

Non-Independent Research MiFID II Exempt

* SP Angel acts as Joint Broker to Hemogenyx and therefore this information should be viewed as a Marketing Communication

25th November 2021

Stock Data

Ticker	HEMO.L
Share Price:	1.8p
Market Cap:	£16.9m
Source: London Stock Exchange (prior trading day's close)	

Company Description

Preclinical stage biotechnology company focused on the development of novel therapies for blood diseases.

Share Price Chart



Source: Bloomberg Terminal

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Hemogenyx Pharmaceuticals plc*

HEMO CAR-T in late preclinical stages

Key points

- **CAR-T cell therapy:** The collaboration with the University of Pennsylvania is progressing well. The Group aims to arrange a pre-investigational new drug (IND) meeting with the FDA prior to submitting an IND application for permission to conduct clinical trials for HEMO-CAR-T, its CAR-T product candidate. The Group has also commenced manufacturing of HEMO-CAR-T.
- **New custom-built laboratory:** Hemogenyx is preparing to move into new laboratory facilities which are to include two cleanrooms for in-house manufacturing of cells, including HEMO-CAR-T.
- **CDX bi-specific antibody programme:** An agreement was struck with Eli Lilly (LLY.NY) to license back IP generated as part of a research collaboration (originally announced in 2018) developing the CDX bi-specific antibody.
- **Refinancing completed:** The Mint financing facility, which created a stock overhang, has been terminated and replaced by new equity capital. As of 30 June 2021, the Group had cash of £10.5m and is well-funded to continue moving its lead product candidates towards clinical trials.
- **Expansion of pipeline:** The Company is continuing work on its additional pipeline, including the CBR platform, which represents a novel form of targeted immunotherapy with a wide range of applications.

Hemogenyx Pharmaceuticals (“the Group”, “the Company”) is continuing efforts to advance its assets into the clinic. Preclinical activities as part of the University of Pennsylvania collaboration regarding HEMO-CAR-T cell therapy are going well. In parallel, the Group has engaged a contract development and manufacturing organisation (CDMO) partner that will manufacture components for the cell therapy. The Company aims to file an IND application with the US FDA to enable clinical testing of HEMO CAR-T. Prior to this, Hemogenyx aims to hold a pre-IND meeting with the FDA to increase the probability of a successful application.

The recent licencing agreement marks the conclusion of the Group’s collaboration with Eli Lilly regarding the CDX antibody programme. Whilst the decision by Eli Lilly not to in-license the programme was disappointing, the partnership has resulted in the generation of CDX antibody variants that appear to be of clinical grade. Hemogenyx has now selected a lead drug candidate and is performing IND enabling studies on the asset prior to filing an IND application with the FDA and entering clinical trials.

The Group’s asset pipeline now consists of six programmes including the CBR platform, a novel cell-based platform technology for the treatment of emerging viral diseases and certain types of cancer. Whilst early-stage, the CBR platform represents a novel form of immunotherapy. The Group aims to generate initial proof-of-concept data and a strong IP estate surrounding the platform to ensure there is adequate protection for the use of CBR across a wide range of diseases.

Peer-group review

We have updated the peer group of ex-UK development-stage companies published in the Update note (July 2020). The table highlights companies with operations within a similar core area as Hemogenyx Pharmaceuticals. The average market capitalisation of the peer-group is £167.8m (Previously: £242m), nearly 10-fold higher than that of Hemogenyx Pharmaceuticals (Table 1).

We also compared the market capitalisation of Hemogenyx Pharmaceuticals to drug developers with Phase 2 assets, or earlier, which are listed on AIM or the LSE standard-list (Table 2). Hemogenyx Pharmaceuticals' current market capitalisation remains well below that of the peer-group average of £114.7m (Previously: £97.9m).

