

Pharmaceuticals & Biotech



Source: Fidessa

Market data

EPIC/TKR	REDX
Price (p)	52.5
12m High (p)	126.5
12 Low (p)	52.5
Shares (m)	65.0
Mkt Cap (£m)	34.1
EV (£m)	22.4
Free Float* (%)	68%
Market	AIM

*As defined by AIM Rule 26

Description

Redx Pharma is a drug discovery and development company formed in 2010, focused on creating best-in-class new drugs in the areas of cancer, infection, autoimmune and inflammatory disease. The company's work has been endorsed by partnerships with global pharmaceutical companies and the NHS

Company information

CEO	Neil Murray
CFO	Philip Tottey
Chairman	Frank Armstrong

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www.redxpharma.com

Major shareholders

Directors	15.2%
Jon Moulton	16.7%
Axa Framlingto	9.8%
NE VCF	5.3%
WCS Nominees	3.6%

Next event

AGM	24-Feb
Interims	June

Analysts

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Redx Pharma

Pipeline progress – Porcupine inhibitor

Redx is a drug discovery company, offering investors access to a new R&D model; not without risk, but one that is mitigated by the breadth, depth and focus given to its pipeline. It has developed a broad early stage preclinical pipeline focusing on cancer, immunology and anti-infectives, particularly microbial resistance – all “hot” areas of scientific and commercial interest – validated to an extent by six partnerships. Its Porcupine inhibitor has started IND-enabling studies with a view to commencing clinical trials by end 2016 is another example of the rapid progress of its discovery engine, and is likely to command plenty of external interest.

- ▶ **Strategy:** to develop potentially “best-in-class” or “first-in-class” therapeutics by focusing on well validated disease targets in therapeutic areas of significant commercial interest to big pharma/biotech. Redx is also seeking complementary assets and capabilities to accelerate growth and development.
- ▶ **Porcupine (PORC) inhibitor:** a 4th development candidate, recently added to its pipeline and targeting a cell signaling pathway that controls the spread and recurrence of cancer as well as resistance to other treatments, is likely to generate substantial external interest. Potentially a best-in-class PORC inhibitor.
- ▶ **Valuation:** Our standard DCF approach to valuing the business is inappropriate given the preclinical pipeline. Recent industry benchmarks, however, point to the fact that the median price paid by big pharma/biotech for immune-oncology preclinical assets is \$17m per target, with a further \$357m of milestones. Redx has 14 such candidate currently.
- ▶ **Risks:** Clearly not without financial risk: a preclinical pipeline with traditionally high attrition rates and funding needs, but its strategy and breadth of portfolio reduces binary risk seen in single product companies. Also, clear precedent that pharma/biotech are willing to pay high prices for the right preclinical assets.
- ▶ **Investment summary:** Although the shares have drifted below the IPO price, partly with the sector but also as the market awaits evidence of further commercial partnerships, Redx offers the investor access to a highly versatile discovery engine, geared specifically towards clinically differentiating its assets to achieve potentially best-in-class and first-in-class status which in turn should translate into highly valuable assets.

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Porcupine inhibitor is its 4th asset to go into IND-enabling preclinical testing – an area of potential significant external interest

Newsflow is expected to be strong over the next 12 months, excluding the potential for licensing or external collaborations

Look at the value that big pharma & biotech put on preclinical assets in the immune-oncology space – a median upfront of \$17m with \$357m milestones and royalties

Porcupine inhibitor

Redx announced on 3rd December that it has identified a novel patented lead development candidate to be used in hard-to-treat cancers such as pancreatic, triple negative breast and head and neck cancers. This is the fourth candidate to have advanced through the pipeline in the past year. It took the Company less than 24 months to reach this stage from concept, meaningfully quicker than the industry average. The porcupine protein is a key target that is implicated in the maintenance of cancer stem cells in multiple cancer types that lead to the recurrence of tumours after initially successful treatment. The PORC protein within the Wnt pathway has generated substantial external interest given that only Novartis has taken its lead compound (WNT974) into Phase I/II trials. Redx believes this could potentially result in a best-in-class drug, given its improved potency and pharmacokinetic (PK) profile.

News flow and milestones

We anticipate the news flow, subject to technical success, over the next 12 months to be strong, any one of which, if achieved, should generate incremental value. This ignores the potential for partnership or licensing deals for any of its assets, both of which would be expected to have a more material impact on valuation.

Milestones – anticipated during calendar 2016

Target	Description
Oncology	
PORC	Progress through IND-enabling studies and announcement of readiness for first in human studies
IDO	Achieve preclinical PoC
BTK (reversible)	Achieve preclinical PoC
Anti-infective	
Gram +ve (MRSA)	Progress clinical candidate through IND enabling studies
Gram -ve	Achieve preclinical PoC
HBV	Achieve preclinical PoC; identify clinical candidate
Other	Potential for commercial deal flow

Source: Company reports

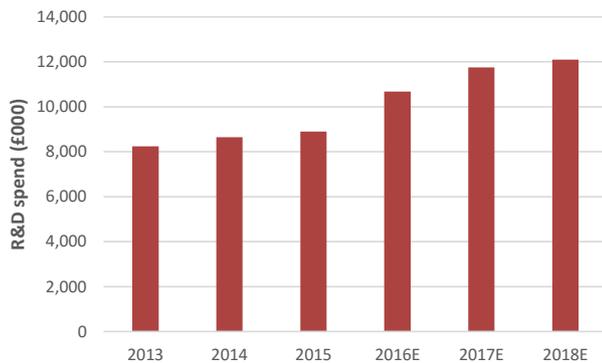
Valuation and investment summary

It's difficult to value a preclinical pipeline. A DCF valuation requires an exhaustive analysis of the market opportunities, penetration rates, potential milestones and royalty payments that a partner might pay. Each programme should then be adjusted for the risk of success – industry benchmarks indicate that this is less than 5%.

However, Redx's approach to developing "best-in-class/first-in-class" assets, targeting markets of significant unmet clinical need, indicative of \$1bn+ sales potential, suggests that these assets will all be attractive to big pharma/biotech companies. The median up-front deal value of preclinical compounds in the immuno-oncology and oncology space is \$17m per target with milestones of up to \$357m. This excludes the acquisition of Flexus Bioscience by BMS for an \$800m upfront cost and potential \$450m of development milestones. It was developing an IDO inhibitor that was completing preclinical testing. A median upfront deal value for Phase I assets of \$40m also demonstrates the incremental value that can be generated should Redx elect to take any of its compounds into first in human studies.

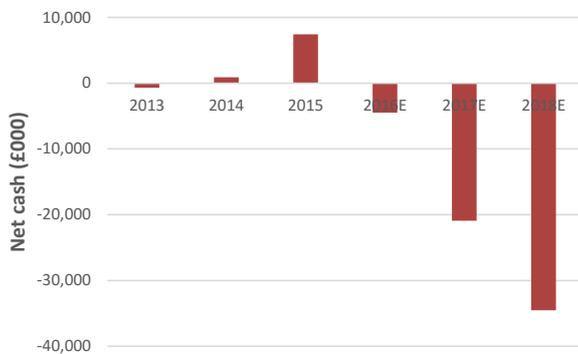
The Company has sufficient cash to fund the ongoing development pipeline to mid-2016 at the current burn rate. Thereafter, it will require additional capital to fund the ongoing programmes. This could come by way of non-dilutive grant funding or exclusive licensing of some of its preclinical assets but, equally, it could raise additional funds through the issue of shares which could be dilutive to shareholders.

