

#### HEMOGENYX PHARMACEUTICALS PLC



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### COMPANY INFORMATION

#### **Directors**

Dr Vladislav Sandler (Chief Executive Officer) Professor Sir Marc Feldmann (Chairman) Alexis Sandler (Non-Executive Director) Peter Redmond (Non-Executive Director)

#### **Company Secretary**

**Andrew Wright** 

#### **Registered Office**

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#### **Registered Number**

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#### **Joint Brokers**

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#### **Independent Auditor**

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#### **UK Solicitors**

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#### **US Solicitors**

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#### **Principal Bankers**

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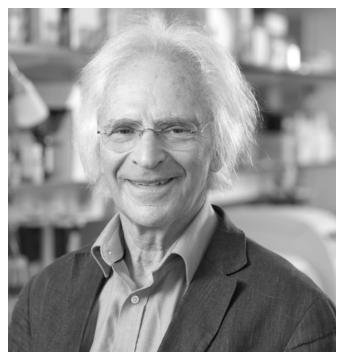
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#### CHAIRMAN'S STATEMENT



It is my pleasure to report that over the past year there was further significant development for Hemogenyx Pharmaceuticals. The period saw further growth and acceleration of the development of the Company's pipeline. This was marked by the creation of additional technologies and product candidates, strengthened intellectual property protection, partnerships with yet more internationally renowned institutions, and – despite the challenges posed by the coronavirus pandemic – continued material steps toward the important transition from a pre-clinical to a clinical study-stage business.

The Company's principal business is the development of new treatments for serious blood diseases such as blood cancers and severe autoimmune diseases, while also focusing on the multi-billion dollar bone marrow/hematopoietic stem cell transplant market. Our products address large and growing needs, and could enable a much wider range of patients to be treated than is presently the case since they should be more suitable for patients who are currently deemed unfit for bone marrow transplants or for whom there is a lack of suitable donors.

The Company's subsidiary, Immugenyx LLC, continues work on Advanced Hematopoietic Chimeras – mice with uniquely humanised blood/immune systems – as a platform for creating models of various diseases and for discovering treatments and developing new drugs. The

last year has also seen the establishment of an exciting and flexible new platform technology that may be applied to create treatments for some forms of cancer and also for viruses such as SARS-CoV-2, the virus responsible for COVID-19. As a result, the pipeline has grown to a roster of six product candidates, compared to two when the Company first listed on the London Stock Exchange in 2017. This number is unusual for such a small company as Hemogenyx Pharmaceuticals.

#### The Company's six product candidates are:

- CDX antibody a bispecific antibody targeting a majority of forms of relapsed/refractory acute myeloid leukaemia ("R/R AML"), subset of acute lymphoblastic leukaemia ("ALL"), and myelodysplastic syndrome (myelodysplasia or "MDS") – conditioning bone marrow transplants to substitute traditional chemotherapy and/or radiation.
- CAR-T cell therapy chimeric antigen receptor T-cells that are engineered for use in immunotherapy, also targeting R/R AML and being developed as a potential alternative conditioning regimen for bone marrow transplants.
- Hu-PHEC stem cell therapy Human Post-natal Hemogenic Endothelial Cells are a type of cell and associated cell therapy that generate cancer-free hematopoietic stem cells for use in transplants to treat blood disorders.
- Humanised mice Advanced peripheral blood Hematopoietic Chimera mice are a novel type of humanised mice that serve as a platform technology to model a wide variety of diseases for drug discovery and target validation.
- Undisclosed the Company's early-stage programme designed for the discovery and validation of novel targets and therapeutic-like molecules for the treatment of Lupus and/or other autoimmune diseases, in collaboration with the global biopharmaceutical company Eli Lilly.
- CBR platform a recently developed platform whose first application is the programming of immune cells for targeting viral pathogens including SARS-CoV-2 and other existing and yet unknown viruses. A further potential application of the CBR platform is to target malignant cells that cause cancers.

These product candidates, their current state of development, and scientific and commercial progress in the financial year and into 2021 are further elaborated below.

