SP Angel Healthcare

Hemogenyx Pharmaceuticals

Initiation of Research

29th August 2019

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Source: Hemogenyx Pharmaceuticals

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INITATION OF COVERAGE

Non-Independent Research
MiFID II Exempt
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29th August 2019

Stock Data

Ticker	HEMO.L
Share Price:	2.35p
Market Cap:	£8.5m

Source: Bloomberg (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*

LSE: HEMO.L ***CORP**

Targeting blood malignancies

Key points

- CDX antibody offers a novel approach to treat acute myeloid leukaemia and condition patients for bone marrow transplantation
- Partnership discussion progressing, could demonstrate significant upside
- Encouraging preclinical datasets, with proof of concept demonstrated *in vivo*
- Pre-IND FDA meeting for CDX Ab platform expected within 12 months
- Bone marrow transplantation represents a large market
- 'Targeted Conditioning' approach for bone marrow transplants could expand patient eligibility and access
- Revenues being generated from AHC mouse model

Hemogenyx Pharmaceuticals Plc (Hemogenyx) is a preclinical stage biotechnology company quoted on the LSE Standard List. The Group is developing therapies for blood diseases which aim to offer a safer and more accessible patient pathway than current practice. Although an early stage company, the Group has struck multiple collaboration agreements with biopharmaceutical companies across its product pipeline and is generating revenue from an R&D tool it has developed.

Hemogenyx has signed multiple collaborations with biopharmaceutical companies and academic institutions, with each product having one or more collaborations. These collaborations provide validation of the Group's technology platforms. Two of the Group's subsidiaries have received investment from Orgenesis (NASDAQ:ORGS), a US biotechnology company. Immugenyx LLC, developing the AHC mouse model received $1m on a pre-money valuation of US$8m whilst Hemogenyx-Cell SPRL, developing the Hu-PHEC cell therapy, received $1m on a pre-money valuation of US$12m. Collectively these valuations are double the Company's current market capitalisation, highlighting the undervalued nature of this stock.

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Investment Thesis

Diversified pipeline with collaborations across all assets

Although Hemogenyx's products are at the preclinical stage, the Group has collaboration agreements signed across its pipeline. This represents a strong validation of the Company's products. The Group is leveraging its platforms with large industry players to accelerate development and share the costs of research.

Advanced discussions with potential partner

In May 2018, Hemogenyx struck a development agreement with an unnamed multinational biopharmaceutical company regarding its CDX antibody (CDX Ab), the Group's lead asset. The partner has initiated preliminary discussions regarding a potential licensing deal. If the partner chooses to in-license the CDX Ab product candidate, we expect the partner would finance and manage the development of the platform through clinical trials, which would significantly reduce the capital required for commercialisation.

AHC mouse model generating revenues

Although Hemogenyx's CDX Ab platform is yet to enter the clinic, the Group is currently generating revenue through its Advanced Hematopoietic Chimera (AHC) mouse model. Originally developed for in-house testing, the model is now generating significant interest from industry as an *in vivo* platform for disease modelling and drug development. Immugenyx LLC, the wholly-owned Hemogenyx subsidiary developing the AHC mouse model, is working with Janssen Pharmaceuticals, a subsidiary of Johnson & Johnson (NYSE: JNJ), to develop a mouse model to further understand and potentially test therapies for the treatment of systemic lupus erythematosus (SLE aka lupus). Also, Hemogenyx is collaborating with an unnamed US biotechnology company on developing the AHC model as a tool for testing the immunogenicity of biologics, which is expected to generate c.$377k in revenue. Furthermore, Immugenyx has agreed to receive a $1m investment from Orgenesis, a US biotechnology company to further develop its AHC platform.

Potential market expansion

Hemogenyx is developing products which aim to de-risk bone marrow transplantation (BMT). This is a large addressable market with Hemogenyx estimating the US market for bone marrow transplants at c.$3-4b, whilst in Europe it is estimated at $5b (CIBMT report). BMTs are a curative treatment, however, they are high risk and have low success rates. Hemogenyx's CDX and Hu-PHEC products aim to make bone marrow transplants safer and reduce the need for bone marrow donors. Collectively, these products could expand patient eligibility and the total number of transplants, substantially increasing the total addressable market.

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Peer-group review

Hemogenyx operates in an area of intense focus for industry. Therefore, we compiled a peer group of ex-UK development-stage companies which operate within similar treatment areas to Hemogenyx (i.e. treatment of blood cancers or alternate therapies for bone marrow transplants). The median-market capitalisation of the peer-group is £129.1m, over 10-fold higher than that of Hemogenyx (Table 1).

We then compared Hemogenyx to several AIM or LSE standard-listed drug developers at a preclinical stage (Table 2). As is demonstrated, Hemogenyx's current market capitalisation is half that of the peer-group median of c.£17.2m. Given that the Company has multiple assets, each with collaboration agreements, we believe that this price discrepancy is unjustified and that Hemogenyx shares consequently have considerable upside potential.

Finally, we note that the two investments by Orgenesis into the Immugenyx and Hemogenyx-Cell subsidiaries are on pre-money valuations of US$8m and US$12m respectively. The combined value of these two subsidiaries is c.20% higher than the current market capitalisation of Hemogenyx. Note this US$20m valuation does not include the CDX Ab platform, the Group's leading technology, over which Hemogenyx is in advanced discussions with a potential partner.

We feel these points highlight the undervalued nature of this stock.

Table 1: Peer-group analysis of blood disease specialists

Name	Ticker	Mkt Cap (£m)	Lead asset stage	Lead Candidate	Lead Indication
Median	-	**129.1**	-	-	-
Hemogenyx Pharmaceuticals	**HEMO LN**	**8.5**	**Preclinical**	**CDX Ab**	**AML and conditioning**
Actinium Pharmaceuticals	ATNM US	31.7	Phase 3	Iomab-B CD45	BMT conditioning step
Allogen	ALLO US	2615.7	Phase 1	ALLO-715	Multiple myeloma
Aptose Biosciences	APTO CN	107.1	Phase 1	APTO-253	AML
Bellicum Pharmaceuticals	BLCM US	47.9	Phase 2/3	Rivo-cel	BMT
Cellectis	ALCLS FP	24.2	Phase 1	UCART19	ALL
Fate Therapeutics	FATE US	420.5	Phase 2	FT516	AML
Forty Seven Inc	FTSV US	895.5	Phase 1	Hu5F9-G4	AML
Gamida Cell	GMDA US	242.9	Phase 3	Omiducel	BMT transplant stage
Kiadis Pharma	KDS NA	111.9	Phase 3	ATIR101	AML
Magenta Therapeutics	MGTA US	129.1	Phase 2	MGTA-456	BMT transplant stage
Molecular Templates Inc	MTEM US	330.5	Phase 1	MT-3724	B-Cell lymphoma

Source: Bloomberg; r/r: relapsed or refractory; AML: Acute Myeloid Leukemia (AML); ALL: Acute Lymphoblastic Leukemia: BMT: Bone marrow transplant

Table 2: Peer-group analysis of AIM or LSE Standard-listed companies at Phase 1 or preclinical stage

Name	Ticker	Mkt Cap (£m)	Lead asset stage
Median	**Median**	**17.2**	-
Hemogenyx Pharmaceuticals	**HEMO LN**	**8.5**	**Preclinical**
Verseon Corp	VERS LN	17.2	Phase 1
C4X Discovery Holdings	C4XD LN	22.3	Preclinical
Sareum Holdings	SAR LN	10.0	Phase 1
Avacta Group	AVCT LN	24.7	Preclinical
Okyo Pharma Ltd	OKYO LN	33.1	Preclinical
Redx Pharma	REDX LN	12.3	Phase 1

Source: Bloomberg

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Company overview

Company Summary

Hemogenyx is preclinical stage biotechnology company based in Brooklyn, New York. The Group is developing treatments for blood disease that offer an efficacious and safer alternative to the current standard of care. The Company is also developing an R&D tool for drug development.