Research & Development



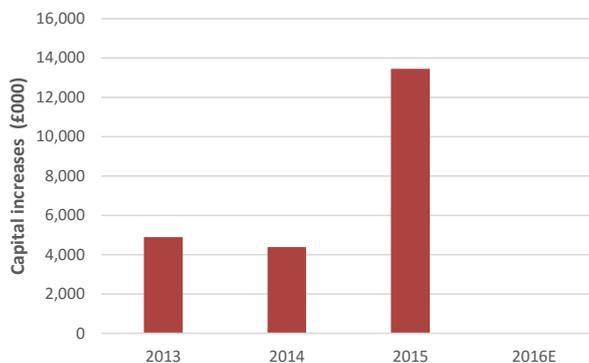
- ▶ R&D costs were running at around £9m per annum in FY15, fully costed, and include £5m of R&D costs (as per Annual Report) as well as c.£4m of £5.4m of staff costs, as reported in 2015 Annual Report
- ▶ R&D costs are forecast to rise to c.£12m in FY18
- ▶ Regional Growth Fund grant funding of £5.9m in April 2012, £4.7m in October 2012 and £4.2m in April 2014 helped fund research & development

Net cash



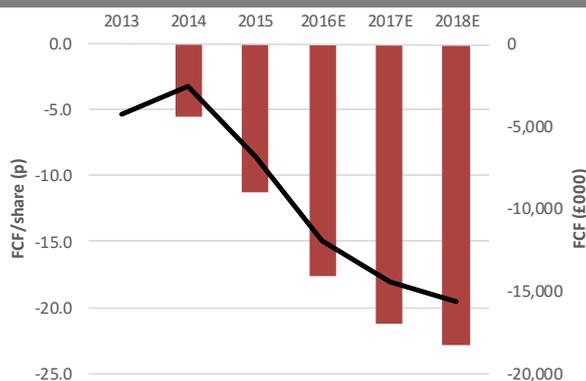
- ▶ Net cash at 30 September 2015 was £7.4m, comprising £9.4m cash and £2.0m of convertible loan with Liverpool City Council
- ▶ Cash position in 2015 bolstered by IPO proceeds of £15m gross (£13.4m net) on 27 March
- ▶ Net cash position reflects largely investment in R&D
- ▶ Excludes any potential cash milestones from potential commercial partners
- ▶ £2.0m convertible loan with Liverpool City Council due to be repaid March 2017 or converts into shares if lender wishes

Capital increases



- ▶ Funded privately up to March 2015
- ▶ IPO proceeds of £15m gross (£13.4m net) in March 2015
- ▶ No assumption of capital increase in 2016 although we forecast a minimum cash requirement of £17m over the next two financial years

Cashflow



- ▶ Free cash outflow increases as programmes continue through developments
- ▶ Reflects cash invested into R&D to support the preclinical programme as well as ongoing administrative overhead, and partially offset by grant income
- ▶ Cash from R&D tax credits expected to be £0.65m in FY16, rising to £0.89m and £1.0m in FY17 and FY18
- ▶ Capital expenditure was £0.5m in 2015 and is expected to rise to c.£0.7m in 2018

Source: Company data; Hardman & Co Life Sciences Research

Redx Pharma

Introduction

Redx Pharma was established in late 2010 with the strategic intent of developing a broad portfolio of high value “best-in-class” or “first-in-class” preclinical therapeutic candidate drugs, targeting well characterised and validated drug targets, that are scientifically and commercially relevant to both big pharma and emerging pharma, both of which are increasingly looking to build and diversify their product pipelines.

Redx’s business model aims to exploit the need of large pharmaceutical companies to broaden and replenish their R&D pipelines to help offset slowing revenue growth and the impact that patent expiries have and will continue to have on bottom line margins. Most large cap pharma competencies are recognised to be in late stage development and in market distribution/marketing of products.

- ▶ Large cap pharma - licence products from smaller drug companies that can undertake the early stage activities more effectively and efficiently than the large and often cumbersome apparatus of big pharma. This is illustrated by the collaboration with AstraZeneca who approached Redx to develop a novel drug against an undisclosed oncology target. In the past year we have also seen several deals in which pharma have used biotech companies to develop their own clinical assets potentially more cost effectively than they can; eg. Novartis/Mereo Biopharma and Lilly/Ignyta.
- ▶ Emerging pharma – looking to broaden and diversify pipelines and, thereby, reduce binary risk profile that is typically seen in companies which, historically, have focused on the research and development of one or two products.

Redx offers the investor access to a highly versatile discovery engine geared specifically towards clinical differentiation with a workforce as of January 2016 of 190 supporting 170 chemists, biologists and analytical support staff.

Strategy

Redx has a clearly defined strategy to:

- ▶ Develop a broad early stage pipeline of products, currently focused on three therapeutic areas (cancer, immunology, infectious disease) in clinical indications where there is a high unmet medical need and with limited competition.
- ▶ Create “best-in-class” or “first-in-class” therapeutics by focusing on well validated disease targets where the biology is understood and where clinical or preclinical validation has already been demonstrated.
- ▶ Build an internal scientific capability in so called “hot” areas where high levels of commercial interest are being shown by big pharma, eg oncology and cancer stem cells, and multi-drug resistant bacteria. This also increases the prospect of developing “first-in-class” drugs, with even greater potential economic value.
- ▶ Commercialise its pharmaceutical assets via out-licensing, strategic alliances and co-developments either at the preclinical stage or, on a case by case basis, in early clinical phases if Redx sees the opportunity to generate further incremental value for shareholders without taking on undue financial risk.
- ▶ Seek complementary assets and capabilities to accelerate growth and development.

To achieve these strategic goals, Redx has:

- ▶ Established a high-quality scientific team with a track record of creating novel drug candidates
- ▶ Focused on delivering drug candidates faster and more cost-effectively than its peer group. For example, Redx recently announced that it had identified a lead compound against PORC in less than 2 years
- ▶ Built a broad-based pipeline of assets in pharmacologically attractive areas of cancer, infection and immunology

To ensure that the development activities remain focused, Redx has five core criteria for undertaking a development programme, namely:

- ▶ Scientifically validated target – minimises biological risk. For example the Porcupine target has been validated preclinically by Novartis with some hints also of efficacy in Phase I trials
- ▶ Differentiable – in the case of PORC, Redx believe its compound is more potent with a more attractive pharmacokinetic (PK) profile, preclinically, than Novartis' WNT974 in Phase II trials
- ▶ Fits with Redx's capabilities in biology and chemistry, eg cancer stem cell targets
- ▶ Limited competition, for example, only Novartis has a PORC inhibitor in Phase I/II clinical trials (A*STAR and Duke University have announced their intention to take a product into the clinic), therefore making this programme attractive either for Redx to undertake additional development work or to partner
- ▶ Commercially attractive markets with high unmet medical need cancers such as pancreatic or Head & Neck

Redx also reserves the option to take selected preclinical assets into the clinic thereby retaining potentially greater economic value. In some instances this might arise because there is a clear and obviously defined route into the clinic. In others it might simply be because the pharma companies will want to see human data before committing to the larger development costs associated with Phase II/III clinical trials, for example its Gram +ve/MRSA multi-drug resistant antibacterial (RDX003) or the SMO inhibitor (RDX001) for cancer indications.