Table 1: Peer-group analysis of blood disease specialists

Name	Ticker	Mkt Cap (GBP)	Lead asset stage	Lead Candidate	Lead indication
Average	-	167.8	-	-	-
Median	-	143.0	-	-	-
Hemogenyx Pharmaceuticals	HEMO LN	16.9	Preclinical	CAR-T/CDX Ab	AML and conditioning
Magenta Therapeutics	MGTA US	286.9	Phase 2	MGTA-456	BMT transplant stage
Actinium Pharmaceuticals	ATNM US	120.7	Phase 3	Iomab-B CD45	BMT conditioning step
Gamida Cell	GMDA US	123.4	Phase 3	Omiducel	BMT transplant stage
Molecular Templates	MTEM US	181.7	Phase 1	MT-3724	B-Cell lymphoma
Collectis	ALCLS FP	288.3	Phase 1	UCART19	ALL
Bellicum Pharmaceuticals	BLCM US	10.7	Phase 2/3	Rivo-cel	BMT
Aptose Biosciences	APS CN	162.6	Phase 1	APTO-253	AML & MDS

Source: Bloomberg; Company websites; BMT – Bone Marrow Transplant, ALL – Acute lymphoblastic leukaemia; MDS – Myelodysplastic syndromes

Table 2: Peer-group analysis of AIM or LSE Standard-listed companies at Phase 2 or earlier

Name	Ticker	Mkt Cap (GBP)	Lead asset stage	Lead Candidate	Lead indication
Average	-	114.7	-	-	-
Median	-	94.2	-	-	-
Hemogenyx Pharmaceuticals	HEMO LN	16.9	Preclinical	CAR-T/CDX Ab	AML and conditioning
N4 Pharma Plc	N4P LN	14.3	Preclinical	Nuvec®	Vaccine delivery
Sareum Holdings Plc	SAR LN	173.6	Phase 2	SRA737	Solid Tumour (partnered)
Redx Pharma Plc	REDX LN	196.8	Phase 2	RXC004	Cancer/Fibrosis
Midatech Pharma Plc	MTPH LN	22.2	Phase 1	MTX110	Brain cancer
C4x Discovery Holdings Plc	C4XD LN	100.2	Phase 1	C4X_3256	Opioid dependence (partnered)
Okyo Pharma Ltd	OKYO LN	69.4	Preclinical	OK-101	Dry eye
E-Therapeutics Plc	ETX LN	230.0	Preclinical	Undisclosed (RNAi)	Undisclosed
Bivictrix Therapeutics Plc	BVX LN	17.2	Preclinical	BVX001	AML
Scancell Holdings Plc	SCLP LN	165.1	Phase 1/2	SCIB1	Melanoma
Evgen Pharma Plc	EVG LN	16.4	Phase 2	SFX01	Breast cancer
Avacta Group Plc	AVCT LN	282.9	Phase 1	AVA6000	Solid tumours
4basebio Plc	4BB LN	88.1	Preclinical	Undisclosed (Cell/gene therapies)	undisclosed

Source: Bloomberg; Company websites

CAR-T development programme

HEMO-CAR-T is a CAR-T cell therapy platform being developed for the treatment of acute myeloid leukaemia (AML), an aggressive form of blood cancer. HEMO-CAR-T has the potential to provide a durable and targeted alternative to standard of care treatments, such as radio/chemotherapy, with an improved safety profile.

The treatment candidate targets FLT3, a receptor protein highly expressed on the surface of AML cells. The Group has demonstrated both *in vitro* and *in vivo* that HEMO-CAR can programme human T-cells (i.e. convert them into HEMO-CAR-T cells) to identify and destroy human AML-derived cells. Work is now underway to progress the asset into first-in-human trials.

Safety switch introduced into CAR-T platform

Whilst CAR-T therapies have generated impressive clinical benefit, there is a risk of a serious adverse event occurring, such as an aberrant immune response or neurotoxicity. To reduce the risk of these events occurring, Hemogenyx Pharmaceuticals has introduced a safety switch within the HEMO-CAR platform.

This version, known as SAFE-HEMO-CAR-T, enables researchers to control the activity of the treatment. *In vitro* tests have been completed and the Group now aims to perform *in vivo* efficacy tests using SAFE-HEMO-CAR-T in an AML mouse model. If successful, Hemogenyx Pharmaceuticals looks to include SAFE-HEMO-CAR-T in the preclinical programmes currently underway at the University of Pennsylvania.

