hardman&co

Pharmaceuticals & Biotechnology

Source: Eikon Thomson Reuters

Market data

EPIC/TKR	**REDX**
Price (p)	11.4
12m High (p)	28.6
12m Low (p)	3.5
Shares (m)	126.5
Mkt Cap (£m)	14.4
EV (£m)	4.4
Free Float*	69%
Market	AIM

**As defined by AIM Rule 26*

Description

Redx is focused on the discovery and development of proprietary, small molecule therapeutics to address areas of high unmet medical need, in cancer and fibrosis. The aim is to develop putative drugs through early trials and then to partner them for late stage development and commercialisation.

Company information

CEO	Lisa Anson
CFO	Dominic Jackson
Chairman	Iain Ross

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www.redxpharma.com

Key shareholders

Directors	0.5%
Jon Moulton	18.2%
Seneca Partners	12.5%
AXA	9.8%
Aviva	8.4%
Directors	0.5%

Diary

2H'18	Submit revised protocol for Ph. I with RXC004
2H'18	Update on Soft-Rock inhibitor

Analysts

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Redx Pharma

"*Focus, Realism and Results*" – Ian Ross, Chairman

Redx Pharma's new management team is focusing its financial resources (ca.£10m) on progressing its lead candidates in oncology and fibrotic disease into the clinic. Although the first patient was treated recently in a Phase I/II proof-of-concept trial with its porcupine inhibitor RXC004, some on-target adverse events (anticipated at higher doses) were observed, which caused management to take the prudent decision to stop patient recruitment and prepare a revised protocol to the MHRA for end 2018. Meanwhile, Redx is continuing to progress its realistic development strategy with a period-end cash balance of £10.3m.

- **Strategy:** Redx is focused on the discovery and early clinical development of small molecule therapeutics in oncology and fibrotic disease. It is also focused on taking assets through proof-of-concept clinical trials and then partnering them to the drug major(s) for late-stage development and commercialisation.

- **Interims:** Redx reported progress on its R&D pipeline which is now focused on two key high value-added areas of cancer and fibrotic disease. Management has tightened control on costs with a lower spend in SG&A and R&D, reducing the annual cash burn by ca.£5m p.a.

- **RXC004 trial:** A decision was made to temporarily suspend the Phase I/IIa trial with RXC004 in light of adverse events in the first patient dosed. Early data suggest a higher exposure and longer half-life in humans that could not have been predicted. A lower dose protocol is expected to be submitted in 2H'18.

- **New CEO appointed:** As from 1 June, REDX has a new CEO, Lisa Anson, who had been President of AstraZeneca (AZN) UK since 2012. She will bring a wealth of experience, having held a variety of senior management roles at AZN in the UK and the US. Lisa is also President of the ABPI.

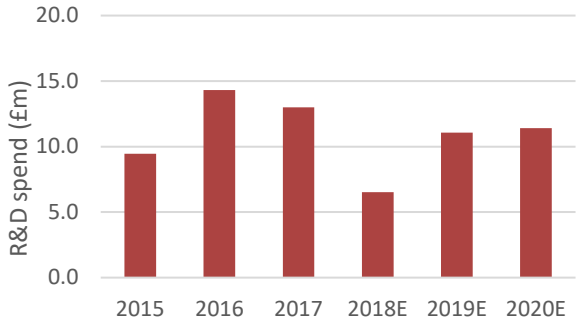
- **Investment summary:** Redx's new management team is moving forward with a revised business plan that focuses cash resources on progressing its drug leads in oncology and fibrotic disease into early clinical development. The temporary 'hold' on the RXC004 clinical trial has extended these cash resources by an estimated four months. While Novartis is paving the way with Wnt inhibition, Redx is a close follower, with a potentially best-in-class compound.