To that extent the following table outlines what a typical deal structure could look like if licensed at the early preclinical stage (eg. hit to lead). Clearly the amounts are dependent on where within the development process one partners but it does serve as a guide that the pharma/biotech industry is familiar with. We would anticipate the PORC inhibitor to generate a larger upfront payment than indicated in the table below, given the commercial interest in this field, if Redx were to licence now.

Theoretical example of early preclinical deal structure		
Milestone	Potential payment (£m)	Sequential timing (mths)
Upfront	0-5	
Lead optimisation development decision	2-3	18 – 24
Candidate selection	1 – 2	6 – 9
First in man (Phase I/IIa)	2 – 5	9 – 15
Clinical milestones (Phase II/III)	10 – 50	24 – 60
Launch milestones (key territories; US, EU)	25 – 40	12 – 24
Commercial milestones	20 – 50	12 – 48
Tiered royalties on sales	2 – 10%	

Source: Redx Pharma

This following list of collaborations provides a degree of external validation for Redx's approach.

Collaborations		
Company	Area	Description
AstraZeneca	Oncology	A 3-year research collaboration and option agreement against an undisclosed oncology target. Significant potential future income in respect of R&D, licence fees, clinical and commercial milestones and single digit, tiered royalties on commercial sales if option is exercised in 2016.
NHS	Anti-infective	A £5.6m fully funded route to clinical proof of concept (PoC) in NHS facilities for Gram +ve antibacterial against MRSA. Redx will license to pharma companies for late stage clinical development and commercialisation.
Pierre Fabre	Oncology	Part funded (90%) PoC for oral and topical applications for skin cancer program.
IMI	Anti-infective	Fully funded option for Gram -ve antibacterial to take to clinical PoC. Non-exclusive option to commercialise via pharma consortium on licence terms to be negotiated in due course.
NIH	Anti-infective	Cost-coverage collaboration including <i>in vivo</i> studies with option to extend to initial clinical trials for flu product.
Horizon Discovery	Oncology	Funded collaboration to determine molecular mode of action for Redx's pan-RAF program in bowel cancer.

Source: Redx Pharma

Oncology pipeline

Redx has developed a portfolio of small molecule inhibitors to receptors/targets that are of significant commercial and scientific relevance. These include SMO, cFMS, BTK, PORC and pan-raf inhibitors, three of which have reached candidate nomination stage (SMO, BTK and PORC).

Oncology pipeline	
Programme	Description
SMO inhibitor (RDX001)	Implicated in skin, brain and blood cancer. Achieved preclinical proof of concept (POC). Candidate topical drug identified with focus on Basal Cell Carcinoma (BCC)
Porcupine (PORC) inhibitor (RDX004)	Implicated in breast, pancreatic and head and neck cancers. Achieved preclinical POC and development candidate drug identified
BTK (reversible) inhibitor	Broad therapeutic opportunities in blood cancer as well as lupus and Sjogren's syndrome. Irreversible BTK inhibitor achieved preclinical POC and development candidate identified. Yet to demonstrate PoC with reversible BTK
cFMS inhibitor	Bone metastasis in breast and prostate cancer. Achieved preclinical POC. Immune-oncology is a major focus
IDO inhibitor	Implicated in solid tumours such as skin and lung cancer
Pan-raf inhibitor	Implications in colorectal cancer

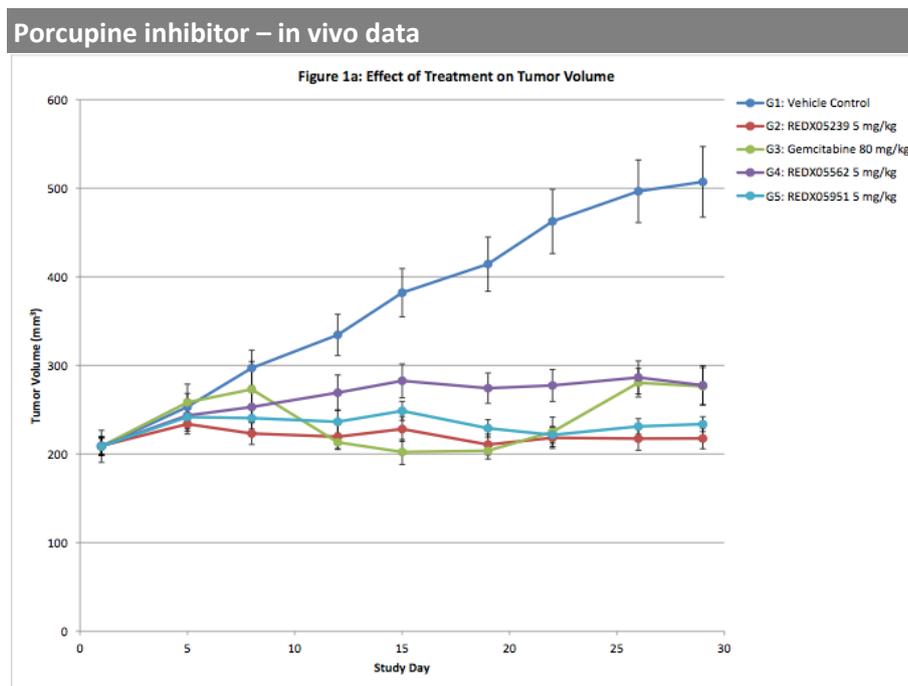
Source: Company reports

Immuno-oncology (I-O) focuses on developing products that stop the cancer from evading the immune system's innate and acquired ability to recognise and destroy cancer cells.

Porcupine (PORC) Inhibitor – RDX004

Redx announced on 3rd December that it has identified a novel patented lead development candidate to treat hard-to-treat cancers such as pancreatic, triple negative breast (doesn't respond to oestrogen, progesterone or HER2 therapies) and head and neck cancers. The PORC protein is a key target within the Wnt pathway which has generated substantial commercial interest with Novartis having taken its lead compound (WNT974) into Phase I/II clinical trials.

- ▶ The porcupine protein is a key target within the Wnt pathway, an embryonic signalling pathway that is implicated in the maintenance of cancer stem cells (CSC) in many cancer types that lead to the recurrence of tumours after initially successful treatment as well as the resistance of tumours to potential cancer therapies. The target is also believed to have an emerging role in the field of immuno-oncology with the potential to be combined with checkpoint inhibitors. There is strong evidence that the Wnt pathway is also involved in immunity and Redx is assessing whether RDX004 can also stimulate the immune system to tackle the cancer, whilst at the same time destroying any remaining CSCs.
- ▶ The improved potency and oral once-daily dosing regimen, could potentially result in a best-in-class drug.
- ▶ *In vivo* proof of concept has been achieved in only 14 months. Its efficacy was achieved in a pancreatic cancer xenograft model (see below).