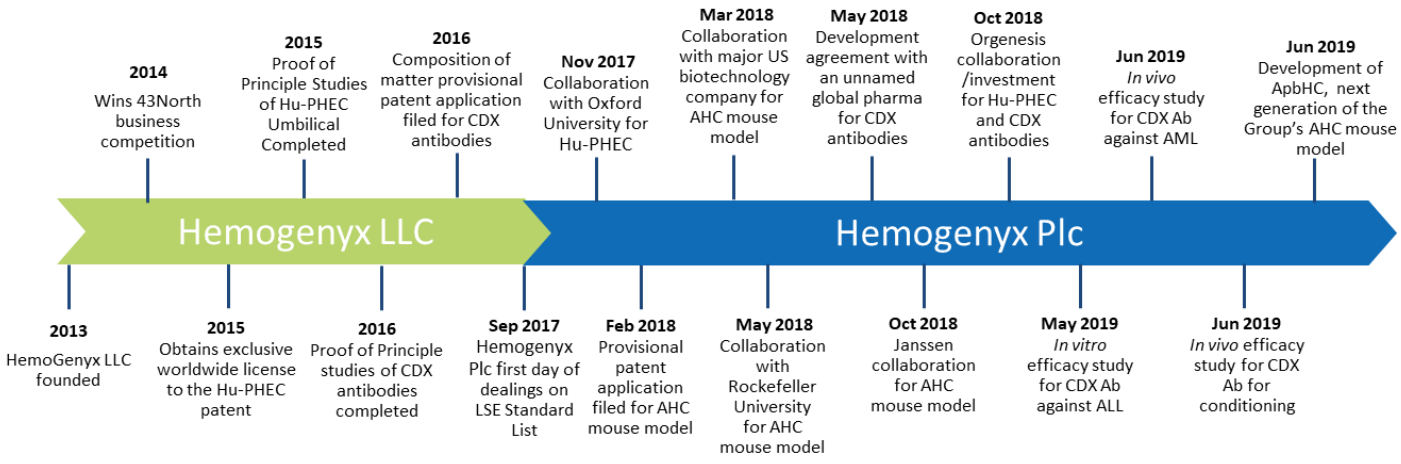
History

Hemogenyx was co-founded in 2013 by Dr Vladislav Sandler, CEO of Hemogenyx, and Ms. Alexis Sandler, a non-executive director of Hemogenyx, to help bring discoveries made whilst at Cornell University into clinical development. In December 2014, Hemogenyx was awarded a $250k investment at the 43North Business Awards in which c.7,000 companies compete. In February 2016, Hemogenyx received a further $1m investment from Bonsai Capital which allowed the Group to establish a lab at the Downstate Biotechnology Incubator in Brooklyn, New York.

In September 2017, Silver Falcon, an LSE standard list special purpose acquisition company, acquired the share capital of Hemogenyx Pharmaceuticals Ltd for £8m via a RTO and renamed itself Hemogenyx Pharmaceuticals Plc. Alongside the acquisition, the Company raised £2m (gross) at 3.5p/share with funds going towards preclinical studies of the CDX Ab, development of the Hu-PHEC cell therapy platform, expanding the IP estate and repaying a loan from Cornell University.

Since listing, the Group has made considerable progress across its asset pipeline, demonstrating potential efficacy in preclinical tests and striking multiple collaboration agreements with large biopharmaceutical companies and research institutions.

Figure 1: Company History



Source: Compiled by SP Angel

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Product offering

Hemogenyx's technology platforms include:

- **CDX bi-specific antibodies (CDX Ab):** Aim to redirect the patient's own immune cells to selectively target blood stem cells and certain types of blood cancer cells. They could be used as a direct therapy to eliminate diseased cells and/or to clear unwanted blood stem cells prior to bone marrow transplantation.
- **Hu-PHEC cell therapy:** Utilises a naturally-occurring type of blood stem cell progenitors that can be collected and modified to generate cancer-free, own-patient blood stem cells, which can be used in bone marrow transplantation.
- **AHC mouse model:** A novel mouse model which exhibits a near fully-functional human immune system. Mouse models built on the AHC platform may enable improved evaluation of emerging therapies prior to entering expensive human trials and are of significant interest to industry as an *in vivo* platform for disease modelling and drug development.

Hemogenyx aims to progress its programmes through to clinical proof-of-concept, (i.e. completion of Phase 2 trials) with the goal of then licensing assets to pharmaceutical companies in return for upfront, milestone and royalty payments.

Figure 2: Hemogenyx assets and target indications

Asset	Product area	Standard-of-care	Issues	Solutions
CDX Ab	**Conditioning** Eliminate diseased blood stem cells from the patients prior to transplant	Chemotherapy/Radiation	Non-specific and toxic	Targeted and low-toxicity removal of diseased blood stem cells.
	AML treatment Directly target cancer cells	Chemotherapy/Radiation	Non-specific and toxic	Targeted and low-toxicity removal of AML cells
Hu-PHEC	**Bone marrow transplantation** Transplant new healthy blood stem cells to the patient to replenish healthy blood supply	Autologous or allogeneic blood stem cell transplants	c.50% transplant rejection rate and 60% of patients fail to find a match	Develop patient-matched, cancer free stem cells for transplantation
AHC Mouse IMMUGENYX	**Animal model testing** Testing potential drugs on animal models to evaluate their potential before going into human trials	PBMC mouse model	May not be an accurate predictor of a human system.	Mouse model with 'human'-immune system allows for more rigorous preclinical tests

Source: Compiled by SP Angel

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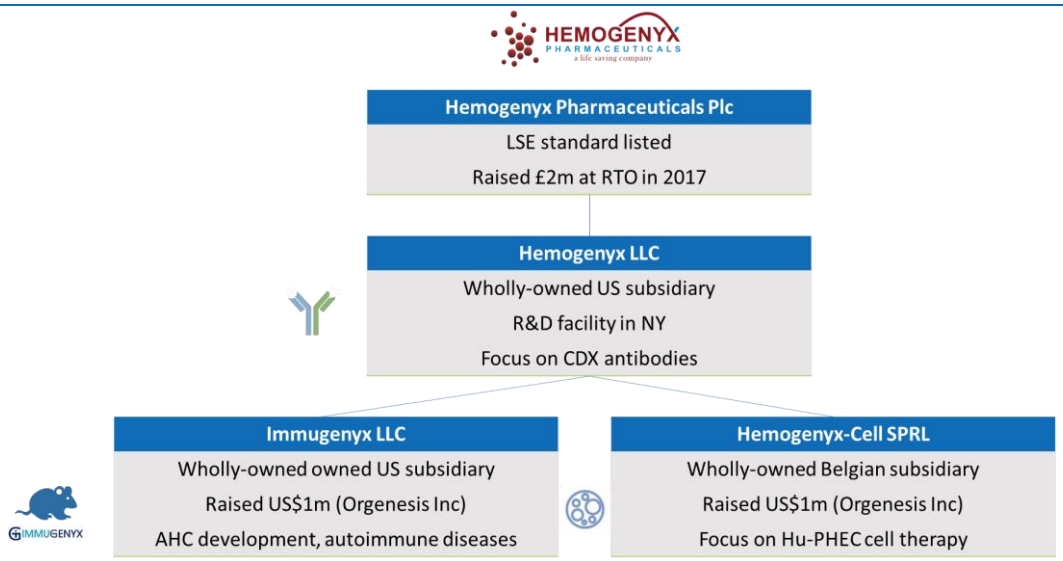
Company Structure

The Group has three fully owned subsidiaries, with each focused on the development of a specific product (Figure 4). This structure allows strategic investment into each platform. This was demonstrated by the investment of Orgenesis into Immugenyx and Hemogenyx-Cell, two subsidiaries developing the AHC mice and Hu-PHEC cell therapy, respectively.

Figure 3: Hemogenyx company structure



Source: Compiled by SP Angel from Hemogenyx data

Figure 4: Product offering

Asset	Indication	Target identification	Lead identification	Lead optimisation	Candidate selection	IND-enabling toxicology	Phase 1	Collaborations
CDX Ab	AML/ALL/Bone Marrow Conditioning							Unnamed Large Biopharmaceutical company
Hu-PHEC	Bone Marrow Transplantation							Orgenesis
AHC Mice	Disease modelling and drug testing	*R&D tool						Janssen, Orgenesis

Source: Compiled by SP Angel

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CDX Antibody: Targeted treatment of blood diseases

Hemogenyx's lead asset is an antibody-based immunotherapy known as a CDX antibody (CDX Ab). CDX Ab aims to redirect the patient's own immune cells to selectively target blood stem cells and certain types of blood cancer cells. The treatment could be used as a direct therapy to eliminate diseased cells and/or to clear unwanted blood stem cells prior to a bone marrow transplant.