Collaboration with University of Pennsylvania

Last year, Hemogenyx Pharmaceuticals began a research collaboration with the University of Pennsylvania (Penn), a leading US medical institution. The partners are focused on advancing the HEMO-CAR-T platform towards clinical proof of concept for the treatment of AML. Dr Saar Gill, Assistant Professor of Medicine and Scientific Co-Director of the Cell Therapy and Transplantation programme, is serving as principal investigator on behalf of Penn.

Working with a leading cell & gene therapy institute

The collaboration is with a leading cell therapy research institution within the university. This not only ensures preclinical activities are conducted by experts in the field but also highlights the clinical interest in the platform.

Dr Gill's laboratory is part of the Centre for Cellular Immunotherapies (CCI) at Penn. The CCI is led by Carl June, a pioneer in the cell therapy space, and there have been several clinical trials conducted at the centre. CAR-T cells invented at the CCI were developed into Kymriah® (tisagenlecleucel), the first CAR T-cell therapy approved by the FDA.

Consequently, Hemogenyx Pharmaceuticals has highlighted Penn as a potential option to run the first-in-human trial for HEMO-CAR-T. This is a sensible choice given the ongoing collaboration and the CCI's clinical experience in the area.

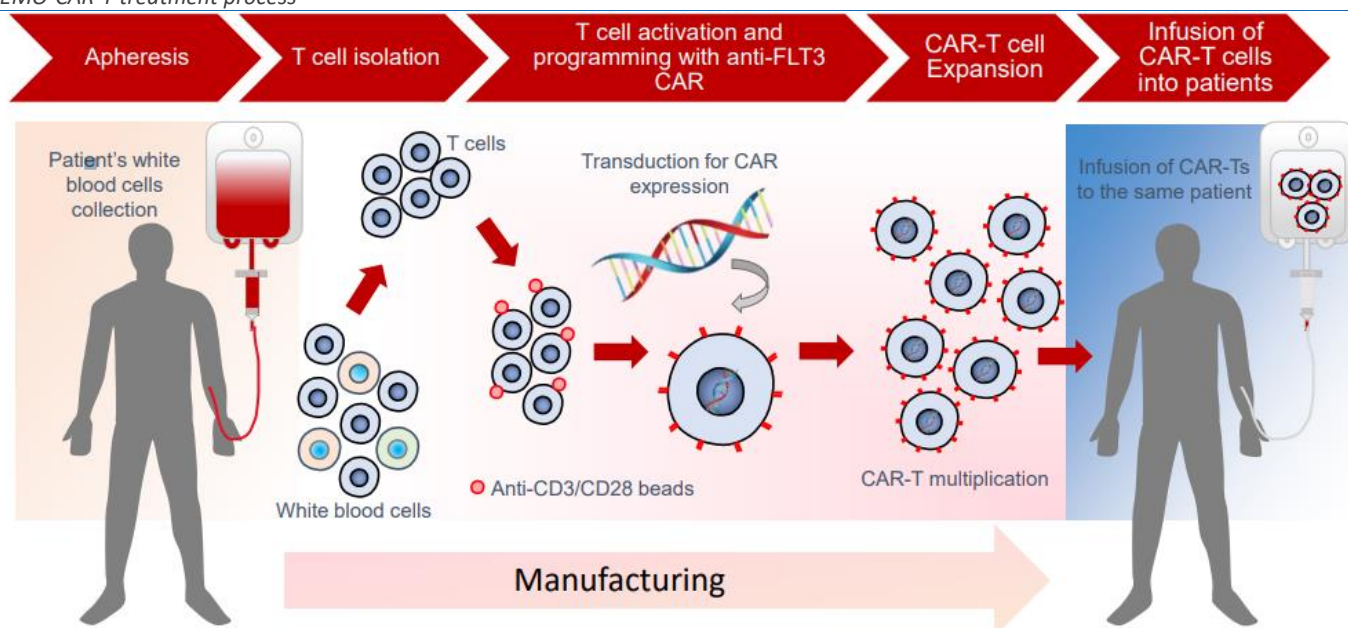
Manufacturing phase underway

The manufacture of CAR-T therapies is a highly complex, multi-step process. Multiple components are required to generate a viable CAR-T cell therapy. These include:

- The DNA plasmid which carries the genetic information to programme the target T-cells.
- Viral vectors to deliver the plasmid into the target T-cells.
- Furthermore, the CAR-T cell population needs to be expanded before being administered to the patient.