Source: Redx Pharma

- ▶ Final development work (IND enabling studies) will take place during 2016 before commencing Phase I/II first-in-man trials.

Only Novartis has a PORC inhibitor (WN974) currently in clinical development (Phase I/II) although A*STAR and Duke University have also announced their intention to evaluate ETC-159 in a Phase I study, making the commercial potential for this new development candidate attractive to other oncology companies, particularly as it has the potential for combination with checkpoint inhibitors which a number of oncology companies already have access to.

BTK Reversible Inhibitor

Bruton's tyrosine kinase (BTK) is an important kinase enzyme in the B-cell antigen receptor (BCR) signalling pathway, implicated in major market areas such as Chronic Lymphocytic Leukaemia (CLL), Diffuse Large B Cell Lymphoma (DLBCL).

- ▶ Development of a patented reversible inhibitor in haematological cancers with the aim of reducing adverse events seen with irreversible BTK inhibitors, eg. Imbruvica/ibrutinib, as well as activity against ibrutinib-resistant mutations
- ▶ Potent and highly selective molecule with no interaction with other signalling pathways (eg. EGFR, ITK and /or Lck)
- ▶ Lead compound selected with lead optimisation ongoing
- ▶ *In vivo* proof of concept studies are planned for early 2016

Imbruvica (ibrutinib) is the first in class BTK inhibitor, approved by the FDA in 2013 for use in four indications to treat three different types of blood cancers. Imbruvica was central to AbbVie's decision in March 2015 to acquire Pharmacyclics in a transaction valued at \$21bn. Imbruvica reported revenues of \$548m in 2014 (first full year) out of group sales of \$730m (\$260m in 2013); illustrating what big pharma is prepared to pay for the right assets.

Acerta Pharma is developing a second generation irreversible BTK inhibitor, acalabrutinib, in multiple haematologic malignancies and solid tumours, as well as rheumatoid arthritis. Although only just entering Phase III trials, having recently published Phase I/II data showing a 95% response rate in relapsed CLL, AstraZeneca purchased a 55% stake in the company for \$2.5bn, with a put/call option for the balance implying a cost of c.\$3.0bn as well as the payment of a \$1.5bn milestone, conditional on approval. AstraZeneca stated that it considers acalabrutinib to be able to generate sales of as much as \$5bn.

SMO Hedgehog Inhibitor – RDX001

Smoothed (SMO) is a protein within the Hedgehog signalling pathway implicated in the tumorigenesis of several cancers. Redx is developing a SMO inhibitor as a topical treatment for the most common skin cancer, Basal Cell Carcinoma (BCC), which afflicts more than 2.5m people annually in the US alone. This is unlike all first generation oral SMO inhibitors which are only targeted at advanced and metastatic BCC and are typically associated with loss of taste, muscle wasting and hair loss. Given this profile, it is likely that potential licensees will want to see human data.

- ▶ Novel potent SMO inhibitors developed, suitable for topical delivery
- ▶ *In vivo* efficacy achieved in mouse allograft model with no safety issues observed
- ▶ A development compound has been selected

IDO Inhibitor

Indoleamine 2,3-dioxygenase (IDO) is an immune-oncology target implicated in a range of solid cancers such as skin and lung cancer.

- ▶ Potent small molecule highly selective inhibitors to both IDO and TDO (tryptophan dioxygenase) as well as dual IDO/FDO inhibitors
- ▶ Potential to combine with other immune modulators such as checkpoint inhibitors (anti PD-1) and targeted chemotherapeutics

- ▶ Lead identification is ongoing
- ▶ *In vivo* pharmacokinetic (PK) and pharmacodynamic (PD) studies are due to commence shortly

IDO is considered a “hot target” with a high level of interest being expressed within the pharmaceutical industry. This is best exemplified by Bristol-Myers Squibb’s acquisition of Flexus Biosciences in February 2015 for up to \$1.25bn (\$800m up front with up to \$450m in development milestones) whose lead preclinical small molecule IDO1-inhibitor was being targeted for IND filing in 2H 2015. There are a number of leading oncology companies that do not yet have exclusive access (others have a non-exclusive tie up with Incyte to use in combination) to an IDO inhibitor (eg. Novartis, Lilly, AstraZeneca) either to be used alone or in combination.

cFMS Inhibitor (Colony Stimulating Factor-1 receptor – CSF-1)

cFMS is an immune-oncology target implicated in Triple negative breast cancer with associated bone metastases, glioblastoma and pancreatic cancer (PDAC). Immune modulation, as part of a combination, is a validated strategy in oncology. For example, Merck is trialling Plexxikon’s CSF-1 inhibitor with its anti-PD1 therapy (Keytruda), potentially providing double blockade of cancer-induced suppression.

- ▶ Potent small molecule inhibitors with unique specificity profile
- ▶ *In vivo* POC data achieved in bone erosion model in rats with lead series
- ▶ Lead optimisation is ongoing to select development candidate which can be progressed towards clinical trials

Anti-infectives pipeline

Redx’s pipeline is made up of antibacterial and anti-viral programmes. In the former the Company is focused on developing compounds that are effective against multi-drug resistant (MDR) bacteria. Given the concerns expressed by the WHO, Lord Jim O’Neill etc on the impact of anti-microbial resistance (AMR), governments and/or big pharma are expected to re-enter this field.

Anti-infectives pipeline	
Programme	Description
Gram +ve/MRSA – RDX003	Development of novel chemotypes that target enzymes implicated in DNA replication for treatment of MRSA skin and soft tissue infections. Fully funded to clinical proof of concept with £5.6m from NHS. Achieved Pre Clinical Proof of Concept
Hepatitis B	Novel small molecule Toll like receptor 7 (TLR7) agonists for the treatment of chronic Hepatitis B Virus infection
Gram –ve (MDR)	Two development programmes targeting ESKAPE (Klebsiella, Acinetobacter, Pseudomonas, Enterobacteriaceae) pathogens with potential in urinary tract and intra-abdominal infections, pneumonia, cystic fibrosis and complicated skin and soft tissue infections. One of these is funded by IMI (the European Innovative Medicines Initiative) consortium (with GSK) with the programme being part funded to clinical proof of concept
Influenza	Novel small molecule inhibitors of neuraminidase for the treatment and prophylaxis of infections caused by influenza A and B viruses, including drug resistant strains. Opportunities in pandemic and seasonal Influenza
Novel anti-infective targets	Novel approaches to Gram -ve bacterial infections