Financial summary and valuation

Year-end Sept (£000)	2015	2016	2017	2018E	2019E	2020E
Milestones/royalties	0	0	0	0	0	0
Other income	2,648	2,380	1,291	1,000	1,000	1,000
R&D investment	-9,463	-14,315	-13,000	-6,528	-11,078	-11,410
SG&A (corp. cost)	-2,008	-2,212	-5,698	-3,150	-3,276	-3,407
Underlying EBIT	-8,823	-14,147	-17,407	-8,678	-13,354	-13,817
Underlying PBT	-9,112	-14,606	-17,737	-8,648	-13,327	-13,817
Statutory PBT	-8,825	-15,407	1,646	-9,240	-13,547	-14,057
R&D tax credit	650	637	-118	392	665	685
Underlying EPS (p)	-14.6	-17.8	-15.8	-6.5	-8.8	-8.2
Statutory EPS (p)	-14.1	-19.8	1.4	-7.0	-9.0	-8.4
Net (debt)/cash	7,436	3,758	23,806	5,595	2,718	-10,382
Capital increase	13,447	9,296	11,066	0	10,000	0

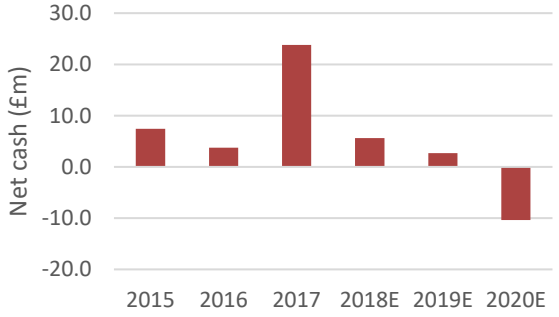
Source: Hardman & Co Life Sciences Research

R&D investment



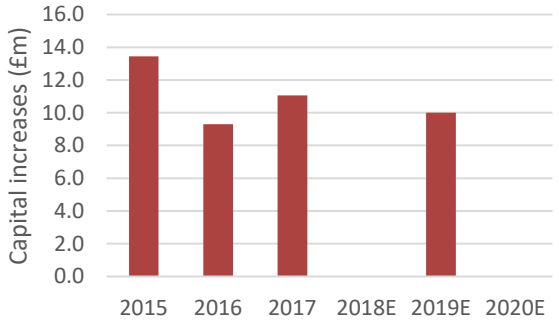
- R&D investment is expected drop and then increase in light of the Phase I/IIa trial anticipated to resume in early 2019 and additional pre-clinical works of other programmes
- Savings from the strategic restructuring will be reallocated to fund two clinical trials
- Less cash will be spent in early projects
- Redx has signed an option and licence agreement with Deinove for its anti-infective programme

Net cash/(debt)



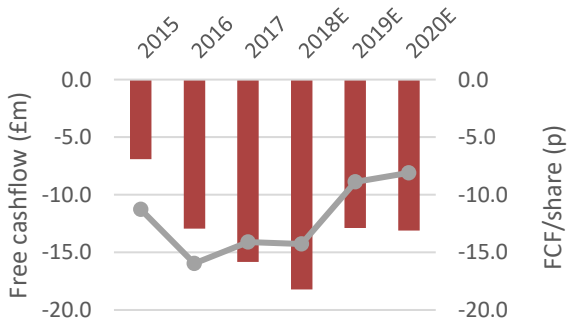
- Net cash at 31 March 2018 was £10.3m,
- Strategic restructuring is aimed at annual savings of £4.2m from the research budget, Redx outperformed and a annual saving of £7m is anticipated in FY2018
- The net cash position mainly reflects investment in R&D and corporate overhead

Capital increases



- IPO proceeds of £15m gross (£13.4m net) in March 2015
- £9.3m net (£10m gross) raised in March 2016 through a Placing
- Gross new funds of £12m (£11.1m net) were raised in March 207 to fund progress into clinical trials
- Cashflow forecasts suggest more capital will be needed to finance fiscal 2018

Free cashflow



- Free cashflow is increasing as Redx is going through clinical development, which is more expensive than discovery
- Influence of the strategic move in research *plus* development
- Maintenance cap-ex in the order of £0.4m p.a.

Source: Company data; Hardman & Co Life Sciences Research

Interim results

Key features

Operational highlights

- Redx existed administration on 2 November 2017, with net cash of £13.6m and having settled with most of its creditors.
- Resources are being concentrated on much more focused R&D activity in two core areas, oncology and fibrotic disease.
- First Phase I trial initiated, and temporally suspended, with the porcupine inhibitor RXC004, due to the manifestation of some adverse events that were anticipated to be seen at much higher doses.
- Strengthened management team and board of directors.
- Appointment of Lisa Anson as new CEO, effective 1st June.