Hemogenyx Pharmaceuticals has been evaluating several contract manufacturing and development organisations (CDMOs) to support the manufacture of HEMO-CAR-T for clinical trials. The Company has now selected a CDMO that is responsible for manufacturing DNA plasmids and viral vectors to produce the HEMO-CAR-T for clinical trials.

HEMO-CAR-T treatment process



Source: Hemogenyx Pharmaceuticals presentation

New personnel to support CMC and GMP protocols

Alongside the selection of manufacturing partners, the Group needs to ensure that appropriate chemistry, manufacturing, controls (CMC) and Current Good Manufacturing Practices (cGMP) data and protocols are in place. These form a vital part of the IND submission to the FDA.

To support these efforts, the Group has contracted Randall Tlachac of Quality Systems LLC, a specialist consultancy. Mr Tlachac has extensive experience in the successful development of cell and gene-based therapies. He has led the development of over 30 products to Phase 1/2 trial stage and played a major role in the definition and implementation of Good Tissue Practices. These are US regulations that govern the use of human cellular, tissue, and tissue-based products.

Pre-IND meeting and clinical trial design

Once the preclinical and manufacturing workstreams are complete, the Group aims to submit an Investigational New Drug (IND) application to the US FDA. An IND submission is required to obtain authorisation from the FDA to administer an investigational drug, such as HEMO-CAR-T, to humans. Prior to submitting the IND, Hemogenyx Pharmaceuticals intends to request a Pre-IND meeting with the FDA. This meeting provides the opportunity for the FDA to provide comments on what the regulators expect in the IND submission. There have been some rejected IND submissions whereby the FDA indicated that a pre-IND meeting might have helped to avoid that outcome, therefore this meeting should reduce regulatory risk. We expect the Pre-IND meeting to take place early next year with the official meeting minutes, which provide guidance, to be received c.30 days after the meeting takes place.

Once the Group has obtained IND approval, it intends to conduct a Phase 1/2 trial using HEMO-CAR-T with the aim of generating safety and preliminary efficacy data. The trial aims to recruit patients with FLT3 positive relapsed or refractory AML who are qualified for bone marrow transplantation.

The initiation of this trial would be a key milestone for the Group, marking the transition from a preclinical to a clinical company. We expect positive data generated from this trial to be of significant interest to potential partners. Multiple deals in the space have been driven by assets at Phase 1 or preclinical stage. For example, Gilead struck an agreement with Appia Bio (Private) worth up to \$875m to develop CAR-T cell therapies against various blood diseases. This highlights the opportunity for future corporate activity regarding HEMO-CAR-T should the asset generate positive late-stage preclinical or early-stage clinical data.

CDX agreement with Eli Lilly

In April 2021, Hemogenyx Pharmaceuticals received notice from Eli Lilly and Company (LLY.NY) that it will not exercise its option to license the IP surrounding the Group's CDX bi-specific antibody (CDX Ab) for the treatment of AML.

Whilst the decision by Eli Lilly to not exercise its option is disappointing, the partnership, originally struck in 2018, has enabled Hemogenyx Pharmaceuticals to receive technical support from a leading biopharma company, including access to advanced antibody-engineering methods and certain IP. This has resulted in the generation of CDX Ab variants which appear to be of clinical grade.