Source: Redx Pharma

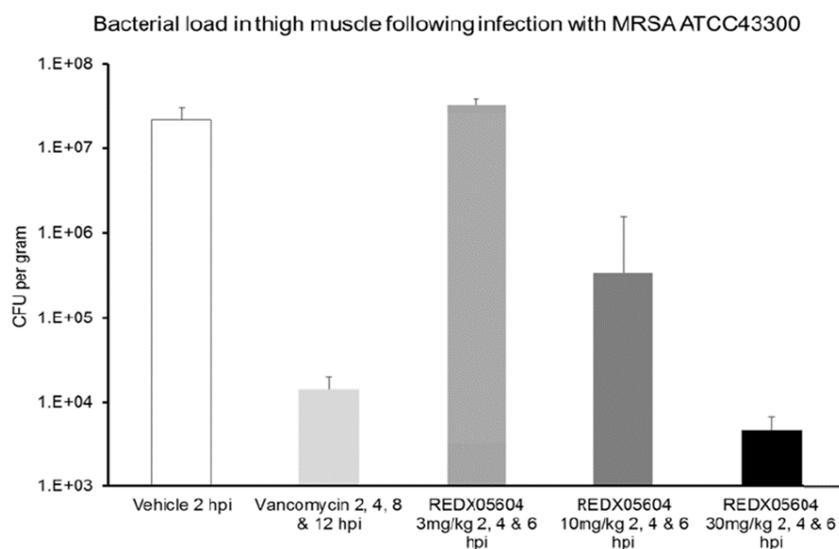
Redx is working on both Gram +ve (eg. Staphylococcus and Streptococcus) and Gram -ve (eg. Pseudomonas, E. coli and Klebsiella) targets with the potential to develop novel chemical classes of antibiotics. Redx also has anti-viral programmes against Hepatitis B and Influenza.

Gram +ve/MRSA – RDX003

Redx has developed a series of bacterial DNA gyrase and topoisomerase IV inhibitors which are quite distinct from the quinolone class of anti-bacterials. In collaboration with the Royal Liverpool and Broadgreen University Hospital, this programme is fully funded through until Phase I/II human trials are completed. Redx is able to license this asset at any time, although, in our opinion, will most likely do so on completion of this study.

- ▶ A dual targeting mechanism of action
- ▶ *In vivo* efficacy achieved in a rat model assessing the impact of its compound compared with Vancomycin in reducing bacterial load in the thigh muscle following infection with MRSA (see below). Whereas Vancomycin is dosed 4x (440mg), RDX003 is a lower dose (90mg) and administered orally 3x daily
- ▶ Shown strong potency against MDR gonorrhoea. Whilst a small commercial market, it does offer a relatively short route to human proof of concept.
- ▶ Phase I trials in humans are due to commence in 2017

Gram +ve (MRSA) – in vivo data



Source: Redx Pharma

Hepatitis B

Redx is developing two chemically distinct series of orally bioavailable immune modulating TLR7 agonists for treatment of chronic Hepatitis B viral (HBV) infection, with the aim of achieving complete viral clearance. There are an estimated 350m+ people worldwide thought to be chronically infected with HBV which is associated with a high incidence of liver cirrhosis and liver cancer, causing an estimated 0.6-1.0m deaths annually. Key therapies include the PEGylated interferons (PEG-IFN- α) and nucleoside inhibitors. Not only are these associated with poor responses and/or systemic side effects but there is increasing evidence of resistance developing.

Key points of note are:

- ▶ Augmentation of the host's immune response is a novel and promising approach for the treatment of chronic hepatitis B
- ▶ TLR7 plays a role in inducing the innate immunity in response to viral infection
- ▶ Selective agonism of TLR7 leads to the induction of IFN- α and other antiviral cytokines, with limited production of inflammatory cytokines, such as TNF- α , which have been shown to be produced by off target TLR agonism and a likely unacceptable safety profile
- ▶ Selective oral TLR7 agonists which are rapidly metabolised are expected to result in maximal activity at the target site (liver) and offer a safe alternative to current mainstay therapies
- ▶ Both series are more selective for antiviral versus pro-inflammatory cytokines
- ▶ *In vivo* POC studies are planned for 1H 2016

Gram –ve

Redx has two development programmes targeting ESKAPE (Klebsiella, Acinetobacter, Pseudomonas, Enterobacteriaceae) pathogens, which are chemically distinct from the quinolone class of antibiotics. Key points of note are:

- ▶ Broad and narrow spectrum of activity with no significant cross resistance with quinolone-resistant strains
- ▶ Lead optimisation underway
- ▶ *In vivo* POC models planned for Q2 2016

Participants of the IMI consortium, led by GlaxoSmithKline and Sanofi, retain full rights to partner these assets at any stage. Unlike the Gram +ve programme which is more likely to require human POC data (fully funded already by the NHS), there is a greater likelihood of an earlier licensing deal given the profile of these compounds and the greater medical need for compounds that are effective against ESKAPE pathogens.

Immunology pipeline

Redx Immunology was only formed in May 2015 targeted with developing up to 8 new drug development candidates in the next 1-3 years for inflammatory disorders in immunology. Its first candidate product is a spinoff from its oncology BTK programme as BTK is also implicated in autoimmune diseases.

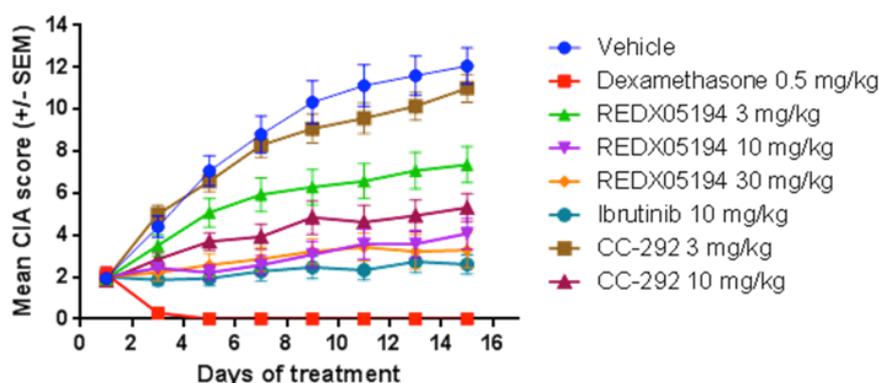
BTK Irreversible Inhibitor – RDX002

Redx has developed an irreversible BTK inhibitor (RDX002) for autoimmune diseases such as lupus and Sjogren's syndrome.

- ▶ Redx believes it has a best-in-class potency without the side effects of ibrutinib or Celgene's CC-292 (Phase II trials). Acerta Pharma is also developing acalabrutinib (irreversible BTK inhibitor) in RA which reported manageable Grade 1-2 toxicities in a Phase I/II trial CLL study

- ▶ *In vivo* data has shown similar activity to ibrutinib and improved activity over Celgene’s CC-292, which is currently in Phase II trials for RA.¹ Animal studies show a clear reduction in inflammation and cartilage damage upon treatment with REDX05194

BTK irreversible inhibitor – in vivo data



Source: Redx Pharma

Expected milestones

The following milestones are expected over the next 12 months.