#### **CDX Antibody**

The Company's work on its bispecific antibody targeting some forms of R/R AML, ALL and MDS, its first major project, continued apace in 2020. Most notably, the collaboration with the global pharmaceutical company referred to as "GlobalCo" to co-develop the antibody continued through the year, with some extensions to allow for the impact of the COVID-19 pandemic on GlobalCo's operations.

The Company believes that the use of FLT3-CD3 (FMSlike tyrosine kinase 3) bispecific antibodies to eliminate hematopoietic stem cells/hematopoietic progenitors ("HSC/HP") will make conditioning for bone marrow transplants safer by eliminating the side effects that accompany traditional methods of patient preparation for bone marrow ("BM")/HSC transplantation. The Company's studies to date suggest that the antibodies will significantly reduce and possibly in some cases eliminate malignant cells and cancer stem cells in patients with refractory or relapsed FLT3-expressing AML. Effective and non-toxic conditioning will extend the use of BM/HSC transplantation to older and more frail patients and potentially target additional indications including autoimmune diseases such as Lupus and Multiple Sclerosis ("MS") for which the risk of conventional BM transplantation has been a major road-block. The risk profile of BM/HSC transplantation using chemo/ radiation conditioning regimes is currently poor. The anticipated drastically improved potential safety profile of conditioning with FLT3-CD3 antibodies will increase the benefit/risk ratio of BM/HSC transplantations, potentially growing the market for such treatments radically and saving greater numbers of lives. These antibodies may also be combined (concurrently or in tandem) with traditional components of conditioning regimens and thus may increase their efficacy while having the potential to lower their dosage, toxicity and corresponding level of undesirable side effects.

The additional time afforded by the extensions to the agreement was used effectively, with a number of additional variants of the antibody developed and tested

systematically. The development stage of the agreement concluded at the start of 2021 with the selection of a highly promising clone with regard to manufacturability, yield and stability, as further described in the section below covering events subsequent to the 2020 financial year.

The antibody is now ready to be taken forward to the final stage of testing prior to filing an Investigational New Drug application with the United States' Federal Drug Administration ("FDA") for approval to commence clinical trials. These remaining pre-clinical studies will involve tests in Rhesus monkeys to demonstrate their safety and predict their efficacy in human trials. Clinical trials would then commence with a group of patients with R/R FLT3+ AML who are qualified for HSC/HP transplantation, in order to obtain preliminary data on safety/dose escalation and on efficacy for elimination of both malignant cells and HSC/HP (i.e. conditioning for bone marrow transplantation).

The Company's patent applications designed to protect its intellectual property progressed during the year and should begin to bear fruit in the near future. An additional composition of matter patent application (covering novel sequences of the antibodies discovered and validated by the Company in collaboration with GlobalCo) is expected to be filed following completion of the GlobalCo collaboration agreement.

#### **CAR-T Cell Therapy**

Chimeric Antigen Receptor T-cells are a novel form of immunotherapy that reprogrammes a patient's own T-cells to recognise antigens expressed by cancerous cells and hence destroy them. The Company's proprietary CAR-T product candidate, which the Company refers to as HEMO-CAR-T, was constructed using its proprietary humanised monoclonal antibody against a target of the FLT3 protein that is over-expressed in AML cells and can be found on their surface. Although a relatively recent addition to the Company's pipeline, this product candidate saw particularly rapid progress during 2020. Testing demonstrated that HEMO-CAR-T was able to effectively programme human T-cells to identify and destroy human AML-derived cells *in vitro* (in non-animal studies) and *in vivo* (in animal studies).

HEMO-CAR-T was further engineered during the year by the Company's scientists in order to increase the safety and versatility of these cells. This led to the introduction of a safety switch mechanism that modulates the activity of HEMO-CAR-T cells and turns them into a "controllable drug" dubbed SAFE-HEMO-CAR-T. This enhancement should dramatically improve the safety and potential versatility of HEMO-CAR-T cells for the treatment of AML and/or conditioning of bone marrow transplants, as well as a number of additional potential indications. SAFE-HEMO-CAR-T therefore represents a tuneable treatment designed to offer control over immune response, alleviating the risk of cytokine release syndrome, a hard-to-predict issue that has arisen during clinical trials of several other CAR-T therapies, slowing their development.