Commercial highlights

- Successfully disposed of the BTK inhibitor programme (all associated assets and IP) to Loxo Oncology Inc (NASDAQ: LOXO) for $40m (£30.2m) cash.
- Option and licence agreement with Deinove for the Gram-negative programme.

Financial highlights

- **R&D:** R&D costs were reduced by 54% to -£3.62m (-£7.92m), which was broadly in line with our forecast. Headcount has been reduced drastically to reflect the revised approach. The temporary pause in the Phase I trial is expected to bring down overall R&D spend for the full year, but this spend will simply move into fiscal 2019 when the trial re-starts later in the year.
- **SG&A:** Reduction of 31% in underlying administration costs to an estimated -£1.55m (-£2.24m) was in line with forecasts that were re-set when Redx returned to the market in November.
- **EBIT:** Earnings before interest and tax has been reduced by 54% to -£4.41m (-£9.51m), which was slightly better than forecast due to an improved 'other income' line.
- **Net cash:** At 31 March 2018, net cash on the balance sheet was slightly ahead of our forecast at £10.32m. Underlying cashburn (excluding external R&D spend) is now estimated to be ca.£0.65m per month.
- **Clinical trial:** The cost of the suspended Phase I/IIa trial with RXC004 – estimated at £2.0m-£2.5m in fiscal 2018 – has been pushed back to fiscal 2019.

Redx interims 2018 – actual vs expectations

Half-year to end-Sept (£m)	1H'17 actual	1H'18 actual	Growth %	1H'18 forecast	Delta Δ
R&D spend	-7.92	-3.62	-54%	-3.74	+0.12
Administration	-2.24	-1.55	-31%	-1.57	+0.02
EBIT loss	-9.51	-4.41	-54%	-4.55	+0.14
Tax credit	+0.29	+0.34	-	+0.39	-0.05
Net loss	**-10.37**	**-4.04**	**-61%**	**-4.16**	**-0.12**
Net cash/(debt)	+5.11	+10.32	+102%	9.96	+0.36

Figures may not add up exactly due to rounding
Source: Hardman & Co Life Sciences Research

Operational update

R&D pipeline

Redx has adopted a new streamlined approach to its R&D activity with a focus on two core areas, oncology and fibrotic disease, together with a vastly reduced workforce (38 vs. 199). In February 2018, Redx achieved an important milestone with the initiation of its first clinical study, which is investigating RXC004 in advanced cancer patients with solid tumours, as a single agent, in a Phase I/IIa trial. However, on 29 March, Redx decided to temporarily stop patient recruitment because the first subject had experienced some adverse events that could be anticipated with Wnt inhibition, but at a higher dose.

Pipeline

Target/Product	Indications	Lead Generation	Lead Optimisation	CTA/ IND-enabling	Phase I	Partner
Porcupine/ RXC004	Single agent: gastric, biliary & pancreatic cancer					
Porcupine/ RXC004	Combination with anti-PD-1: melanoma					
Pan-RAF	Colorectal cancer					
AZ Collaboration	Not disclosed					AstraZeneca
SHP2	Not disclosed					
ROCK	IBD-related fibrosis					
Porcupine – Fibrosis	NASH IPF					
ROCK2	NASH IPF Diabetic nephropathy					

Cancer Fibrosis

Source: Redx Pharma

Redx aims to develop small molecule therapeutics through Phase I and up to Phase II proof-of-concept trials and then to out-license these assets for late-stage development and commercialisation. This will maximise shareholder value per product. Redx is also opened to partnering programmes at an earlier stage, if considered appropriate. The price of $40m (£30.2m) paid by Loxo for the pre-clinical BTK programme is clear evidence that this strategy can be successful – the price paid was in line with standard pre-clinical small molecule projects in the field of oncology. If Redx can develop an asset even further along the pipeline to include clinical data, then even greater fees could be expected, together with development and regulatory milestones, and royalties on net sales.