In-licensing of IP from Eli Lilly now complete

As part of the initial collaboration agreement, Eli Lilly conducted development and validation activities on the CDX platform and thus created IP of its own. In order to progress the development of the asset, Hemogenyx Pharmaceuticals struck an agreement with Eli Lilly to license back this IP. The terms of the agreement are as follows:

- Eli Lilly has granted Hemogenyx Pharmaceuticals an exclusive worldwide licence for certain IP related to the CDX platform.
- In return, Hemogenyx Pharmaceuticals is to pay Eli Lilly \$250k upfront and Eli Lilly is eligible for milestone payments of up to \$1m through to Phase 2 trials.
- Eli Lilly is also eligible for additional milestone payments based on the achievement of clinical, regulatory, and commercial milestones as well as tiered royalties on sales.
- In addition, the Company will pay Eli Lilly a percentage of any cash payments received in respect of any sub-licence of the licensed IP.

Next steps

The licensing agreement marks the conclusion of the Group's collaboration with Eli Lilly regarding the CDX platform. Hemogenyx Pharmaceuticals has now selected a lead drug candidate from this platform and is performing investigational new drug (IND)-enabling studies on the asset. An IND submission is required to obtain authorisation from the FDA to administer an investigational drug to humans. If the IND application is successful, the Group looks to test the CDX antibody in patients with relapsed or refractory FLT3 positive AML who are qualified for bone marrow transplantation.

CBR Platform

Hemogenyx is developing an additional cell therapy platform, known as CBR. CBR is thought to be a novel approach to targeting both viral diseases and cancer. This project originally stemmed from developing a neutralising antibody treatment for COVID-19. With several neutralising antibody treatments for COVID-19 now available, we believe the CBR platform represents a more durable asset for the Company that can target multiple disease indications.

Like CAR-T, the process involves the programming of immune cells using a novel type of modifiable synthetic receptor to destroy viral pathogens and cancer cells. However, the novel synthetic receptor has no connection to, and does not resemble, any known or widely used CAR platform. The Company is not aware of any direct competitor for this product candidate at this time.

Preclinical proof-of-concept programme underway

Hemogenyx Pharmaceuticals is currently focused on the development of two CBR-based potential product candidates: one for the treatment of COVID-19, and the other for the treatment of an undisclosed type of cancer. The Group looks to perform preclinical studies on these candidates to provide an early indication of proof of concept. Data generated from these studies should guide further development decisions regarding the platform.

First-mover advantage offers opportunity for landgrab

As CBR represents a novel approach to immunotherapy, the Group aims to build a strong IP estate around the concept. This should ensure there is adequate protection for the use of CBR across a wide range of diseases.

General Update

Intellectual property update

Hemogenyx Pharmaceuticals is looking to build a robust IP estate surrounding its portfolio to protect the use of the assets and support discussions with potential partners.

In September, the Group announced the approval of a patent entitled “*Monoclonal antibodies to human FLT3/FLK2 receptor protein*”. The patent was issued by the United States Patent and Trademark Office (US PTO) as patent number US11104738. The composition of matter patent covers sequences of monoclonal antibodies that target the human FLT3/FLK2 receptor protein. The FLT3/FLK2 receptor is found on the surface of acute myeloid leukaemia (AML) cells, hematopoietic stem cells and dendritic cells.

This approval followed an additional US patent approval related to the Group’s CDX Ab platform. The patent (US11021536B2) covers a method of use for the CDX Ab for conditioning bone marrow/hematopoietic stem cell transplantation. The patent also covers a composition of matter related to monoclonal antibodies that target proteins existing on the surface of blood stem cells and certain malignant cells, including AMLs, as well as a protein that exists on the surface of T cells.

The Company has made further patent applications in relation to both to HEMO-CAR-T and to the CDX Ab platform. As previously mentioned, the Group is also focused on filing patents surrounding the CBR platform.

Lease of new laboratory building

Hemogenyx Pharmaceuticals has signed a lease for a new laboratory in Manhattanville, New York City. The new laboratory space will support the growth of Hemogenyx Pharmaceuticals in terms of headcount and capability. The site is close to two universities, Columbia University and the City College of New York, offering the potential for collaborations. The laboratory is to be custom-designed and built and will contain two cleanrooms. Cleanrooms are controlled environments with low levels of contaminants. The availability of these rooms will enable Hemogenyx Pharmaceuticals to perform developmental and manufacturing activities on its cell therapy product candidates, such as HEMO-CAR-T and CBR.