We were delighted to announce in August that we entered into a Sponsored Research Agreement with the University of Pennsylvania ("Penn"), one of the pioneers in this field, to advance HEMO-CAR-T through INDenabling studies towards clinical trials. Moreover, if the collaboration with Penn continues to prove successful, the work will continue right through to achievement of clinical proof of concept. Penn's work is led by Dr Saar Gill. Assistant Professor of Medicine, a haematologistoncologist physician scientist and Scientific Co-Director of the Cell Therapy and Transplantation program at Penn. Dr Gill's laboratory is part of the Center for Cellular Immunotherapies ("CCI") whose Director, Dr Carl H. June, conducted pioneering clinical trials of genetically engineered cells including CAR-T cells in patients with HIV and diverse forms of cancer.

It is noteworthy that Penn is one of the global leaders in this field and does not often work with pharmaceutical groups. The CCI team was responsible for the development of the first of only two CAR-T cell therapies that have received approval to date from the FDA, tisagenlecleucel, now sold by Novartis under the Kymriah® brand name for the treatment of ALL. The Directors believe that this is arguably the best-qualified academic team in the world with which to partner to take this product candidate forward.

#### **Hu-PHEC Stem Cell Therapy**

The Company's Human Postnatal Hemogenic Endothelial Cells ("Hu-PHECs") are a stem cell therapy product

candidate based on Co-Founder and CEO Dr Vladislav Sandler's discovery that hematopoietic progenitor stem cells survive into adulthood. The cells address the problem of blood stem cell donor availability and issues around relapse or cell rejection after transplantation. Hu-PHECs may be used as a source of cancer-free, patient-matched blood stem cells for transplantation into a patient.

The Company's subsidiary in Belgium, Hemogenyx-Cell SPRL, has been considering plans with a number of potential Belgian-based partners, including Orgenesis, Inc. – the provider of funding to Hemogenyx-Cell and also to Immugenyx in a separate agreement through convertible loans – regarding key building blocks for the path through development towards clinical trials of Hu-PHECs, including the establishment of a cell bank.

The Company's intellectual property portfolio began with the licensing of the then-pending patent to Dr Sandler's discovery from Cornell University, where he worked at the time, titled Post-Natal Hemogenic Endothelial Cells and their isolation and use. Patent applications were approved by the United States Patent and Trademark Office and issued on 25 February 2020 as Patent Number 10,570,373, and by the European Patent Office on 13 May 2020 as Patent Number 3068875. The patent applications were filed in 2014 and are the subject of Hemogenyx Pharmaceuticals' exclusive, worldwide sublicensable licence first granted in 2015 and restated in 2019.

#### **Humanised Mice**

The Company's work is greatly accelerated by its uniquely humanised mice, referred to as Advanced Hematopoietic Chimeras ("AHC") and a further enhanced form, Advanced peripheral blood Hematopoietic Chimeras ("ApbHC") that produce a wide range of mature blood cell populations such as human T-cells, B-cells and antibody-producing plasma cells. Unlike other humanised mice, ApbHC do not suffer from Graft versus Host Disease, a disease that complicates and often renders impossible the efficient use of peripheral blood mononuclear cells in transplanted mice, shortening their lifespan and suitability for testing, due to immune cells attacking the host. ApbHC mice also survive for longer than other known mouse models, enabling more testing and more robust results, and thus making them a better

potential predictor of outcomes in human studies.

In addition to their inherent value to the Group internally, the Company or its subsidiary Immugenyx LLC have struck several past and ongoing collaboration agreements involving ApbHC with such highly-regarded pharmaceutical industry names as Eli Lilly and Company ("Lilly") and Janssen Research & Development LLC (a J&J company).

#### **Undisclosed**

On 26 June 2020, we announced the aforementioned Biological Investigation and Material Supply Agreement with Lilly. Under the agreement, Lilly supplies the Company with biological materials and related confidential information in order for the Company to perform research and development activities aimed at the discovery and validation of novel materials to be used for the treatment of Lupus and possibly other autoimmune diseases. This work is complementary to the Company's own development currently being undertaken in this field. Confidentiality stipulations in the agreement mean that developments must remain undisclosed for the time being.