The Group aims to complete further preclinical studies on the CDX Ab and then file an Investigative New Drug (IND) application to the FDA. An IND is required to test a new drug in humans and, if accepted by the FDA, the Group aims to move into Phase 1 clinical trials.

Collaboration agreement with unnamed global biopharma company progressing well

In May 2018, Hemogenyx struck a development agreement with an unnamed, multinational biopharmaceutical company regarding the CDX Ab. As part of the agreement, Hemogenyx is receiving technical support including access to the partner's advanced antibody-engineering methods and certain IP, and the partnership has resulted in the generation of CDX Ab variants which appear to be of clinical grade.

Partnership discussions ongoing

Hemogenyx has granted the partner the option of an exclusive worldwide licence to commercialise the CDX antibodies. The parties have initiated preliminary discussions regarding the potential licensing deal. The timing or outcome of these discussions is difficult to predict, however, should the unnamed partner license the CDX Ab product we would expect the partner to pay Hemogenyx a substantial upfront payment and then finance and manage the rest of the development of the programme. We would also expect Hemogenyx to secure significant future milestone and royalty payments on such an agreement.

CDX Ab: 'off the shelf' elimination of blood malignancies

CDX Ab is a recombinant bi-specific antibody. The antibody has two 'arms', each recognising a specific protein target. One arm binds to FLT3 (fms-like tyrosine kinase 3), a receptor protein highly-expressed on the target (diseased) cells. The other arm binds to CD3, a surface protein expressed on T-cells, a form of immune cell. Collectively, the CDX Ab allows the immune cell to recognise and eliminate the diseased cell.

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Potential treatment areas

Preclinical studies performed by Hemogenyx have demonstrated the potential efficacy of CDX Ab in treating patients with FLT3 positive relapsed or refractory AML as well as conditioning for bone marrow transplantation.

Conditioning: Preparing the patient for a bone marrow transplant

CDX Ab may be used to eliminate blood stem cells as part of the conditioning step that is necessary to clear the existing blood stem cells, prior to a bone marrow transplantation. The rationale for conditioning is to eliminate the patient's blood stem cells and depress the immune system to allow the transplanted bone marrow to successfully engraft.

This can be achieved as blood stem cells express FLT3, which CDX Ab recognises. The use of CDX Ab could make the conditioning step safer and less damaging by eliminating side effects that accompany the traditional methods of chemotherapy and radiotherapy. Using CDX Ab for conditioning may increase the total number of transplants as patients too weak to undergo chemotherapy may be eligible for this pathway. This could shift the use of bone marrow transplantation from a risky last-line therapy to an earlier stage treatment, as well as expand its use into other non life-threatening disease indications such as Lupus and Multiple Sclerosis.

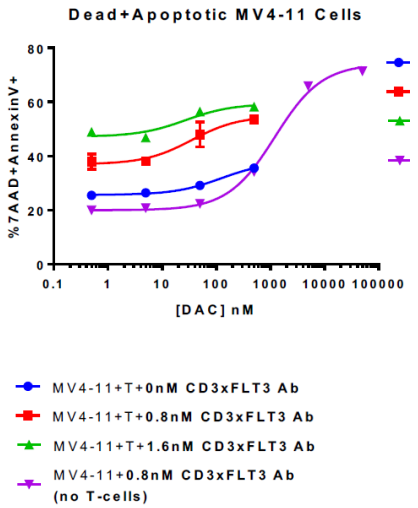
Direct cancer treatment

CDX Ab could be used as a direct treatment for blood cancers such as AML and acute lymphoblastic leukaemia (ALL). Preclinical data using the AHC mouse model have indicated CDX Ab can eliminate AML cells which express the FLT3 protein. The use of CDX Ab as a direct therapy may extend into other blood cancers such as ALL. *In vitro* studies performed by Hemogenyx demonstrated that CDX Ab can eliminate a subset of ALL cells which overexpress FLT3 and have a MLL1 genetic rearrangement, seen in c.10% of ALL patients (*Winters A., et al, frontiers in paediatrics, 2017*).

Use of CDX Ab in drug combinations may be an effective strategy

CDX Ab could be used in combination with other AML therapies to improve patient outcomes. Hemogenyx has performed preclinical studies testing CDX Ab in combination with Decitabine, an approved chemotherapy (Figure 5). The results indicated that the combination approach had an enhanced ability in eliminating AML cancer cells. Decitabine is a DNA methyltransferase inhibitors (DNMT1), meaning that it targets cancer cells when they are dividing. As CDX Ab functions by a different pathway, it can target both fast, slow and non-dividing cancer cells. Pharmaceutical companies and clinicians are constantly trying to develop new combination treatments to enhance the utility of their therapeutics and we believe that with some human data regarding CDX Ab, drug-developers would be attracted to test CDX Ab in combination with their own therapies.

Figure 5: in vitro studies indicate CDX Ab may be used in combination with Decitabine



Mv4-11: leuakemia cell line; T: T-cells; CD3xFLT3 Ab: CDX Antibody; [DAC]: Concentration of Decitabine

Source: Hemogenyx (note this is preclinical data please see Key Risk section)

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Future clinical development of CDX Ab

The Group plans to initiate IND-enabling studies and file for an IND with the FDA and initiate clinical trials testing the CDX Ab in AML patients eligible for bone marrow transplantation.

Pre-IND meeting with the FDA expected in the next twelve months

In the next twelve months, the Group aims to meet with the FDA in the form of a pre-IND meeting. A pre-IND meeting is an opportunity to present the Group's planned development program for CDX Ab and to obtain valuable FDA feedback regarding the studies which can support the initiation of clinical trials as well as any FDA designations that the Group should apply for, such as Accelerated Approval or Orphan Drug Designation.

IND-enabling studies

An Investigational New Drug (IND) application is the request for permission from the FDA to initiate human studies of a new drug. IND applications should contain information regarding animal pharmacology and toxicology studies, manufacturing information and clinical protocols.

The Group plans to perform ADME (absorption, distribution, metabolism and excretion) and toxicology tests of CDX Ab in non-human primates (macaques). As well as demonstrating the safety profile of CDX Ab, conducting toxicology studies in Rhesus monkeys should help indicate whether CDX Ab would eliminate the primate's blood stem cells and provide an indication of efficacy in human trials.

Clinical studies

If the Hemogenyx application receives IND approval, the Group is looking to conduct an initial Phase 1 study in patients with relapsed or refractory FLT3-positive acute myeloid leukaemia (r/r AML) who are eligible for bone marrow transplantation. This would take the form of a dose-escalation study and, as well as evaluating safety, should generate data on the ability of CDX Ab to:

- Eliminate blood stem cells (myeloablative conditioning)
- Eliminate diseased cells (i.e. FLT3-positive AML cancer cells)

By performing the trial in r/r AML patients eligible for bone marrow transplants the Group could gain information for the CDX Ab's potency as a conditioning therapy for bone marrow transplants as well as for the direct treatment of AML.

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CDX Ab: Rationale and preclinical data

Why is FLT3 an attractive target for a targeted blood therapy?

The CDX Ab recognises FLT3 on the target (diseased) cell. FLT3 is a receptor protein involved in cell signalling for proliferation and differentiation of blood stem cell cells. FLT3 expression is normally restricted to blood stem cells, making it an attractive target for a conditioning therapy. FLT3 has also been shown to be overexpressed in several diseased blood cells, such as AML cancer cells. Mutations of FLT3 are found in c.40% of AML patients, therefore CDX Ab could be used to treat FLT3-positive AML cancer cells.

