revenue adequate to support the Group's cost structure.

The Board have adopted the going concern basis in preparing these accounts after assessing the Group's cash flow forecasts and principal risks.

At 31 March 2023 the Group held £34.6 million of cash and cash equivalents. The Group has a history of recurring losses from operations, including a net loss of £20.8 million for the six months ended 31 March 2023 and an accumulated deficit of £101.9 million at that date. In addition, operational cash outflows continue to be driven by the ongoing focus on the research, development and clinical activities to advance the programmes within the Group's pipeline. The Group recorded a net decrease in cash and cash equivalents of £19.2 million for the six months ended 31 March 2023.

As part of its approval of the Group's interim financial statements for the six months ended 31 March 2023, the Board concluded that the Group holds sufficient cash and cash equivalents to provide a cash runway into February 2024 at currently budgeted levels and timings of expenditure and also on the assumption that the Group's convertible loans will be converted into equity of the Group, or that there will be an extension of the term of those convertible loans (see further discussion below).

In undertaking the going concern review, the Board has reviewed the Group's cash flow forecasts to 31 May 2024 (the going concern period). Accounting standards require that the review period covers at least 12 months from the date of approval of the financial statements, although they do not specify how far beyond 12 months a Board should consider. Further funding is required under the Board's long-term plan to continue to develop its product candidates and conduct clinical trials, and the Group requires significant further finance within this period, and is exploring a number of different options to raise the required funding. Given these plans and requirements, a review period of 12 months is considered appropriate.

The Board has identified and assessed downside risks and mitigating actions in its review of the Group's cash flow forecasts. The potential requirement to repay the convertible loan notes and the ability of the Group to raise further capital are both circumstances outside the control of the Directors. Accordingly, the downside risks include severe but plausible scenarios where external fund raising is not successful, where the Group underperforms against the business plan, and where the convertible loan notes are recalled rather than converted or extended. Mitigating actions include the delay of operating expenditure for research activities and restriction of certain discretionary expenditure including capital expenditure. In the event that the convertible loan notes are not converted or extended, the stated mitigating actions would be insufficient such that the Group would need to raise additional capital within the going concern period and this is outside of the control of the Directors. Similarly, converting or extending the convertible loan notes would not provide sufficient free cash flow to allow the Group to meet its liabilities for at least 12 months from the date of approval of these financial statements. Based on these conditions, the Group has concluded that the need to raise further capital and the potential need to repay the convertible loan notes represent material uncertainties regarding the Group's ability to continue as a going concern.

Notwithstanding the existence of the material uncertainties, the Board believes that the adoption of the going concern basis of accounting is appropriate for the following reasons:

- the Directors consider it highly unlikely that the convertible loan notes will be repaid in August 2023 given that the conversion price of 15.5p represents a significant discount to the open market price of Redx Pharma Plc share capital. This discount is around 52% when compared to the share price at 11 May 2023.
- the Directors do not currently expect the convertible loan notes to be recalled in August 2023.
- based on plans and discussions with its advisors and investors the Directors have an expectation that further funding will be obtained.
- the Group has a track record and reasonable near-term visibility of meeting expectations under its collaboration agreements and receiving milestone payments which have the potential to increase the Group's cash runway but are not included in the Directors' assessment given they are outside the control of management.
- the Group retains the ability to control capital and other discretionary expenditure and lower other operational spend.

There can be no assurance that the convertible loan notes will be converted or extended rather than recalled. If the loan notes are not converted or extended, the Group may not have sufficient cash flows to support its current level of activities beyond the maturity date. While the Group has successfully accessed equity and debt financing in the past, there can be no assurance that it will be successful in doing so now or in the future. In the event the loan notes are recalled, or additional financing is not secured, the Group would need to consider:

- new commercial relationships to help fund future clinical trial costs (i.e., licensing and partnerships); and/or
- reducing and/or deferring discretionary spending on one or more research and development programmes; and/or
- restructuring operations to change its overhead structure.

The Group's future liquidity needs, and ability to address those needs, will largely be determined by the success of its product candidates and key development and regulatory events and its decisions in the

future. Such decisions could have a negative impact on the Group's future business operations and financial condition.

The accompanying financial statements do not include any adjustments that would be required if they were not prepared on a going concern basis. Accordingly, the financial statements have been prepared on a basis that assumes the Group will continue as a going concern and which contemplates the realization of assets and satisfaction of liabilities and commitments in the ordinary course of business.