Milestones – anticipated during calendar 2016

Target	Description
Oncology	
PORC	Progress through IND-enabling studies and announcement of readiness for first in human studies
IDO	Achieve preclinical PoC
BTK (reversible)	Achieve preclinical PoC
Anti-infective	
Gram +ve (MRSA)	Progress clinical candidate through IND enabling studies
Gram -ve	Achieve preclinical PoC
HBV	Achieve preclinical PoC; identify clinical candidate
Other	
	Potential for commercial deal flow

Source: Company reports

Valuation

Discounted cashflow

The best approach to valuing biopharmaceutical companies is to prepare detailed discounted cashflow analyses of key products through to patent expiry and then to risk-adjust the NPV based upon industry standards for the probability of the product reaching the market. In this instance the assets are at too early a stage to do a DCF valuation without exhaustive analysis of the market opportunities, penetration rates and potential milestones and royalty payments. Equally the probabilities of successfully reaching the market for preclinical assets is typically less than 5%.

¹ <https://clinicaltrials.gov/ct2/show/NCT01975610>

Suffice to say, Redx's approach to developing "best-in-class" assets targeting markets of significant unmet clinical need, indicative of \$1bn+ sales potential, suggests that these assets will all be attractive to big pharma and or biotech companies. To that extent it is probably more relevant to look at what large pharma is prepared to pay to gain access to such molecules.

Comparative valuation – M&A

The following table provides some indication of the value that big pharma and biotech put on novel assets even in early stages of preclinical development, including screening, discovery, lead optimisation, toxicology and IND enabling studies. It is not exhaustive but looks at the transactions where financial terms were disclosed. There are many more deals where financial terms were not disclosed at all. We have also looked at a number of transactions where the assets were in clinical development to better illustrate the value inflections points on successful completion of preclinical phases and demonstration of safety in first-in-man studies.

- ▶ The median up-front license deal value of preclinical compounds in the Immuno-Oncology and oncology space is \$17m per target compound with milestones of up to \$357m
- ▶ This excludes the acquisition of Flexus Bioscience by BMS for an \$800m upfront payments and potential \$450m development milestones. It was developing an IDO inhibitor that was completing preclinical testing
- ▶ A median deal value for Phase I assets of \$40m

Deal comparators – Pharmaceutical assets

Licensor	Licensee	Type of deal	Stage of Development	Date	Upfront (\$m)	Milestones (\$m)	Milestones
Merck & Co	Iomet Pharma	Acquisition	Preclinical	Jan-16	Undisclosed	400	\$400m acquisition
Novera Therapeutics	Janssen	Collaboration, License option, License agreement	Discovery	Sep-15	Undisclosed	344.5	\$344.5m in dev/reg & sales milestones
Gencia	Takeda	License	Discovery	Sep-15	Undisclosed	500	\$500m in dev/reg and sales milestones
Xencor	Amgen	License	Discovery	Sep-15	45	1700	\$1.7bn in clinical, regulatory and sales milestones
Jiangsu Hengrui	Incyte	License	Discovery	Sep-15	25	770	\$770m (\$90m regulatory; \$150m development; \$530m commercial)
Heptares	AstraZeneca	License	Preclinical	Aug-15	10	500	\$500m in dev/reg and sales milestones, plus double digit royalties
Inhibrx	FivePrime Therapeutics	License, Option	Preclinical: Lead selection	Jul-15	10	380	up to \$380m
Sprint Biosciences	Bayer	License	Preclinical	Jul-15	Undisclosed	Undisclosed	Undisclosed milestone payments
Globavir	Sorrento Therapeutics	License	Preclinical	Jul-15	No upfront	80	\$80m in dev/reg and sales milestones, plus royalties
Almac Discovery	Genentech	License	Preclinical	Jun-15	14.5	349	\$349m in dev/reg & sales milestones, plus royalties
Curadev	Roche	License, Collaboration	Preclinical	Apr-15	25	530	\$530m in dev/reg & sales milestones, plus tiered DD royalties
Checkpoint Therapeutics	TG Therapeutics	Collaboration, License	Preclinical	Mar-15	0.5	164	\$164m in development and sales based milestones, plus tiered single digit royalties
NeuPharma	Coronado Biosciences	License	Preclinical	Mar-15	1		Undisclosed dev/reg and sales milestones, plus tiered single digit royalties
Sorrento Therapeutics	NantWorks	License	Discovery	Mar-15	10	100	\$100m in milestone payments, 5% royalties
Flexus Biosciences	BMS	Acquisition	Preclinical: IND	Feb-15	800	450	\$450m. Just IDO/ TDO acquired
Aurigene	Curis	License	Preclinical	Jan-15	Undisclosed	52.5	\$52.5m/ programme
iTeos	Pfizer	License	Preclinical: Lead op	Dec-14	30	Undisclosed	Undisclosed
Mars Symbioscience	Calithera	License	Preclinical	Dec-14	Undisclosed	24.7	\$24.7m in dev/reg milestones
Aduro BioTech	J&J	License	Discovery	Oct-14	30	817	\$817m
Aduro BioTech	J&J	License	Discovery	May-14	Undisclosed	365	\$365m in upfront and milestones
Anaptybio	Tesaro	License	Preclinical: Lead op	Mar-14	17	108	\$18m (R&D), \$90m (reg., submissions & approvals). Undisclosed sales
Five Prime Therapeutics	BMS	License	Preclinical: Discovery	Mar-14	41	300	\$300m per target
Aurigene	Pierre Fabre	License	Preclinical: Clin cand	Feb-14	Undisclosed	Undisclosed	Not disclosed
Collectis	Servier	License	Preclinical	Feb-14	10	140	\$140m for each of 6 products developed
Ablynx	Merck	License	Preclinical: Discovery	Feb-14	27	2300	€1.7bn (\$2.3bn) for all targets
CoStim Pharmaceuticals	Novartis	Acquisition	Preclinical: Lead Op	Feb-14	Undisclosed	Undisclosed	Contingent milestones
Immunocore	MedImmune	License	Preclin: Screening	Jan-14	20	300	\$300m per target
immatics	Roche	License	Preclin: IND	Nov-13	17	1000	\$1000m (includes research funding)
Compugen	Bayer	License	Preclin: Screening	Aug-13	10	530	\$530m (Preclin: \$30m; Clin/ comm: \$500m)
Immunocore	GSK	License	Preclin: Lead op	Jul-13	Undisclosed	513	Preclin: £142m (\$213m) across all targets. Clin/comm: £200m for each product
Immunocore	Genentech	License	Preclin: Screening	Jun-13	10	300	\$300m+ per target
Beigene	Merck Serono	License	Preclinical	May-13	Undisclosed	233	\$233m dev/reg milestones for China and RoW
MDA	GSK	License	Preclinical	Dec-12	Undisclosed	335	\$335m
ImmunNext	J&J	License	Preclin: Screening	Sep-12	Undisclosed	150	\$150m: Upfront & milestones
MannKind Corporation	Tolero Pharmaceuticals	License	Preclinical	Apr-12	Undisclosed	Undisclosed	Undisclosed, plus royalties and a percentage of sublicensing revenue
AgonOx	MedImmune	License	Preclinical	Oct-11	Undisclosed	Undisclosed	Undisclosed
Applimmune	GSK	License	Preclin: Clinical cand.	Aug-10	23	485	\$485m: Regulatory, development and sales
				Average	56.0	474.0	
				Median	17.0	357.0	