The involvement of Lilly is another major vote of confidence in the Company and its talented team of scientific researchers, as it joins the other global pharmaceutical companies mentioned previously on the roster of the Company's collaborators. This close collaboration offers the potential for ongoing value-adding licensing arrangements with a major pharmaceutical company with the benefit of its global reach and large-scale resources.

#### **CBR**

The Company has been developing a new cell therapy platform which the Company refers to as CBR, the essence of which is the programming of immune cells using a novel type of modifiable synthetic receptor to destroy viral pathogens including SARS-CoV-2, which causes COVID-19. Not only can this type of synthetic receptor potentially combat viral pathogens, it can also potentially be modified to programme immune cells to destroy malignant cells causing cancer. The novel synthetic receptor has no connection to, and does not resemble, any known or widely used CARs (e.g., HEMO-CAR-T), and the Directors are not aware of any

direct competitor for this product candidate at this time. Hemogenyx Pharmaceuticals is now engaged in preclinical validation of two CBR-based product candidates: one for the treatment of COVID-19, and the other for the treatment of an undisclosed type of cancer.

#### **Scientific Community Engagement**

The Company's talented team of scientists has continued to receive recognition from the scientific community and has made well-received presentations on its CDX antibody and CAR-T therapy product candidates at the highly influential Keystone Symposia for Advances in Cancer Immunotherapy in August, and at the American Society of Hematology meeting and exposition in December. Following the year end, the Company also presented its expanded range of product candidates at the H.C. Wainwright Global Life Sciences Conference in March 2021, showcasing Hemogenyx Pharmaceuticals as a leader in the field of development of medicines for the treatment of blood and autoimmune diseases to the investment community.

#### Miscellaneous

In July, the Company announced that its U.S. subsidiary was renamed Hemogenyx Pharmaceuticals LLC in order to align the Company's names across entities and countries, and henceforth always should be referred to as Hemogenyx Pharmaceuticals.

#### **Post Period End Updates**

Following the end of the period under review, the Company has continued to make progress in a number of areas and can highlight to shareholders the following developments:

#### **Convertible Debt Facility**

In November 2020, Mint Capital Limited ("Mint") and the Company entered into a Financing Facility agreement ("Financing Facility") whereby Mint agreed to subscribe for up to £60 million in aggregate principal amount of unsecured Convertible Loan Notes ("CLNs") pursuant to a subscription agreement. The shareholders of the Company approved the facility at a general meeting in January 2021. Further details of the Financing Facility are set out under the Financial Results heading below.

The proceeds of the first tranche of £12,000,000 should



enable the Company to progress at least two of its product candidates – the CDX antibody and HEMO-CAR-T – through IND-enabling studies into clinical trials and, ultimately, to achieve clinical proof of concept.

#### **CDX Antibody**

The Company announced in January 2021 that work with GlobalCo has concluded under the CDX antibody development agreement. The result was the selection of a clone of the antibody that is ready for IND-enabling studies, the key step toward clinical trials. The Company recently received notice that GlobalCo will not in-license the CDX antibody at this juncture, and accordingly gave notice to GlobalCo of its intention to exercise its own option to license GlobalCo's contributions on an exclusive, worldwide basis. As at the date of this document, the Company and GlobalCo are engaged actively in discussions regarding its future development and their respective intellectual property embodied in the final selected clone.

#### **CAR-T Cell Therapy**

Further to the Sponsored Research Agreement with the University of Pennsylvania that commenced in August 2020, a further Master Translational Research Services Agreement was signed in January 2021 under which the Company has retained Penn to conduct additional R&D activities with the involvement of various organisations within Penn. As with the prior agreement, these activities will involve Dr Saar Gill and his laboratory. The intended outcome of the complex of activities under the agreement is attaining clinical proof of concept for HEMO-CAR-T, including its variations such as SAFE-HEMO-CAR-T, for the treatment of AML. The principal stages of activity are:

- Vector manufacturing for the delivery of HEMO-CAR-T to the patient's T-cells;
- 2. An investigational new drug ("IND") filing for permission to conduct clinical trials; and
- 3. Clinical manufacturing of patient-specific HEMO-CAR programmed T-cells.