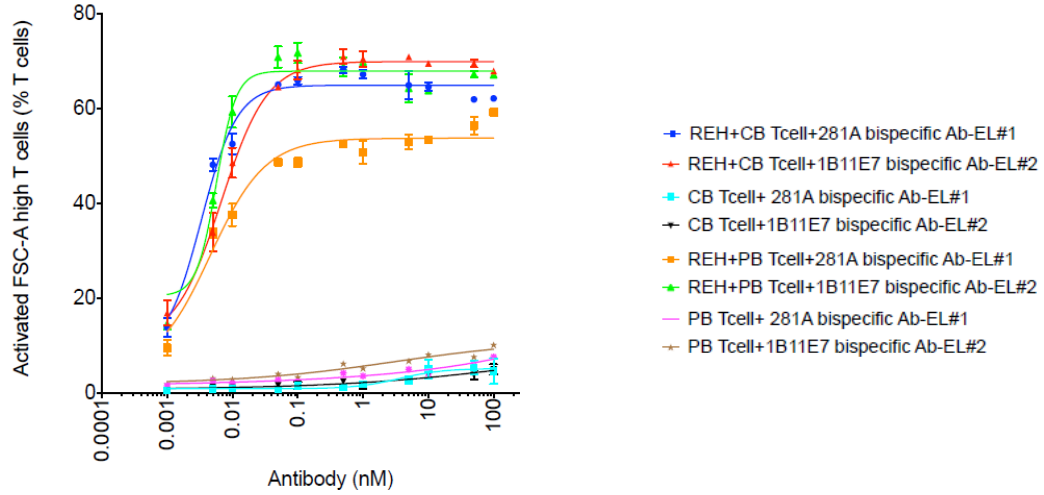
High specificity to FLT3 is a promising indication of safety

CDX Ab are highly specific to FLT3 and have been shown to not activate T-Cells in the absence of target (diseased) cells. This is because the binding affinity on the FLT3 'arm' of the antibody is c.10x higher than that of the CD3 'arm'. This means the CDX Ab does not activate T-cells in the absence of the target cell, which can lead to immune-mediated adverse reactions (Figure 6). Expression levels of FLT3 are low in non-blood stem cells reducing the risk of off-target effects.

High efficacy in clearing AML at low concentration

Hemogenyx has performed preclinical tests indicating that CDX Ab is effective in eliminating AML cancer cells. Figure 7 shows that AHC mice with AML cancer were treated with either CDX Ab or a placebo. Samples at Day 21 show that the number of AML cells in the CDX Ab treated group had fallen to c.0% of blood cells (MNCs). This suggests that treatment with CDX Ab nearly eliminated AML.

Figure 6: in vitro studies indicate CDX Ab is only activated in presence of both T-cell and FLT3 positive cells



CB: Cord blood; PB: Peripheral blood; reh: (leuakemia cell line i.e expressing FLT3)

Source: Hemogenyx (note this is preclinical data please see Key Risk section)

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Figure 7: Preclinical studies in AHC mouse model indicates CDX Ab can activate T-cells and eliminate AML

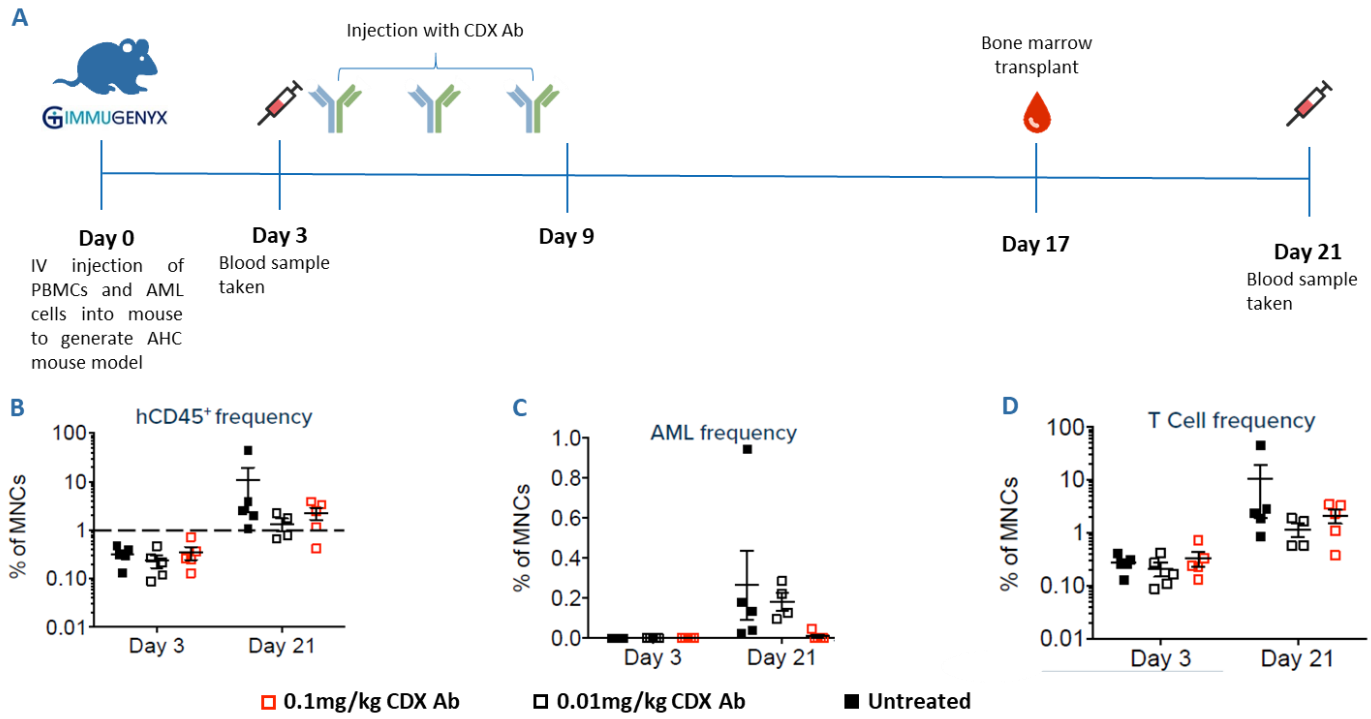
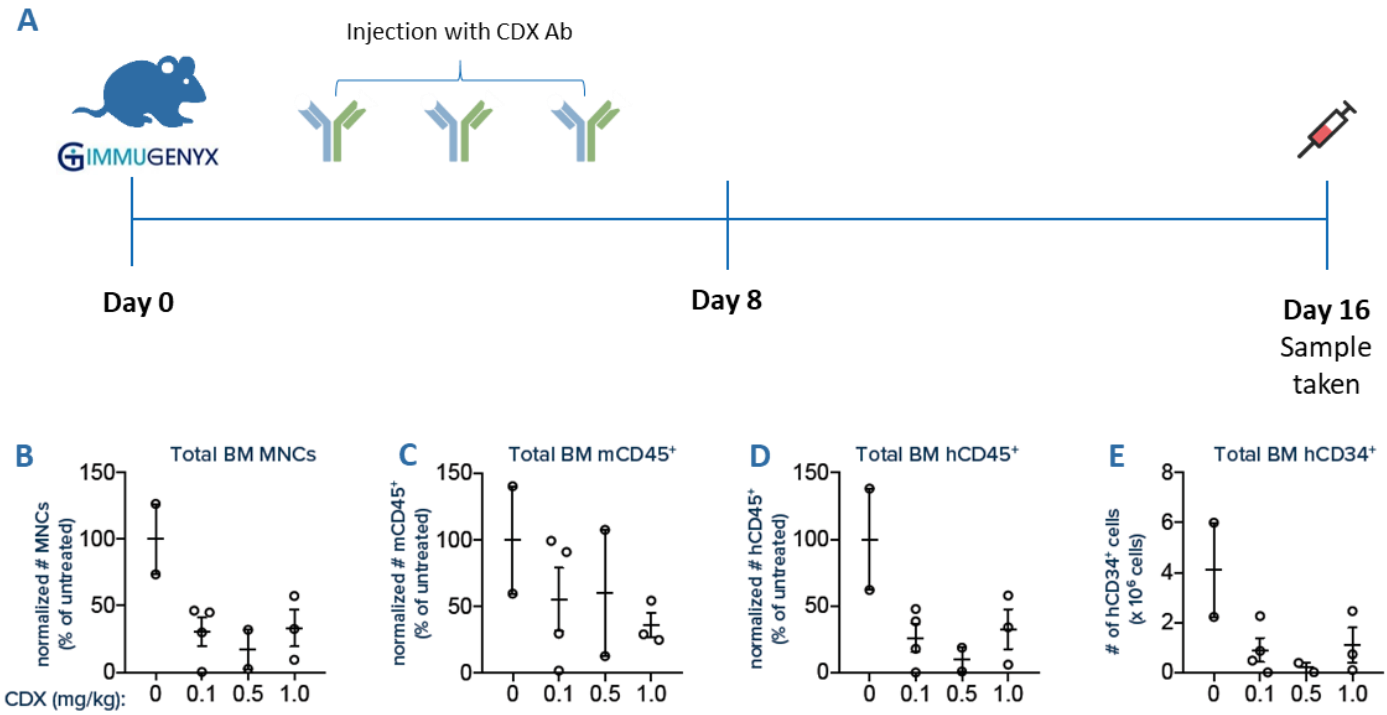


Figure 8: Preclinical studies in AHC mouse model indicates CDX Ab utility as a conditioning agent



Source: Compiled by SP Angel from Hemogenyx data (note this is preclinical data please see Key Risk section)

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Mighty mouse: The AHC mouse model

Mouse models are the workhorse of preclinical testing. Hemogenyx has developed a new humanised mouse model, known as an advanced hematopoietic chimera (AHC), which has been modified to exhibit a near fully-functional human immune system. Originally developed for internal R&D purposes, such as testing the CDX Ab, the AHC model is attracting significant interest from industry.