2. Revenue

	Unaudited	Unaudited	Audited
	Half year to	Half year to 31	Year to 30
	31 March	March	September
	2023	2022	2022
	£'000	£'000	£'000
Revenue from milestones on scientific programmes Revenue from research collaboration Revenue from research and preclinical development services	-	6,684	10,693
	2,311	701	6,852
	-	968	1,145
	2,311	8,353	18,690

3. Reverse merger expenses

On 23 February 2023 the Group announced a unanimously recommended business combination with Jounce Therapeutics, Inc. ("Jounce"). Work continued on the project until, following an unsolicited cash offer for its shares, the board of directors of Jounce withdrew its recommendation for the combination on 27 March 2023 in favour of an acquisition by another party. Given the nature and materiality of the expense, it has been disclosed separately within the Consolidated Statement of Comprehensive Loss. No further expense is expected, and the proposed transaction formally lapsed on 3 April 2023.

4. Share-based compensation

Share options have been issued to certain Directors and staff, and the charge arising is shown below. The fair value of the options granted has been calculated using a Black-Scholes model. 17,570,779 of the options granted are subject to performance conditions based on scientific, clinical and commercial milestones. There are no further conditions attached to the vesting of other options other than employment service conditions.

	Unaudited	Unaudited	Audited
	Half Year to 31 March 2023	Half Year to 31 March 2022	Year to 30 September 2022
	Number	Number	Number
Outstanding at the beginning of the period Options granted and vested in period Options exercised in period	36,560,098 - -	33,577,104 - -	33,577,104 - (1,558,297)
Options surrendered and lapsed in period	(1,283,758)	(616,667)	(2,283,709)
Options granted and vesting in future periods	7,300,000	2,100,000	6,825,000
Outstanding at the end of the period	42,576,340	35,060,437	36,560,098
- -	£000	£000	£000

Assumptions used were an option life of 5 years, a risk free rate of 0.6% - 9.4% and no dividend yield. Other inputs were:

- Volatility 111% 141%
- Share price at date of grant in a range between 25p and 81p
- Exercise price in a range between 15.5p and 81p
- Weighted average fair value of each option in a range between 21.8p and 69.2p

At 31 March 2023, a total of 6,948,168 options were vested.

5. Finance income and expense

	Unaudited	Unaudited	Audited
	Half Year to 31 March 2023 £'000	Half Year to 31 March 2022 £'000	Year to 30 September 2022 £'000
Finance income Bank and other short-term deposits	704	8	187
	704	8	187
Finance expense Loan interest Interest on lease liabilities	795 102	724 126	1,484 241
	897	850	1,725

6. Income tax

	Unaudited	Unaudited	Audited
	Half Year to 31 March 2023 £'000	Half Year to 31 March 2022 £'000	Year to 30 September 2022 £'000
Current income tax Corporation tax Amounts in respect of previous periods	119	81	199 2
Income tax charge per the income statement	119	81	201

7. Loss per Share

Basic loss per share is calculated by dividing the net income for the period attributable to ordinary equity holders by the weighted average number of ordinary shares outstanding during the period. In the case of diluted amounts, the denominator also includes ordinary shares that would be issued if any dilutive potential ordinary shares were issued following exercise of share options. The basic and diluted calculations are based on the following:

Unaudited Unaudited Audited

	Half Year to 31 March 2023 £'000	Half Year to 31 March 2022 £'000	Year to 30 September 2022 £'000
Loss for the period attributable to the owners of the Company	(20,766)	(9,763)	(18,005)
	Number	Number	Number
Weighted average number of shares - basic & diluted	334,911,458	275,282,205	294,182,774
	Pence	Pence	Pence
Loss per share - basic & diluted	(6.2)	(3.5)	(6.1)

The loss and the weighted average number of shares used for calculating the diluted loss per share are identical to those for the basic loss per share. This is because the outstanding share options would have the effect of reducing the loss per share and would therefore not be dilutive under IAS 33 *Earnings per Share*.

8. Trade and other receivables

	Unaudited	Unaudited	Audited
	31 March 2023 £'000	31 March 2022 £'000	30 September 2022 £'000
Trade receivables VAT recoverable Prepayments and other receivables Accrued income	- 667 4,675 103	356 815 3,634 76	12 909 4,577
	5,445	4,881	5,498

Included within prepayments other receivables at March 2022, September 2022 and March 2023 is another receivable of £0.6 million which is due after more than one year.