Termination of Loan Facility

In May 2021, Hemogenyx Pharmaceuticals terminated a financing facility agreement (originally announced in November 2020) with Mint Capital, a Bahamas-based investment management company. Mint Capital had conditionally agreed to subscribe for up to £60m in aggregate of unsecured convertible loan notes (CLNs). As part of the termination, Hemogenyx Pharmaceuticals redeemed £1.6m of the CLNs, whilst Mint Capital sold £6.5m of CLNs to places who agreed to immediately convert the CLN's into ordinary shares at a conversion price of 1.5p. As a result, there are now no CLNs outstanding and the facility with Mint Capital is terminated.

It is good to see the termination of the facility, which created a stock overhang, restricting any price appreciation in the Company's shares. Hemogenyx Pharmaceuticals has indicated that it is funded to continue moving its product candidates forward towards clinical trials.

Repayment of convertible loans

Hemogenyx Pharmaceuticals recently announced that Hemogenyx-Cell S.A. and Immugenyx LLC, two wholly owned subsidiaries of the Group, have repaid convertible loan notes which were originally struck as part of a 2018 agreement with Orgenesis (ORGS.NQ), a US biotechnology company. The total sum in principal and interest repaid was \$2.1m. The repayment of these loans further clears the balance sheet and the Group noted that it retains a substantial cash balance that will enable it to continue its product development as planned.

Expansion of management team

In July 2021, Hemogenyx Pharmaceuticals appointed Dr Alan E. Walts as a board observer and business advisor. Dr Walts is a Venture Partner with Advent Life Sciences, a specialist life sciences fund. He is on the board of multiple public and private biopharma companies, including Eloxx Pharmaceuticals (ELOX.NQ) and Artax Biopharma (Private). He also is a business advisor and board observer for several private companies. Prior to Advent Life Sciences, Dr Walts spent over 25 years at Genzyme, a biotechnology company acquired by Sanofi in 2011 for \$20.1b. The addition of Dr Walts provides the Group with considerable commercial and scientific experience as it continues to make progress across its asset pipeline.

Financials

Income Statement (£)

Fiscal Year	2018A	2019A	2020A	H1-21A
Fiscal Period end date	31/12/2018	31/12/2019	31/12/2020	30/06/2021
Revenue	-	-	-	-
Administrative expenses	(1,630,222)	(1,589,407)	(2,043,633)	(1,099,320)
Depreciation Expense	(51,805)	(94,726)	(106,753)	(62,177)
Operating profit	(1,682,027)	(1,684,133)	(2,150,386)	(1,161,497)
Other income	91,357	213,126	85,237	170,244
Finance costs	4,374	14,191	3,365	9,677
Finance costs	(1,779)	(31,328)	(33,239)	(2,650,762)
Profit before tax	(1,588,075)	(1,488,144)	(2,095,023)	(3,632,338)
Income tax credit (expense)	43,751	35,000	-	-
Profit after tax	(1,544,324)	(1,453,144)	(2,095,023)	(3,632,338)
Translation of foreign operations	51,031	16,176	(61,119)	(300,329)
Comprehensive income/(loss) to the year	(1,493,293)	(1,436,968)	(2,156,142)	(3,932,667)
Weighted average number of ordinary shares in issue	360,125,230	360,125,230	414,833,093	546,669,219
EPS	(0.004)	(0.004)	(0.005)	(0.007)

Source: Company announcements, SP Angel estimates

Cash flow (£)