The development of the AHC model is conducted through Immugenyx LLC, a wholly owned subsidiary of Hemogenyx. Immugenyx aims to continue to strike collaboration agreements with major biopharmaceutical companies to expand the use of the AHC mouse model and generate revenue.

Industry interest in AHC model as R&D tool

The AHC mouse model is generating significant interest as an *in vivo* platform for disease modelling and drug development. The Company has multiple ongoing collaborations with major biopharmaceutical companies and is currently in talks with other companies regarding potential collaborations. Current collaborations include:

- **Unnamed US biotech company**: In March 2018, Hemogenyx partnered with an unnamed US company which is using the AHC model to evaluate its drug candidates. This collaboration is expected to generate $377k in revenue with scope for future revenue.
- **Johnson & Johnson**: In October 2018, Hemogenyx partnered with Janssen LLC, a subsidiary of Johnson & Johnson. The collaboration aims to develop a model of human lupus using AHC which can be used to understand mechanisms of the disease and to develop new treatments. This collaboration is expected to generate an undisclosed amount of revenue. Janssen has an extensive rheumatology portfolio including ustekinumab, a treatment for Lupus in Phase 3 trials.
- **Orgenesis:** In October 2018, Immugenyx signed a collaboration agreement with Orgenesis, Inc (NASDAQ: ORGS) to further develop the AHC model. Orgenesis invested US$1m into Immugenyx through a convertible loan note with the option to invest a further US$1m.
- **Rockefeller University:** In May 2018, the Group entered into a collaboration agreement with Rockefeller University which aims to develop the AHC mouse for autoimmune disease modelling to develop new treatments for Lupus.

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Applications of AHC mouse model

- **Disease modelling:** AHC mice can be used for disease modelling for mapping disease progression and testing therapies. This approach was previously applied to test CDX Ab against AML cancer cells transplanted into AHC mice. It is the focus of the J&J collaboration to develop a form of AHC mouse which can be used for modelling of autoimmune diseases such as lupus.
- **Drug testing:** As the mice have a near-human immune system they can can be used to test the safety profile of drugs and their effect on the immune system. Immune-mediated adverse drug reactions are rare but serious events and the ability to evaluate the risk of a serious side effect occurring prior to testing in humans is valuable to drug developers.
- **Biodefence applications:** The AHC mice are able to rapidly generate human antibodies when stimulated with an antigen. This could be useful in developing therapies against potential bioweapons, where speed is of the essence.
- **Personalised medicine:** The AHC model can be modified with patient-specific blood cells to enable patient-specific drug tests.

AHC mice: Rationale and preclinical data

Mechanism of action

Currently some methods of generating mice with a humanised immune system involve transplanting human peripheral blood mononuclear cells (PBMC) into immune-compromised mice. Immugenyx has developed a novel method of processing the human PBMC prior to transplantation into the mouse. This method has been shown to support successful engraftment and reduce the development of Graft vs Host Disease (GvHD). GvHD is a complication whereby the transplanted immune cells attack the host. GvHD often occurs in mice models which use transplanted material making them difficult to use.

Preclinical studies demonstrate features of AHC mice versus standard models

Immugenyx has performed studies with its mouse model against the current standard model. The AHC mice generate human forms of most of the major blood cell lineages such as T-cells and B-cells. These cell lines have been shown to be functional and can generate human antibodies and cytokines upon *in vitro* stimulation. The mice also survive longer than current models which have a shorter lifespan. Hemogenyx's AHC mice exhibit a high level of similarity to the human immune system. Having an animal model comparable to a human system allows researchers to make a stronger prediction about the potential efficacy and safety profile of a drug prior to entering expensive human trials.

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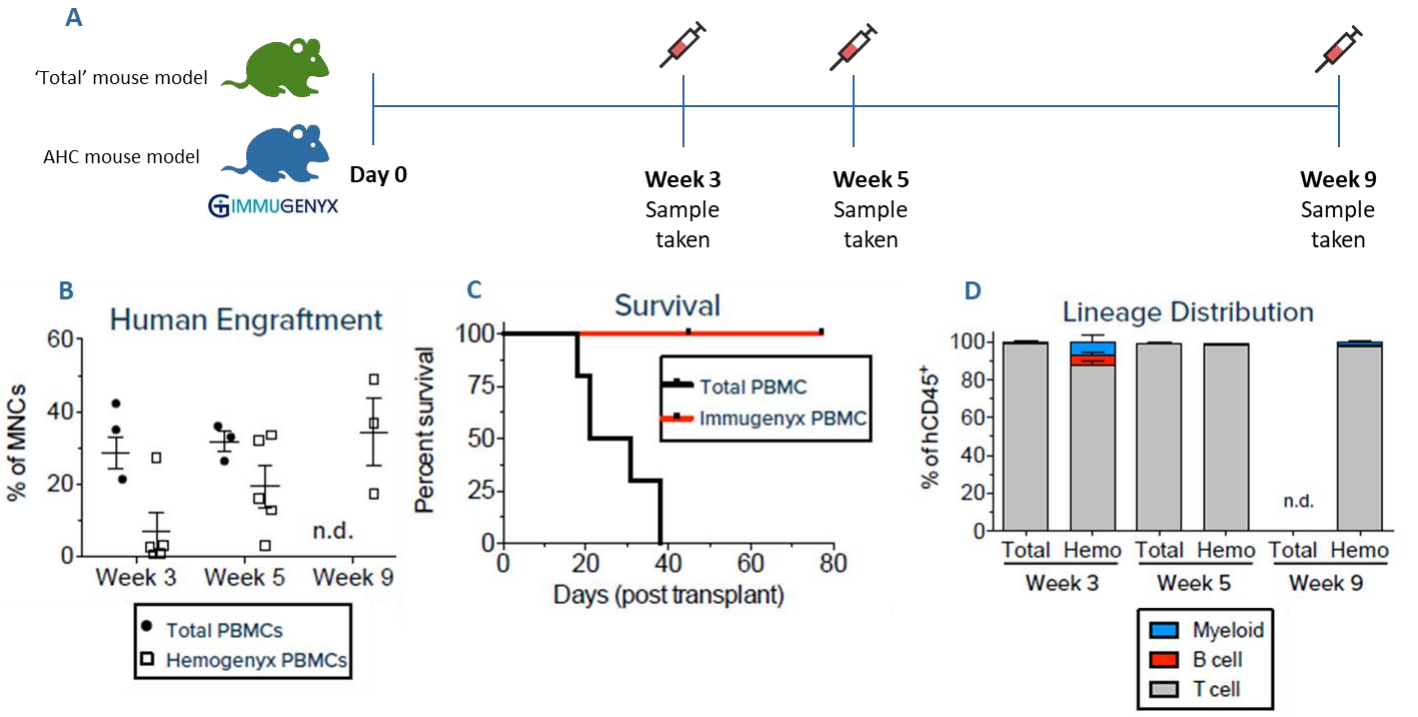
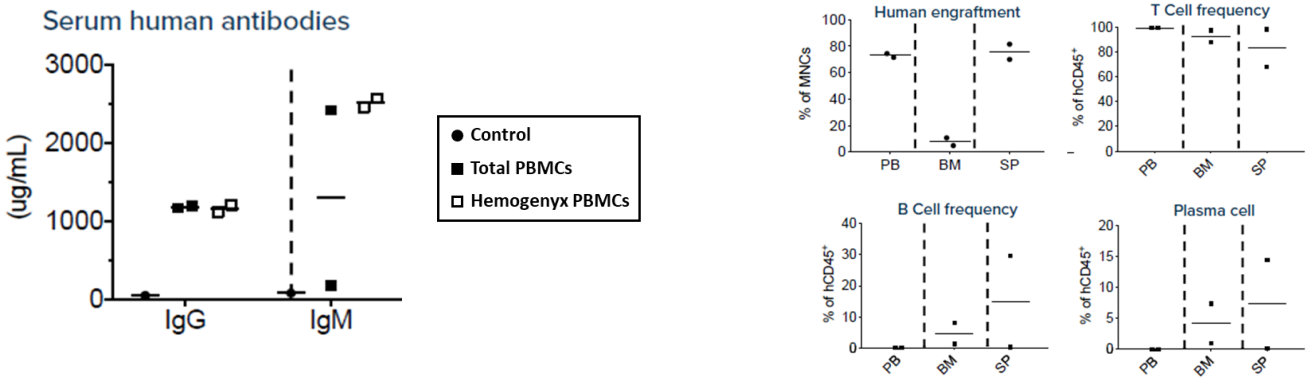
Figure 9: Preclinical study testing the AHC mice against a standard model (PBMC)