9. Trade and other payables

	Unaudited	Unaudited	Audited
	31 March	31 March	30 September
	2023	2022	2022
	£'000	£'000	£'000
Trade payables Employee taxes and social security Other payables Accruals	2,181	2,201	2,792
	268	224	250
	31	9	18
	4,066	3,244	2,898
	6,546	5,678	5,958

10. Contract liabilities

	Unaudited	Unaudited	Audited
	31 March 2023 £'000	31 March 2022 £'000	30 September 2022 £'000
Contract liabilities	2,582	11,044	4,893
Reconciliation Balance b/fwd Contract asset debtor received Transfer to revenue	4,893 - (2,311)	4,318 7,427 (701)	4,318 7,427 (6,852)
	2,582	11,044	4,893

The contract liability relates to a single research collaboration contract.

11. Borrowings

	Unaudited	Unaudited	Audited
	31 March 2023 £'000	31 March 2022 £'000	30 September 2022 £'000
Convertible loan notes Current	16,526	-	15,731
Non-current	-	14,971	-
	16,526	14,971	15,731

On 4 August 2020 Redx Pharma Plc issued convertible loan notes with a value of £22.2m. No interest is payable during the first 3 years, thereafter it is payable at a maximum rate equal to the US prime rate at that time. The notes are convertible into Ordinary shares of Redx Pharma Plc, at any time at the option of the holder, or repayable on the third anniversary of the issue. The conversion rate is 1 Ordinary share for each £0.155 of convertible loan note held. The convertible loan notes are secured by a fixed and floating charge over all the assets of the Group.

As of 31 March 2023, an aggregate of £17.1 million in principal amount was outstanding under the convertible loan notes. This equates to 110,288,887 Ordinary shares at £0.155 per share.

The remaining gross principal of £17.1 million has been discounted at the effective interest rate determined on initial measurement, resulting in a discounted liability of £16.5 million (March 2022 £15.0 million, September 2022: £15.7 million).

12. Share capital

	Unaudited	Unaudited	Audited
	Half Year to 31 March 2023 Number	Half Year to 31 March 2022 Number	Year to 30 September 2022 Number
Number of shares in issue In issue at 1 October Issued for cash Exercise of share options	334,911,458 - -	275,282,205 - -	275,282,205 58,070,956 1,558,297
	334,911,458	275,282,205	334,911,458
	£'000	£'000	£'000
Share capital at par, fully paid Ordinary shares of £0.01	3,349	2,753	3,349

13. Post period end events

On 3 April 2023, Redx Pharma Plc confirmed the formal lapse of the proposed business combination with Jounce Therapeutics, Inc. All cost relating to the transaction had been incurred prior to 31 March 2023 and are disclosed within these interim results.

FURTHER INFORMATION FOR SHAREHOLDERS

AIM: REDX

Company number: 07368089

Investor website: http://redxpharma.com/investors

Registered office: Block 33, Mereside, Alderley Park, Macclesfield, SK10 4TG

Directors: Dr Jane Griffiths (Chair)

Lisa Anson (CEO)

Peter Presland (Non-Executive Director)

Dr Bernhard Kirschbaum (Non-Executive Director)

Sarah Gordon Wild (Non-Executive Director)
Dr Thomas Burt (Non-Executive Director)
Natalie Berner (Non-Executive Director)
Dr Rob Scott (Non-Executive Director)

Company Secretary: Claire Solk

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^[1] KEYTRUDA® is a registered trademark of Merck Sharp & Dohme LLC, a subsidiary of Merck & Co., Inc., Rahway, NJ, USA

^[2] https://invivo.pharmaintelligence.informa.com/IV147701/Harbingers-For-IPF-Drug-Development?

^[3] OPDIVO® is a registered trademark of Bristol-Myers Squibb Company

^[4] KEYTRUDA® is a registered trademark of Merck Sharp & Dohme LLC, a subsidiary of Merck & Co., Inc., Rahway, NJ, USA

^[5] The asset was subsequently sold outright to Loxo Oncology, now part of Eli Lilly, Redx has no remaining economic interest Jaypirca[™] is a trademark owned by or licensed to Eli Lilly and Company, its subsidiaries, or affiliates