Fiscal Year	2018A	2019A	2020A	H1-21A
Fiscal Period end date	31/12/2018	31/12/2019	31/12/2020	30/06/2021
Operating Profit	(1,544,324)	(1,453,144)	(2,095,023)	(3,632,338)
Depreciation & Amortisation	51,805	94,726	106,753	62,177
EBITDA	(1,492,519)	(1,358,418)	(1,988,270)	(3,570,161)
Other Non-cash items	-	-	172	(65,040)
Foreign exchange gain	(49,000)	20,745	(146,772)	(300,232)
Interest income	(4,374)	(14,191)	(3,365)	(9,677)
Interest expense	1,779	31,328	33,239	-
Finance costs	-	-	-	1,413,607
Charge recognised upon conversion of debt	-	-	-	1,212,475
Share based payments	309,322	122,487	363,104	82,833
Change in trade and other payables	(98,670)	(17,880)	(35,738)	111,822
Change in trade and other receivables	(19,266)	16,056	(21,397)	19,711
Pre-paid and deposits	-	-	623	-
Net cash outflow used in operating activities	(1,352,728)	(1,199,873)	(1,798,404)	(1,104,662)
Proceeds from issuance of debt securities	1,175,915	-	461,776	12,000,000
Repayment of convertible debt	-	-	-	(1,600,000)
Payment of debt issuance costs	-	-	-	(505,235)
Proceeds from issuance of equity securities	4,993	-	3,148,200	-
Proceeds from exercise of warrants	-	-	35,070	-
Share issue costs	-	-	(168,160)	-
Deferred financing costs	-	-	(223,615)	-
Payment of lease liabilities	-	(39,393)	(41,249)	(19,641)
Net cash flow generated from financing activities	1,180,908	(39,393)	3,212,022	9,875,124
Interest income	4,374	14,191	3,365	9,677
Purchase of PPE	(6)	(11,918)	(173,047)	(13,925)
Loan to related parties	(24,589)	-	-	-
Net cash flow generated from investing activities	(20,221)	2,273	(169,682)	(4,248)
Net increase/(decrease) in cash and cash equivalents	(192,041)	(1,236,993)	1,243,936	8,766,214
Effect of exchange rates on cash	77,814	(26,756)	69,684	(14,845)
Cash and cash equivalents at the beginning of the period	1,876,655	1,762,428	498,679	1,812,299
Cash and cash equivalents at the end of the period	1,762,428	498,679	1,812,299	10,563,668

Source: Company announcements, SP Angel estimates

Balance sheet (£)

Fiscal Year	2018A	2019A	2020A	H1-21A
Fiscal Period end date	31/12/2018	31/12/2019	31/12/2020	30/06/2021
PPE	173,943	123,922	222,858	179,648
Right of use asset	-	109,442	45,885	27,130
Intangible assets	272,753	262,050	254,955	251,243
Deferred financing costs	-	-	223,615	-
Non-current assets	446,696	495,414	747,313	458,021
Trade and other receivables	90,475	55,804	104,972	84,740
Cash and cash equivalents	1,762,428	498,679	1,812,299	10,563,668
Current assets	1,852,903	554,483	1,917,271	10,648,408
Called up share capital	3,601,762	3,612,429	4,336,363	9,797,493
Share premium	7,340,267	7,699,789	9,990,965	16,808,827
Other reserves	620,059	399,229	764,815	847,330
Reverse asset acquisition reserve	(6,157,894)	(6,157,894)	(6,157,894)	(6,157,894)
Foreign currency translation reserve	37,047	53,223	(7,896)	(308,225)
Retained Earnings	(4,482,075)	(5,953,294)	(8,035,514)	(11,667,854)
Equity attributable to owners of the Company	959,166	(346,518)	890,839	9,319,677
<i>Non-controlling interests</i>		<i>(2,517)</i>	<i>(15,158)</i>	<i>(16,354)</i>
Total equity	959,166	(349,035)	875,681	9,303,323
Trade and other payables	167,607	141,677	160,771	269,442
Current borrowings	-	-	1,579,378	1,504,333
Lease liabilities	-	39,896	38,726	29,331
Current liabilities	167,607	181,573	1,778,875	1,803,106
Lease liabilities		73,192	10,028	-
Non-current Borrowings	1,172,826	1,144,167	-	-
Non-Current liabilities	1,172,826	1,217,359	10,028	-

Source: Company announcements, SP Angel estimates

Disclaimer: Non-independent research

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Buy - Expected return >15%

Hold - Expected return range -15% to +15%

Sell - Expected return < 15%