***PBMC**: peripheral blood mononuclear cells; **MNC**: mononuclear cells*
***Description**: (A) The AHC mouse model was compared against a 'Total' mouse model with samples taken at week 3, 5 and 9. (B) The number of human blood cells present in mouse model (C) Survival of mouse models after transplantation (D) Percentage of human blood cells which express CD45 (biomarker) that are myeloid or B/T immune cells*

Source: Hemogenyx (note this is preclinical data please see Key Risk section)

Figure 10: AHC mice are able to produce human antibodies; AHC mice have human blood cells



***IgG**: Immuglobulin G; **IgM**: Immuglobulin M; (forms of antibodies); **PB**: Peripheral Blood; **BM**: Bone marrow; **SP**: Bone Marrow Side Population*

Source: Hemogenyx (note this is preclinical data please see Key Risk section)

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Hu-PHEC Cell Therapy

Hemogenyx is developing a cell therapy known as Hu-PHEC (post-natal Hemogenic Endothelial Cells) which can generate cancer-free, patient matched blood stem cells for transplantation during bone marrow transplants.

Hu-PHEC is based on naturally-occurring cells known as adult hemogenic endothelial cells. These cells are easily isolated from the patient and do not accumulate cancer-related mutations. Using Hu-PHEC, a patient's diseased blood and bone marrow can be regenerated from a transplanted population of blood stem cells obtained from either a non-self-donor or the patients themselves. Furthermore, these Hu-PHEC cells are amenable to genetic modification which gives the option of introducing beneficial traits into the cells, as seen in CAR-T. The proof of principle for Hu-PHEC has been demonstrated in mice studies which showed successful engraftment generate healthy blood stem cells.

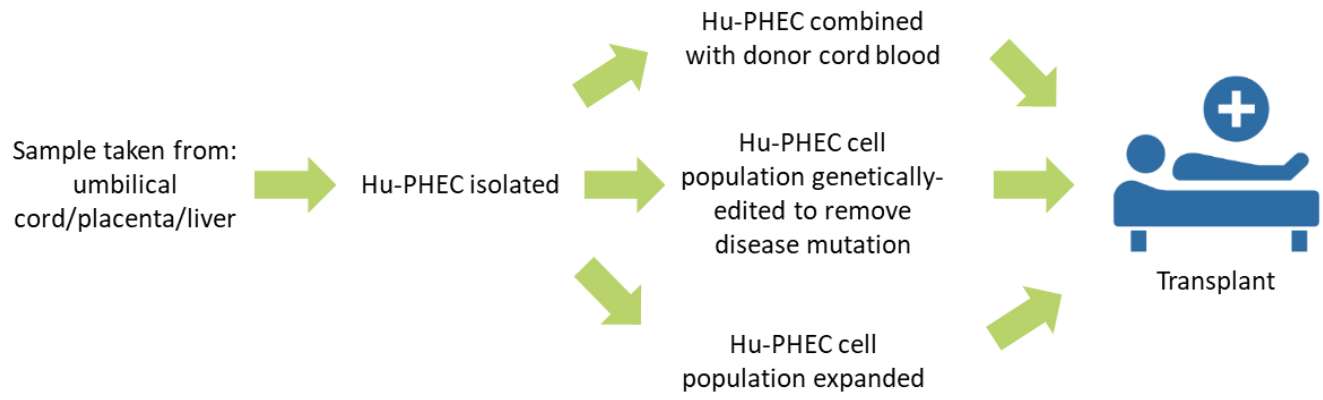
There are three segments of the Hu-PHEC platform:

1. **Hu-PHEC Umbilical:** Cells are isolated and purified from the umbilical cord.
2. **Hu-PHEC Liver**: Hu-PHEC cells derived from the liver cells.
3. **Hu-PHEC Expanded:** A method of expanding Hu-PHEC cells to generate a supply of healthy blood stem cells.

Scope for non-dilutive funding

The Hu-PHEC platform is being developed through Hemogenyx-Cell SPRL, a wholly-owned subsidiary of Hemogenyx. Hemogenyx-Cell was incorporated in Belgium on 9 April 2019. Being registered in Belgium allows Hemogenyx-Cell to be eligible for financial support from the Belgian government in the form of non-dilutive matching grants. The subsidiary has lodged an application for a matched funding grant with the Belgian government.

Figure 11: Hu-PHEC potential treatment pathways for bone marrow transplants



Source: Compiled by SP Angel

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FDA Orphan Drug Designation

In 2015, Hemogenyx received Orphan Drug Designation from the FDA regarding the use of Hu-PHEC to treat aplastic anaemia, a condition whereby blood stem cells cannot produce enough new blood cells, resulting in fatigue and uncontrolled bleeding. Although an orphan indication (c.2 new cases per million population), Hemogenyx chose to target this disease as it is a simple condition where results of Hu-PHEC therapy application may be easily observed.

Collaboration agreements

The Company has achieved multiple collaborations and investments to help develop Hu-PHEC to commercialisation including:

University of Oxford

- In November 2017, the Company entered a collaboration with the University of Oxford to test methods of accelerating and improving the growth of blood stem cells to produce healthy blood cells. The collaboration will apply certain biologics developed by Oxford University to blood stem cells to test if they can improve the engraftment of blood stem cells after transplantation. This collaboration should help the development of the Hu-PHEC platform.

Orgenesis

- In October 2018, Hemogenyx-Cell entered a collaboration agreement with Orgenesis for the development and commercialisation of Hu-PHEC. Orgenesis is investing into Hemogenyx-Cell through a convertible loan of c.S$1m with the right to convert into Hemogenyx-Cell shares based on a pre-money valuation of US$12m. Orgenesis has an option to invest additional funds between US$0.5m and US$1m over the next three years. In return, Orgenesis is receiving a non-exclusive global licence to commercialise and market Hemogenyx-Cell's technology, whilst Hemogenyx-Cell will receive a 12% royalty on Orgenesis' net revenues generated from Hemogenyx-Cell technology. The agreement provides capital to further the development of the Hu-PHEC cell therapy product and has the potential to provide future revenue from royalties.

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Blood diseases: Background

There is an increasing demand for effective therapies against blood diseases. Blood cancers affect over 1.3 million people in the US, and it is estimated that c.174,000 new blood cancer diagnoses were made in 2018 alone (Source: Leukaemia & Lymphoma Society).

Initial treatment of blood diseases has historically relied on chemotherapy or radiotherapy to eliminate diseased blood cells, however these treatments also target healthy cells and have toxic side-effects. Immunotherapies such as antibodies and CAR-T are becoming more established as first-line treatment, however if these treatments fail the last-line option is a bone-marrow transplant. Bone marrow transplants involve the removal and replacement of damaged blood stem cells with healthy blood stem cells to restore the function of healthy blood cell production. There are two main bone marrow transplant methods:

- **Autologous:** Uses blood stem cells obtained from the patient themselves.
- **Allogeneic:** Uses blood stem cells obtained from a donor.

Both autologous and allogeneic BMTs are inefficient and risky, with a high probability of disease relapse or post-operative complications. The bone marrow transplant procedure involves three main steps:

1. **Conditioning:** The patient is treated with radiation and/or chemotherapy. This is necessary to generate both space and an immune-suppressed environment to allow healthy blood stem cells to be transplanted and eliminate diseased blood stem cells to prevent disease relapse.
2. **Transplantation:** Healthy blood stem cells are transplanted into the conditioned patient.
3. **Recovery:** Patient recovers and is monitored to ensure there are no complications after the transplant operation.