Oncology

Porcupine inhibitor RXC004

Suspension of the Phase I/IIa trial has been seen as a setback. The side effects observed were in line with those that could reasonably be expected in situations where patients were being treated with too high doses of the drug. On the one hand, this means that that RXC004 was well absorbed and has a clear on-target action. On the other hand, it also provides primary information of the maximum tolerated dose and the effect of the drug in humans. RXC004 has a different pharmacokinetic profile in humans compared with that seen in animal studies with a non-expected extended half-life in the circulation, thereby giving longer exposure in the body.

These events could not have been predicted from translational studies performed in different animal species (allometric scaling). The trial was initiated at a dose level of 10mg per day and, when discussions with the regulatory body, the MHRA, are concluded, management intends to submit a new protocol, which starts at a much lower dose of drug. Redx currently anticipates that the trial will resume in early 2019.

The consequence of this is that about £2.0m-£2.5m that would have been spent on the RXC004 clinical trial programme in fiscal 2018 has been pushed back to fiscal 2019, which will extend the company's cash runway accordingly.

- **Novartis Wnt programme:** Regarding the safety profile and clinical relevance of a porcupine inhibitor, Novartis leads the way with WNT974/LGK974, which is currently in a Phase I/II study with a range of solid tumours. Results to date suggest that WNT974 affects the immune cell signatures in the tumour microenvironment, an effect observed also with RXC004 in preclinical models. In addition, Novartis indicated at the AACR meeting that a second arm of the study is currently running using WNT974 in combination with its anti-PD-1 antibody, spartalizumab. Although Novartis is leading the field, Redx remains a close follower with a compound that seems to have greater exposure (longer half-life) compared with WNT974.

Other oncology programmes

Redx has consolidated its early discovery activities to pursue a diverse portfolio of small molecules that support its clinical focus.

Early discovery oncology pipeline

Programme	Description
Pan-Raf inhibitor	Small molecule in lead optimisation with application in colorectal cancer
AZ collaboration	Undisclosed target in oncology approaching the Lead Optimisation stage
SHP-2	Small molecule allosteric inhibitor in Lead Generation stage for hard-to-treat / resistant solid tumours

Source: Company reports

Fibrotic diseases

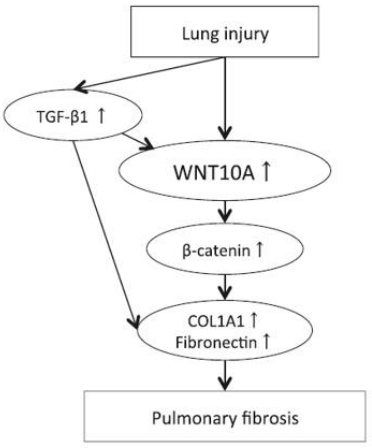
The second area of focus is the large spectrum of fibrotic disease with high unmet medical needs. With three programmes, Redx projects to encompass a vast range of fibrotic conditions that severely affect the quality of life and could also be life threatening, like the idiopathic pulmonary fibrosis (IPF) condition.

Targeting fibrotic diseases

Idiopathic Pulmonary Fibrosis (IPF)	Inflammatory Bowel Disease (IBD)
Products: Porcupine, ROCK2	***Product: "soft"-ROCK***
Diabetic nephropathy	NASH/ Liver fibrosis
Product: ROCK2	***Products: Porcupine, ROCK2***

Source: adapted from Redx Pharma

Lung fibrosis



Source: Oda et al, 2016

Porcupine programme

Inhibiting the porcupine protein, and thus the Wnt pathway, has an influence also in the development of fibrotic conditions through its role in increasing the level of several pro-fibrotic proteins. The influence of Wnt activation of β-catenin signalling in fibroblasts is believed to trigger the fibrotic pathology in various organs such as lung, liver and kidney. There is currently no cure for idiopathic pulmonary fibrosis (IPF), and the standard of care is just to relieve the symptoms as much as possible and slow down the scarring of the lungs.