Cancer Immunotherapy Deals

Licensor	Licensee	Type of deal	Stage of Development	Date	Upfront (\$m)	Milestones (\$m)	Milestones
Five Prime Therapeutics	BMS	License	Phase 1	Oct-16	350	1,390	\$1390m (up to \$1.05bn and \$340m in dev/reg milestone payments per anti-CSF1R product for oncology and non-oncology indications respectively)
Alligator Bioscience	Janssen	License	Phase 1	Aug-15	Undisclosed	700	\$700m deal size including upfront payments, dev/reg & sales milestones, plus royalties
Newlink Genetics	Genentech	License	Phase 1	Oct-15	150	1,000	>\$1bn. US co-promote option
CureVac	Boehringer Ingelheim	License	Phase 1	Sep-14	45	556	€430m (\$556m)
Adaptimmune	GSK	License	Phase 1	Jun-14	Undisclosed		Undisclosed
Macrogenics	Servier	License option	Phase 1	Dec-11	20	40	\$40m: Exercise fee and early dev. Received \$10m for start of Phase 1 dose expansion in 8/13
Innate	BMS	License	Phase 1	Jul-11	35	430	\$430m
				Average	120.0	686.0	
				Median	45.0	628.0	

Source: Company reports; Hardman & Co Life Sciences Research

Financials & Investment case

Profit & Loss

The financial statements of Redx are fairly straight-forward and dominated by three figures. First, the amount of cash being invested into R&D to support the preclinical trial programme and, secondly, the ongoing SG&A costs to execute on the company's strategy and thirdly, other income which is related to grant income supporting the three therapeutic businesses. These, in turn, drive the cashflow and determine the point at which management needs to raise more capital. The Group has to date been funded through a mixture of equity funding, RGF grant funding and a working capital loan from Liverpool City Council in 2012.

Sales

We have not assumed any sales from product revenues, given the early stage of development, nor any milestone payments or licensing fees from potential licensors.

Research & Development

Research & Development costs are our estimates of the true cost of undertaking its R&D which include staffing costs (estimated to be c.£4m of the £5.4m staff costs reported for FY15) as well as costs associated with the purchase of consumables and services (£5m in FY 15). In 2013, following the receipt of grant funding to establish Redx Oncology, expenditure on R&D accelerated from £3.0m to £8.2m as the Company invested in rapidly building its science base, increasing the number of employees from 42 to 145, with c.95 of the 103 being science-based. R&D staff costs, as outlined in the admission document, rose from £2.0m in 2012 to £3.7m in 2013. This has continued to rise to the extent that the Redx now employs 170 scientists (85 chemists/55 biologists and 30 analytical and science support). As a consequence R&D expenses were c.£8.9m in FY 2015 (of which staff costs were £5m – annual report) and are estimated to rise to £11.7m in FY17.

SG&A expenses

SG&A costs are our estimates. Historically they reflect the difference between our R&D forecasts and the total operating expenses as reported by the Company. .Again, with the increased grant funding, the company was able to strengthen its executive and operational management team in 2013. These costs rose further in 2015 (up c.70%) to reflect the additional Plc costs post IPO in March 2015. Looking to the future we are forecasting a 15% in FY16 to reflect full year Plc costs and 3-5% in FY17 and FY18.

Other Income

Other income relates to the grant income as well as milestone payments on the Gram +ve/MRSA programme. To date, Redx has generated c.£5.0m of commercial revenue which funded the running costs of the NHS MRSA program. Redx has received three grants from the Department for Business Innovation and Skills (BIS) through RGF grant funding in the form of industrial research grants under European state aid exemptions:

- ▶ In April 2012, £5.9m under RGF2 for Redx Oncology
- ▶ In October 2012, £4.7m under RGF3 for Redx Anti-infectives

- ▶ In April 2014, £4.2m under RGF4 for Redx Immunology. To date, only a small proportion of this income has been received so far. This grant runs to March 2017

Profitability

We do not forecast that Redx becomes profitable as we do not have visibility to the timing of any licensing agreements and/or the scale of up-front payments and milestones that would likely be made by the licensor.

R&D tax credits

Redx undertakes qualifying R&D activities in the UK that qualify for tax credits from the UK government. As the company makes increased investment in R&D, so the tax credits, payable in arrears, will increase. For FY15 this was £890k. For FY2016 and 2017, the tax credits are calculated to be c.£1m and £1.2m, respectively. Where R&D tax credits are not receivable due to grant support i.e. both R&D tax credits and RGF grant are seen as state aid and therefore cannot “double fund”, Redx is eligible for R&D expenditure credit (RDEC).

Profit & Loss account						
Year end Sep (£000)	2013	2014	2015	2016E	2017E	2018E
Sales	0	0	0	0	0	0
SG&A	-1,340	-1,509	-2,571	-2,957	-3,104	-3,198
R&D	-8,246	-8,648	-8,900	-10,680	-11,748	-12,100
Deprec & Amortis	-239	-252	-139	-300	-500	-500
Licensing/Royalties	0	0	0	0	0	0
Other income	6,396	6,157	2,648	2,100	800	0
Underlying EBIT	-3,190	-4,000	-8,823	-11,837	-14,552	-15,798
Share based costs	-138	-14	-608	-618	-638	-658
Exceptional items	0	0	895	0	0	0
Statutory Operating profit	-3,328	-4,014	-8,536	-12,455	-15,190	-16,456
Net financial income	-253	-249	-289	-212	-464	-700
Pre-tax profit	-3,443	-4,249	-9,112	-12,049	-15,016	-16,498
Exceptional items	0	0	0	0	0	0
Reported pre-tax	-3,581	-4,263	-8,825	-12,667	-15,654	-17,156
Reported taxation	389	910	650	890	1,068	1,175
Underlying net income	-3,054	-3,339	-8,462	-11,159	-13,948	-15,324
Statutory net income	-3,192	-3,353	-8,175	-11,777	-14,586	-15,982
Period-end shares (m)	n/a	47	65	65	65	65.0
Weighted average shares (m)	n/a	44	58	65	65	65.0
Fully diluted shares (m)	n/a	44	58	65	65	65.0
Underlying Basic EPS (p)	n/a	-7.5	-14.6	-17.2	-21.5	-23.58
U/I Fully-diluted EPS (p)	n/a	-7.5	-14.6	-17.2	-21.5	-23.58
Statutory Basic EPS (p)	n/a	-7.6	-14.1	-18.1	-22.4	-24.59
Stat. Fully-diluted EPS (p)	n/a	-7.6	-14.1	-18.1	-22.4	-24.59
DPS (p)	0.0	0.0	0.0	0.0	0.0	0.0