Hemogenyx could de-risk the bone marrow transplant procedure

Bone marrow transplants are a risky surgical procedure with risk of infection and/or transplant rejection and are therefore reserved for patients with imminently life-threatening disease. There is an acute shortage of bone marrow transplant donors. It is estimated that over 65% of patients eligible for a bone marrow transplant are unable to find an appropriate match for a donor. Finally, there is also a high failure rate of bone marrow transplant procedures. It is estimated that up to 50% of bone marrow transplants fail due to transplant rejection, disease relapse or complications from the procedure. Due to these risks, bone marrow transplantation is not available to many patients who may benefit from the procedure. Hemogenyx's CDX and Hu-PHEC platforms may de-

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risk the entire transplant pathway, increasing patient eligibility and the total number of transplants, while reducing the need for bone marrow donors.

Furthermore, Hemogenyx's products could expand the total addressable population. Currently, c.50% of patients who need a transplant are not fit enough to undergo chemotherapy for conditioning and c.50% of patients cannot find a donor whilst c.40% of transplants fail. By providing a less toxic conditioning step through the CDX Ab, whilst eliminating the need for donors through Hu-PHEC, Hemogenyx may allow more patients to receive this life-saving treatment.

Market size

Bone marrow transplants

As mentioned, Hemogenyx's products could provide a superior alternative to standard-of-care treatments but also expand patient eligibility.

In 2017 there were c.22,000 bone marrow transplants per year in the US and c.40,000 in Europe (US HRSA, transplants outcomes and data; EBMT annual report 2017). With the average cost of a bone marrow transplant costing roughly $890k (allogeneic) and $400k (autologous) (Source: Milliman Inc), this represents a large addressable market. Bone marrow transplants are a specialist procedure performed mainly in specialised hospitals. In the US there are c.176 transplant centres (National Marrow Donor Program) with the leading 20% of institutions performing c.50% of transplant volume. In 2015 there werec.22,000 transplants performed in the US which is forecast to increase by c.5% y/y whilst in Europe there were c.45,500 (EBMT Annual report 2018).

AML

AML is an aggressive form of blood cancer where the bone marrow is unable to produce the components of the blood, resulting in anaemia and immunodeficiency. There are c.50k AML patient in the US with c.19k new cases diagnosed in 2018. CDX Ab have been shown to eliminate cancerous AML cells thus presenting a potential use as a therapy either standalone or in combination with an existing therapy. There is a considerable market opportunity in AML. Xospata (gilteritinib), an FLT3 inhibitor developed by Astellas Pharma, received FDA approval for use in AML patients with a FLT3 mutation as detected by an FDA-approved test (link to FDA article. Astellas predicts Xospata revenues of c.$137m in FY20.

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Intellectual property

Hemogenyx is developing an IP portfolio to protect the assets across its pipeline and aims continues to extend its patent portfolio to provide adequate protection from competition.

Table 4: Hemogenyx patents

Application Country	Application Number	Application Date	*Title*	Expiration Date	Owner
US	PCT/US2017/02595 1	4 April 2017	*Method of eliminating hematopoietic stem cells/hematopoietic progenitors (hsc/hp) in a patient using bi-specific antibodies*	2037	Hemogenyx
US	PCT/US2014/065469	Nov. 13, 2014	*Post-natal hematopoietics endothelial cells and their isolation and use*	2034	Cornell University

Source: USPTO

CDX bi-specific antibodies

The provisional patent application relating to CDX Ab was filed by Hemogenyx LLC in April 2016. In April 2017, Hemogenyx filed a Patent Cooperation Treaty (PCT) application which protected specific sequences of several CDX Ab variants discovered and validated by Hemogenyx. The claim transformed the original method of use application into a composition of matter application.

Hu-PHEC cell therapy patent

The patent relating to Hu-PHECs was filed by Cornell University in November 2014. The patent covers a method of isolation and identification of Hu-PHEC cells as well as methods to utilise the cells to regenerate the blood system in a patient.

Cornell licencing

Hu-PHEC Cornell Patent licencing

Hemogenyx was granted an exclusive global licence effective from January 2015 to develop and commercialise Hu-PHECs. The consideration for the license was $347,500 which was paid off as part of the RTO placing. The remaining terms of the licence for the Hu-PHEC patent include conditional milestone payments and an annual licence fee of up to £55k until commercial sales are achieved. If commercialised, Cornell receives 2-5% royalties on all net sales.

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Financials

Income Statement

Table 5: Income Statement (£)

Fiscal Year	2016A	2017A	H1 2018	2018A
Fiscal Period end date	31/12/2016	31/12/2017	30/06/2018	31/12/2018
Revenue	-	-	-	-
Gross profit	**-**	**-**	**-**	**-**
Administrative expenses	(447,152)	(837,060)	(715,474)	(1,563,430)
Depreciation Expense	(11,870)	(33,614)	(24,747)	(51,805)
Operating profit/EBIT	**(459,022)**	**(870,674)**	**(740,221)**	**(1,615,235)**
Other income	-	101,138	92,798	91,357
Finance costs	(11,817)	(10,741)	-	4,374
Reverse acquisition expense	-	(1,631,020)	-	(1,779)
Profit before tax	**(470,839)**	**(2,411,297)**	**(647,423)**	**(1,521,283)**
Income tax credit (expense)	-	49,698	-	43,751
Profit after tax	**(470,839)**	**(2,361,599)**	**(647,423)**	**(1,477,532)**
Translation of foreign operations	26,526	(36,652)	20,783	51,031
Comprehensive income/(loss) to the year	**(444,313)**	**(2,398,251)**	**(626,640)**	**(1,426,501)**
Weighted average number of ordinary shares in issue	145,166,853	260,270,699	260,270,699	360,125,230
EPS	**(0.00)**	**(0.01)**	**(0.00)**	**(0.41)**

Source: Hemogenyx financial statements

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Cash flow

Fiscal Year	2016A	2017A	H1 2018	2018A
Fiscal Period end date	31/12/2016	31/12/2017	30/06/2018	31/12/2018
EBIT	**(470,839)**	**(2,361,599)**	**(647,423)**	**(1,477,532)**
Depreciation & Amortisation	11,870	33,614	24,747	51,805
EBITDA	**(458,969)**	**(2,327,985)**	**(622,676)**	**(1,425,727)**
Share based payments	-	35,492	77,507	242,530
Change in trade and other payables	9,507	7,637	32,276	(98,670)
Change in trade and other receivables	(163,209)	86,260	(113,430)	(19,266)
Change in prepayments	-	-	-	-
Working capital movements	(153,702)	93,897	(81,154)	(117,936)
Operating CF	**(612,671)**	**(2,198,596)**	**(626,323)**	**(1,301,133)**
Interest	12,035	10,462	0	1,773
Capex	(188,785)	(64,257)	(24,351)	(24,589)
Tax	-	-	-	
FCF	**(789,421)**	**(2,252,391)**	**(650,674)**	**(1,323,949)**
Acquisitions/Disposals	-	-	-	-
Cash acquired on acquisition	-	1,098,640	-	-
Working capital changes applicable to pre-acquisition retained earnings	-	(1,145)	-	-
Share issues/reverse acquisition	754,914	1,616,129	4,993	4,993
Debt movements	-	(399,422)	-	1,175,915
Reverse Acquisition Expense	-	1,631,020	-	-
Other non cash items	60,358	105,000	-	-
Change in cash	**25,851**	**1,797,831**	**(645,681)**	**(143,041)**
FX effect on cash	13,982	(8,399)	11,952	28,814
Cash at beginning of period	47,390	87,223	1,876,655	1,876,655
Cash at end of period	**87,223**	**1,876,655**	**1,242,926**	**1,762,428**