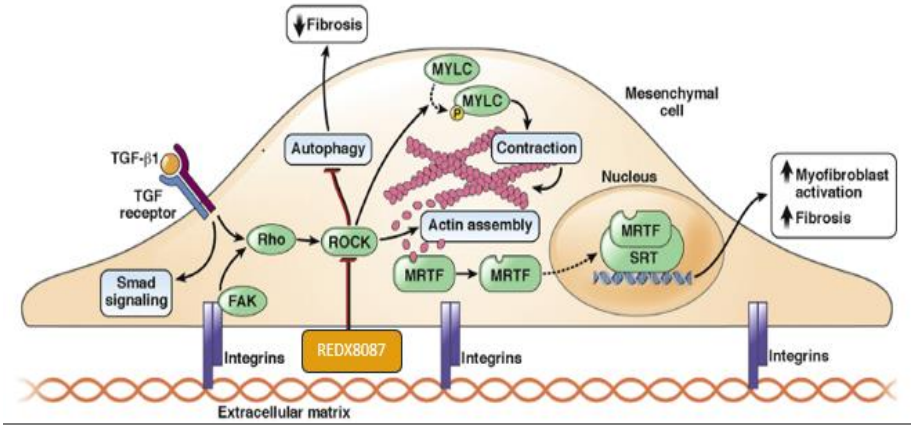
Given that RXC004 modulates the Wnt pathway, Redx has the opportunity to target another large market with high unmet medical need, with a relatively modest investment – the planned Phase I/IIa oncology trial with RXC004 will provide human safety and tolerability data.

A back-up porcupine inhibitor compound REDX06109 is also in development, which is chemically distinct from RXC004 and protected by a different patent family. Redx disclosed that REDX06109 has demonstrated encouraging results in suppressing fibrosis in different *in vivo* disease model that include kidney, liver and lung. At this stage of the discovery, it is normal to have a follow-up compound to spread the risk over two series with the best progressing to the clinical stage.

"soft"-ROCK inhibitors

Systemic exposure of Redx's "soft"-ROCK inhibitor is limited through rapid degradation by specific blood esterases, and allows selective targeting of the gut and potentially the liver. This avoids the known hypotensive side effect of systemic dual ROCK1/2 inhibition. With the 'soft' pan-ROCK inhibitors, Redx targets primarily the population of patients affected by Crohn's disease that will develop intestinal wall fibrosis, a complication that occurs in 30%-40% of IBD suffering patients. There is currently no pharmaceutical treatment for Crohn's-related fibrosis and Redx believes it can be the first to reach the clinic in this indication.

Targeting fibrotic diseases for immunology projects



Source: Holvoet et al; Gastroenterology 2017, 1054-1067

Redx has disclosed that the lead product, the locally acting "soft"-ROCK inhibitor REDX8397, shows a good anti-fibrotic effect in an adoptive T-cell model of intestinal fibrosis. Redx acquired the rights to this programme from Amakem NV when it reached late-stage lead optimisation. Redx will be targeting primarily the population of patients affected by Crohn's disease that go on to develop intestinal wall fibrosis. The aim is to complete the lead optimisation phase and start the pre-clinical development work during 2H'18.

The locally acting "soft"-ROCK inhibitors, have already demonstrated efficacy in a range of animal IBD fibrosis models. Redx's molecule has the potential to be first-in-class. Redx has the opportunity to develop a product that has the potential to not only stop, but also to eventually reverse the formation of fibrotic tissues.

ROCK2 programme

The ROCK2 programme is at the lead optimisation stage, and Redx's focus is on its application in pro-fibrotic cell types that could potentially cover a large spectrum of diseases. The benefit of having a potent selective ROCK2 inhibitor is the fact that systemic anti-fibrotic effects can be achieved without the hypotensive side effect seen with dual ROCK1/2 inhibition. Potential indications would be Diabetic Nephropathy (DN), IPF, non-alcoholic steatohepatitis (NASH) and orphan fibrotic diseases such as scleroderma.

Non-core assets

Following the new strategy to focus only on cancer and fibrotic diseases, Redx signed, in March 2018, an option and licence agreement with the French biotech Deinove for the bacterial topoisomerase inhibitor programme, a programme that was awarded a grant of $1m in March 2017 from the CARB-X initiative. Deinove will have to decide on the option by the end of 2018.

CEO appointment

Redx has announced the appointment of Lisa Anson as CEO, having been President of AstraZeneca (AZN) UK since 2012. She will bring a wealth of experience, having held a variety of senior management roles over 20 years at AZN in the UK and the US, including Global Vice President Oncology and Vice President of Emerging Brands. Lisa is also President of the Association of the British Pharmaceutical Industry (ABPI).