Source: Company reports; Hardman & Co Life Sciences Research

Balance sheet

- ▶ Redx ended FY2015 with net cash of £7.4m, comprising cash and cash equivalents of £9.4m and a £2m convertible loan agreed with Liverpool City Council (12% pa interest; repayable in March 2017 or convertible into shares)
- ▶ We assume Liverpool City Council loan is repaid in March 17, in which case the accrued interest (c.£1.3m) will also be repaid. Accrued interest to March 2015 was £0.792m and is included in other payables
- ▶ Cash position was bolstered by IPO proceeds of £15m (£13.4m net) on 27 March 2015. Our forecasts for 30 September 2016 assume a cash deficit of £2.5m
- ▶ Our forecasts assume that Redx continues to invest behind its pipeline
- ▶ To continue funding R&D investment at current levels further capital will be required. This could come either from licensing agreement, collaborative deals with equity component and/or an equity placing by the company

Balance sheet						
at 30th Sep (£'000)	2013	2014	2015	2016E	2017E	2018E
Property, plant & equipment	328	130	353	553	678	897
Intangible assets	309	309	309	309	309	309
Other receivables	-	-	750	750	750	750
Total non-current assets	637	439	1,412	1,612	1,737	1,956
Inventories	-	-	-	-	-	-
Trade receivables	-	-	21	22	23	24
Other receivables	3,582	2,597	1,386	1,386	1,386	1,386
Cash and cash equivalents	1,028	2,892	9,436	(2,484)	(20,200)	(35,829)
Current tax	389	948	1,501	2,391	3,459	4,634
Total current assets	4,999	6,437	12,344	1,315	(15,332)	(29,785)
Assets held for sale	-	183	-	-	-	-
Total assets	5,636	7,059	13,756	2,927	(13,595)	(27,829)
Liabilities						
Trade payables	1,443	1,151	1,601	1,281	1,089	1,110
Other payables	1,417	1,926	2,455	3,105	2,723	3,791
Borrowings	2,000	2,000	-	-	-	-
Total current liabilities	4,860	5,077	4,056	4,386	3,812	4,901
Liabilities (items held for sale)	-	162	-	-	-	-
Net current assets	139	1,360	8,288	(3,071)	(19,144)	(34,686)
Borrowings	-	-	2,000	2,000	-	-
Total liabilities	4,860	5,239	6,056	6,386	3,812	4,901
Net (liabilities)/assets	776	1,820	7,700	(3,459)	(17,407)	(32,731)
Share capital	6	7	650	650	650	650
Share premium	7,931	12,313	13,516	13,516	13,516	13,516
Share based compensation	138	152	622	1,240	1,878	2,536
Capital redemption reserve	-	-	1	1	1	1
Retained deficit	(7,299)	(10,652)	(7,089)	(18,866)	(33,452)	(49,434)
(Deficit)/equity attributable	776	1,820	7,700	(3,459)	(17,407)	(32,731)
Key metrics	2013	2014	2015	2016E	2017E	2018E
Net cash/(debt)	(972)	892	7,436	(4,484)	(20,200)	(35,829)
Net debt/equity (%)	-125%	49%	105%	96%	105%	102%
After-tax ROIC	-26%	-20%	38%	41%	44%	43%
Cap-ex/sales (%)	0%	0%	0%	0%	0%	0%
Net asset value/share (p)	n/a	4.1	12.2	(7.2)	(29.7)	(54.3)

Source: Company reports; Hardman & Co Life Sciences Research

Cashflow

- ▶ Redx ended the year to 30 September 2015 with net cash of c.£7.4m, comprising £9.4m of cash offset by the £2.0m convertible loan facility agreed with Liverpool City Council in 2012
- ▶ The incremental increase in R&D investment in FY2016-2018, to fund the ongoing development pipeline, drops straight through the cashflow statement
- ▶ Free cash outflows, therefore, are expected to continue to rise to an estimated £11.9m in FY16, £14.4m in FY17 and £15.6m in FY18
- ▶ To fund the business over the next two years, we forecast there to be a minimum cash requirement of c.£17m which could come from one or more of the following: licensing up-front payments; milestone payments; equity participation in a collaborative deal; an equity fund raise. The most likely scenario is that it will be derived from a combination of these.

Cashflow						
Year end Sep (£'000)	2013	2014	2015	2016E	2017E	2018E
Trading profit	-3,190	-4,000	-8,823	-11,837	-14,552	-15,798
Depreciation	239	252	139	300	500	500
Amortisation	0	0	0	0	0	0
Stocks	0	0	0	0	0	0
Trade receivables	0	0	1,194	-1	-1	-1
Trade payables	796	-292	815	-320	-192	22
Exceptionals/provisions	0	0	0	0	0	0
Disposals	6	-21	21	0	0	0
Other	0	0	0	0	0	0
Company op cashflow	-3,882	-2,567	-6,654	-11,858	-14,246	-15,277
Net interest	-253	-249	16	-212	-464	-700
Tax	188	351	97	650	890	1,068
Operational cashflow	-3,947	-2,465	-6,541	-11,420	-13,819	-14,910
Capital Expenditure	-277	-54	-362	-500	-625	-719
Sale of fixed assets	0	0	0	0	0	0
Free cashflow	-4,224	-2,519	-6,903	-11,920	-14,444	-15,629
Dividends	0	0	0	0	0	0
Acquisitions	0	0	0	0	0	0
Disposals	0	0	0	0	0	0
Other investments	0	0	0	0	0	0
Cashflow after investments	-4,224	-2,519	-6,903	-11,920	-14,444	-15,629
Share repurchases	0	0	0	0	0	0
Share issues	4,893	4,383	13,447	0	0	0
Currency effect	0	0	0	0	0	0
Borrowings acquired	300	0	0	0	-3,272	0
Change in net debt	969	1,864	6,544	-11,920	-17,716	-15,629
Opening net cash	-1,641	-972	892	7,436	-4,484	-20,200
Closing net cash	-672	892	7,436	-4,484	-22,200	-35,829
Hardman cashflow/share (p)	n/a	-5.6	-11.3	-17.6	-21.3	-22.9

Source: Company reports; Hardman & Co Life Sciences Research

Risks

Background

Investments in small early stage companies carry a significant risk and investors must be aware of this fact. In our opinion, the following risks are particularly relevant. Each of them could have an impact on time to reach market, cash flow breakeven and profitability.

Financial/Dilution risk

The company has sufficient cash to fund the ongoing development pipeline, at current investment rates, until mid-2016. Thereafter, it will most likely require additional capital to fund the ongoing programmes. This could come by way of non-dilutive grant funding or exclusive licensing of some of its preclinical assets but, equally, it could raise additional funds through the issue of shares which could be dilutive to shareholders.

Commercialisation

Management currently intends to out-license, partner or co-develop its pipeline assets rather than fund them through clinical development and then to market. There is no guarantee that management will be able to execute on this strategy.

Patent robustness

As with all IP-rich companies, there is risk that the intellectual property is insufficiently covered by the global patents, allowing a competitor to gain market access. Any litigation could involve significant costs and uncertainties.

Regulatory

It is important for companies to liaise with regulators on a regular basis throughout the development programme. Any inadequacies could lead to regulatory action such as cessation of product development and loss of manufacturing or product licences.

Share liquidity

As with many small cap companies listed on AIM, there can be difficulty in buying and selling shares in volume. Market makers only guarantee prices in a very small number of shares.

Competition

The Company operates in a market dominated by larger competitors, many of which have greater financial resources to fund development programmes, marketing activities, etc.

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