Source: Hemogenyx financial statements

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Balance Sheet

Fiscal Year	2016A	2017A	H1 2018	2018A
Fiscal Period end date	31/12/2016	31/12/2017	30/06/2018	31/12/2018
PPE	175,797	191,578	194,326	173,943
Intangible assets	281,577	257,525	263,132	272,753
Non-current assets	**457,374**	**449,103**	**457,458**	**446,696**
Trade and other receivables	162,059	69,784	183,296	90,475
Cash and cash equivalents	87,223	1,876,655	1,242,926	1,762,428
Current assets	**249,282**	**1,946,439**	**1,426,222**	**1,852,903**
TOTAL ASSETS	**706,656**	**2,395,542**	**1,883,680**	**2,299,599**
Called up share capital	1,010,849	3,600,514	3,601,762	3,601,762
Share premium	-	7,341,056	7,340,631	7,340,267
Other reserves	-	369,147	450,824	620,059
Reverse asset acquisition reserve		(6,157,894)	(6,157,894)	(6,157,894)
Foreign currency translation reserve	22,668	(13,984)	6,799	37,047
Retained Earnings	(645,383)	(3,006,982)	(3,654,405)	(4,482,075)
Total equity	**388,134**	**2,131,857**	**1,587,717**	**959,166**
Trade and other payables	16,687	7,333	283,250	167,607
Accruals and deferred income	-	256,353	-	-
Current borrowings	38,489	-	-	-
Current liabilities	**55,176**	**263,686**	**283,250**	**167,607**
Non-current Borrowings	263,346	-	12,713	1,172,826
Non-Current liabilities	**263,346**	**-**	**12,713**	**1,172,826**
TOTAL LIABILITIES	**318,522**	**263,686**	**295,963**	**1,340,433**
TOTAL EQUITY + LIABILITIES	**706,656**	**2,395,543**	**1,883,680**	**2,299,599**

Source: Hemogenyx financial statements

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Key risks

As an early-stage healthcare company Hemogenyx is exposed to risks inherent to the sector. Of these potential risks, development risk and the regulatory pathway and are the most relevant to the Group.

Preclinical developmental risk

As a preclinical company Hemogenyx has not yet generated human data using its product candidates. Preclinical testing can be lengthy and uncertain and there is no guarantee that Hemogenyx will receive IND-approval from the US FDA to test their products in humans. Candidates may be subject to delayed entry into clinical trials or may not progress to the clinic. There is no guarantee that results in preclinical tests will be replicated in humans.

Clinical trial risk

The outcome of clinical trials cannot be pre-determined and there is no guarantee that any future clinical trial conducted by Hemogenyx will meet the primary endpoint. The Company's development programmes are always at risk of termination should any future trial raise any concerns about a product's safety or efficacy. Clinical trials may raise safety issues and there may be requests for additional clinical data by the FDA. Both of these possibilities would require additional working capital.

Regulatory risk

There is no guarantee that Hemogenyx will receive marketing approval for its proposed treatments and a delay or failure to receive marketing approval could have a negative impact on the Company's operation.

Commercial risk

Potential commercial uptake of the Company's products may be slower than expected and there is no guarantee that the Group will successfully partner its assets.

Key personnel

The loss of personnel such as Vladislav Sandler, CEO, may have a negative impact on the Company's strategy and ability to achieve future milestones.

Financial Risk

To fund its ongoing operations, we expect the Company to require additional capital over the coming years.

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Management team

Hemogenyx benefits from a management team with a wealth of experience running life-science companies.

Professor Sir Marc Feldmann – Non-Executive Director & Chairman

Marc Feldmann is a medically trained immunologist at the University of Oxford where he was Head of the Kennedy Institute of Rheumatology until 2014 and now Emeritus Professor. He trained in medicine at Melbourne University and then earned a Ph.D. in Immunology at the Walter & Eliza Hall Institute with Sir Gus Nossal, before working in London at the Imperial Cancer Research Fund. Sir Marc's main research interests are immunoregulation, understanding mechanisms of autoimmunity and the role of cytokines in disease, and working out how to fill unmet medical needs.

His work in London led to the generation of a new hypothesis for the mechanism of autoimmunity, linking upregulated antigen presentation and cytokine expression. Testing this hypothesis led to the discovery, with colleague Sir Ravinder Maini, of the pivotal role of TNFα (Tumor Necrosis Factor alpha) in the pathogenesis of rheumatoid arthritis. This major discovery has revolutionised therapy not only of rheumatoid arthritis but other chronic inflammatory diseases (e.g. Inflammatory bowel disease, psoriasis and ankylosing spondylitis), and helped change the perception of monoclonal antibodies from niche products to mainstream therapeutics. Anti-TNF therapeutics are the current leading drug class with 2016 sales exceeding US $36 Billion.

Dr Vladislav Sandler – Chief Executive Officer

Dr Vladislav Sandler is the Co-Founder and CEO of Hemogenyx and a research Assistant Professor at the State University of New York (SUNY) Downstate. Dr. Sandler is a widely published stem cell scientist with decades of experience in scientific research. He received his PhD from the University of British Columbia and is a member of the International Society for Stem Cell Research.

Dr Sandler has conducted his research in Russia, Israel, Canada and the United States, including at Children's Hospital, Harvard Medical School, the Salk Institute for Biological Sciences, Harvard University and Albert Einstein College of Medicine, among others. He also led a team of scientists at Advanced Cell Technologies, Inc. and was most recently on the faculty of Weill Cornell Medical College. While at Cornell, Dr Sandler made the significant discovery that the cells that give rise to blood stem cells during mammalian development continue to exist after birth, and he developed the method of isolation of these cells from humans. As a result of this important work, Dr Sandler was awarded the inaugural Daedalus Fund Award for Innovation at Cornell. He went on to found

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Hemogenyx in order to further pursue this significant scientific discovery and his dedication to the translation of science into clinical practice.

Alexis M. Sandler – Non-Executive Director

Alexis M. Sandler is the co-founder of Hemogenyx, for which she has served as the Chief Operating Officer. Ms. Sandler is an attorney specialising in intellectual property, with almost 15 years of experience representing a range companies and institutions. Ms Sandler is especially skilled at handling diverse interests in day-to-day matters of organisations, multi-party agreements and long-term strategic planning.

Ms. Sandler began her legal practice in Los Angeles at Hogan & Hartson LLP (now Hogan Lovells), where she specialised in entertainment and media law and intellectual property. She then worked for several years at Katten Muchin Rosenman LLP representing studios, production companies, television networks and other major media companies in all aspects of entertainment, media and intellectual property law. For three years, Ms Sandler worked as the Director of Business and Legal Affairs for a division of the Fox Entertainment Group, during which time she was named one of Southern California's Best Young Lawyers by Los Angeles magazine. While at Fox Ms. Sandler successfully negotiated hundreds of major distribution agreements, in addition to advising the company on important corporate and other legal matters. Ms Sandler went on to become the General Counsel at a Smithsonian affiliate museum in New York City. Ms. Sandler is currently the Associate General Counsel for a major New York City cultural institution. She also serves as the Secretary of the Board of Directors for MoMA PS1, the contemporary art space.

Ms. Sandler received her AB from Harvard University and her JD from the UCLA School of Law, and is a member of the State Bar of New York and the State Bar of California.

Peter Redmond – Non-Executive Director

Peter Redmond is a corporate financier with some 30 years' experience in corporate finance and venture capital. He has acted on and assisted a wide range of companies to attain a listing over many years, on the Unlisted Securities Market, the Full List and AIM, whether by IPO or in many cases via reversals, across a wide range of sectors, ranging from technology through financial services to natural resources and, in recent years has done so as a director of the companies concerned. He has been active over many years in corporate rescues and reconstructions on AIM and in reverse transactions into a range of investing companies. He was a founder director of Cleeve Capital plc (now Satellite Solutions plc) and Mithril Capital plc (now BeHeard Group plc), both of which were admitted to the Standard List of the London Stock Exchange, and took a leading role in the reconstruction and refinancing of AIM-quoted

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Kennedy Investments plc and 3Legs Resources plc (now SalvaRx plc). Peter is Chairman of AIM-quoted Pires Investments plc and URA Holdings plc.

Andrew Wright – Financial Controller

Andrew began his career in audit at PricewaterhouseCoopers and has an MBA in Finance and Strategy from the UCLA Anderson School of Management in Los Angeles, USA. He serves as Director of Corporate Development and Technology for Thomas Murray, a post-trade capital markets data and advisory firm. Andrew is also an Executive Director of Trayned Insight Ltd, a data science company serving the healthcare and pharmaceutical industries.

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Recommendations are based on a 12-month time horizon as follows:

Buy - Expected return >15%

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

Sell - Expected return < 15%

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