Financial forecasts

Profit & Loss

- **SG&A:** Net reduction of 31% in corporate overhead at -£1.5m following the restructuring of the company compared with the same period last year (-£2.2m). Our forecasts suggest a reduction of 55% at year-end.
- **R&D:** Drastic reduction of 55% in R&D cost at -£3.6m following the change and the new focus in the pipeline compared to the same period last year (-£7.9m). The number is expected to increase in the following years in relation to additional pre-clinical and regulatory work.
- **EBIT:** As a consequence, Redx has a strong reduction in negative underlying EBIT at -£4.4m (1H'17: -£9.5m).
- **Extraordinary item:** The sale of the BTK programme represent a net value of £30.5m which was accounted for in fiscal 2017.
- **Sub-letting of building & facilities:** Sub-let agreement signed during the period with Cancer Research UK for surplus lab space and facilities at Alderley Park providing some cash income.

Profit & Loss account

Year-end Sept (£000)	2015	2016	2017	2018E	2019E	2020E
Sales	0	0	0	0	0	0
SG&A	-2,008	-2,212	-5,698	-3,150	-3,276	-3,407
R&D	-9,463	-14,315	-13,000	-6,528	-11,078	-11,410
Depreciation	-139	-262	-327	-176	-176	-176
Licensing/Royalties	0	0	0	0	0	0
Other income	2,648	2,380	1,291	1,000	1,000	1,000
Underlying EBIT	**-8,823**	**-14,147**	**-17,407**	**-8,678**	**-13,354**	**-13,817**
Share-based costs	-608	-245	-13	-200	-220	-240
Exceptional items	895	-556	-7,518	-392	0	0
Statutory EBIT	-8,536	-14,948	-24,938	-9,270	-13,574	-14,057
Net interest	-289	-279	-330	29	27	0
Net financials	-289	-459	-3,890	29	27	0
Pre-tax profit	**-9,112**	**-14,606**	**-17,737**	**-8,648**	**-13,327**	**-13,817**
Extraordinary items	0	0	30,474	0	0	0
Reported pre-tax	-8,825	-15,407	1,646	-9,240	-13,547	-14,057
Reported taxation	650	-114	-118	392	665	685
Underlying net income	**-8,462**	**-13,969**	**-17,855**	**-8,256**	**-12,663**	**-13,133**
Statutory net income	-8,175	-15,521	1,528	-8,848	-12,883	-13,373
Ordinary 1p shares:						
Period-end (m)	65.0	93.6	126.5	126.5	159.8	159.8
Weighted average (m)	58.0	78.4	113.0	126.5	143.1	159.8
Fully-diluted (m)	60.8	82.3	117.3	131.1	147.7	164.4
Underlying basic EPS (p)	**-14.6**	**-17.8**	**-15.8**	**-6.53**	**-8.85**	**-8.22**
Statutory basic EPS (p)	-14.1	-19.8	1.4	-7.00	-9.00	-8.37
U/l fully-diluted EPS (p)	**-13.9**	**-17.0**	**-15.2**	**-6.30**	**-8.57**	**-7.99**
Stat. fully-diluted EPS (p)	-13.5	-18.9	1.3	-6.75	-8.72	-8.13
DPS (p)	0.0	0.0	0.0	0.0	0.0	0.0

Source: Hardman & Co Life Sciences Research

Balance sheet

- **Net cash:** At 31st March 2018, Redx had net cash of £10.3m on its balance sheet.
- **Unspent cash:** £2.0m-£2.5m that would have been spent on the RXC004 clinical trial programme in fiscal 2018 has been pushed back to fiscal 2019, which will extend the company's cash runway accordingly.
- **Loan:** Redx is now loan-free.

Balance sheet

@31 Sept (£000)	2015	2016	2017	2018E	2019E	2020E
Shareholders' funds	7,700	1,720	14,327	5,479	2,596	-10,777
Cumulated goodwill	0	0	0	0	0	0
Total equity	7,700	1,720	14,327	5,479	2,596	-10,777
Share capital	650	936	1,265	1,265	1,598	1,598
Reserves	7,050	784	13,062	4,214	998	-12,375
Capitalised R&D	21,210	30,099	36,049	34,710	36,536	37,648
Long-term loans	2,000	0	0	0	0	0
Short-term debt	0	2,000	0	0	0	0
less: Cash	9,436	5,758	23,806	5,595	2,718	-10,382
Invested capital	**20,724**	**27,456**	**26,570**	**34,593**	**36,414**	**37,254**
Fixed assets	353	533	222	196	178	167
Intangible assets	309	309	430	430	430	430
Capitalised R&D	21,210	30,099	36,049	34,710	36,536	37,648
Inventories	0	0	0	0	0	0
Trade debtors	*0*	*0*	*0*	*0*	*0*	*0*
Other debtors	*1,407*	*1,553*	*2,588*	*2,188*	*2,188*	*2,188*
Tax credit/liability	*1,501*	*637*	*643*	*392*	*665*	*685*
Trade creditors	*-1,601*	*-1,601*	*-3,812*	*-800*	*-840*	*-882*
Other creditors	*-2,455*	*-4,074*	*-9,550*	*996*	*683*	*621*
Debtors less creditors	-1,148	-3,485	-10,131	-742	-729	-991
Invested capital	**20,724**	**27,456**	**26,570**	**34,593**	**36,414**	**37,254**

Source: Hardman & Co Life Sciences Research

Cashflow

- **Closing net cash:** At end-March 2018, Redx had closing net cash of £10.3m.
- **Cash burn:** Underlying cash burn of ca.£0.65m per month (nearer -£1.0m per month including out-sourced clinical trial costs).
- **Payables:** The large working capital outflow was related directly to creditor payments due when the company was handed back by the administrators, which were all settled in the first half of fiscal 2018. The new management team has adopted a rapid payment of trade creditors when due.
- **Capital increase:** Taking account of the modestly delayed Phase II trial, our cashflow forecasts suggest that the company will need to raise more capital in fiscal 2019, which we believe would need to be a figure of ca.£10m.

Cashflow

Year-end Sept (£000)	2015	2016	2017	2018E	2019E	2020E
Underlying EBIT	-8,823	-14,147	-17,407	-8,678	-13,354	-13,817
Depreciation	139	262	327	176	176	176
Amortisation	0	0	0	0	0	0
Inventories	*0*	*0*	*0*	*0*	*0*	*0*
Receivables	*1,194*	*-124*	*-1,185*	*0*	*0*	*0*
Payables	*815*	*1,272*	*8,871*	*-9,512*	*40*	*42*
Change in working capital	2,009	1,148	7,686	-9,512	40	42
Exceptionals/provisions	0	-556	-4,985	-392	0	0
Disposals	21	0	0	-3	0	0
Other	0	0	0	0	0	0
Company op. cashflow	**-6,654**	**-13,293**	**-14,379**	**-18,409**	**-13,138**	**-13,599**
Net interest	16	36	-1,549	-19	27	0
Tax	97	750	0	358	392	665
Operational cashflow	**-6,541**	**-12,507**	**-15,928**	**-18,069**	**-12,720**	**-12,935**
Capital expenditure	-362	-444	-33	-150	-158	-165
Sale of fixed assets	0	2	124	8	0	0
Free cashflow	**-6,903**	**-12,949**	**-15,837**	**-18,211**	**-12,877**	**-13,100**
Dividends	0	0	0	0	0	0
Acquisitions	0	0	-120	0	0	0
Disposals	0	0	30,474	0	0	0
Other investments	0	0	-3,560	0	0	0
CF after investments	**-6,903**	**-12,949**	**10,957**	**-18,211**	**-12,877**	**-13,100**
Share repurchases	0	0	0	0	0	0
Share issues	13,447	9,296	11,066	0	10,000	0
Cash/(debt) acquired	0	-25	-1,975	0	0	0
Change in net debt	**6,544**	**-3,678**	**20,048**	**-18,211**	**-2,877**	**-13,100**
Opening net cash	892	7,436	3,758	23,806	5,595	2,718
Closing net cash	**7,436**	**3,758**	**23,806**	**5,595**	**2,718**	**-10,382**
Hardman FCF/share (p)	-11.3	-16.0	-14.1	-14.3	-8.9	-8.1

Source: Hardman & Co Life Sciences Research

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