The Company has initiated the process of engaging contract manufacturing organizations for product development and manufacturing of DNA plasmids, viral vectors and HEMO-CAR-T cells under Current Good Manufacturing Practices ("CGMPs") to support Phase I clinical trials and has contracted Randall Tlachac and his company Quality Systems LLC ("Quality Systems") to provide oversight and direct product development,

manufacturing and quality control operations.

Mr Tlachac has extensive experience in the successful development of cell and gene-based therapies, having led the development of more than 30 products to Phase I/II clinical trial stage, and played a major role in the implementation of Good Tissue Practices regulations since their promulgation in 2004. Quality Systems will be responsible for supporting the Company's chemistry, manufacturing, and controls ("CMC") efforts, including providing support for product development, operations, and quality, and for assisting the Company in the implementation of internal documentation systems, development of CMC sections of regulatory submissions, manufacturing supply agreements, Master Files and other tasks.

Randall Tlachac has played the principal role in the approval of 7 New Drug Applications ("NDAs"), and has extensive experience with development of a wide array of products: over 70 Investigational New Drug ("IND") applications including multi-specific antibodies, cell, tissue and gene therapy products, CAR therapies, therapeutic proteins, peptides, peptide conjugates, cationic antimicrobial peptides, small molecule pharmaceuticals nanoparticle formulations, and sterile injectable pharmaceuticals. Mr Tlachac's agreement to work with the Company is further testament - if further proof were needed than the involvement of Dr Gill and University of Pennsylvania, and of multiple pharmaceutical company partners - of the quality of the Company's work and its prospects to proceed to clinical trials and beyond rapidly.

#### **Paycheck Protection Program Loan Forgiveness**

A loan from the U.S. Small Business Administration under the Paycheck Protection Program – described in Note 23 to the financial statements – was forgiven in April 2021.

Overall, very rapid progress has continued despite the restrictions of COVID-19.

#### **Financial Results**

During the year the Group made a loss of £2,095,023 (2019: £1,453,144 loss).

As at 31 December 2019 a total of US\$1,500,000 of the total facilities available from convertible loan facilities from Organesis Inc. had been paid over to the company. The remaining \$500,000 was paid over in February 2020.

On 30 January 2020 the Company announced that it had raised £648,200 before expenses through a placing and subscription of 36,011,116 ordinary shares at a price of 1.8p per share. In May, the Company announced a conditional fundraising of £2,500,000 (before expenses) through an oversubscribed placing of 35,714,286 ordinary shares at a price of 7p per share. The raise was conditional on shareholders approving corresponding resolutions at the 4 June AGM and completed immediately thereafter. In May, the Company issued and allotted 668,000 shares at an exercise price of 5.25p per share for a total consideration of £35,070, pursuant to the exercise of warrants.

In July, the Company's principal broker, SP Angel Corporate Finance LLP ("SP Angel"), published an updated research note that emphasised the Company's ongoing research progress and diversification of its product candidate portfolio. The note draws comparisons with the valuations of peer companies specialising in blood diseases and with early-stage (preclinical through to Phase II clinical trial stage) UK-listed companies, and concluded that at the time - as now - the Company's market capitalisation remains well below its peergroup averages and indicates upside potential for the Company's shareholders, particularly taking into account the pipeline of assets in development and multiple collaboration agreements with leading names in the pharmaceutical industry. The Directors and the Company's management and staff remain focused on delivering value to shareholders and saving lives.

The key terms of the Mint Financing Facility and CLNs include:

 A principal amount of up to £60,000,000, split into denominations of £50,000 per loan note, subscribed for at par and with no interest payable.

- The CLNs are to be issued in up to nine tranches.
   The first tranche of £12,000,000 in principal amount was issued on 3 February 2021. The subsequent eight tranches are issuable at the sole discretion of, and in the amounts determined by, the Company at respective intervals of 90 days after this date.
- Each tranche of CLNs is redeemable at par on the date falling 36 months after the relevant issue date.
- Each of the CLNs is convertible into ordinary shares
  of 1 pence each at any time during the period
  commencing on the fifth business day following the
  relevant issue date and ending at 5.00 p.m. London
  time on the business day immediately prior to the
  relevant maturity date.
- The price used for conversion will be equal to a 10 per cent discount to the lesser of (i) 125 per cent. of the closing-bid price as reported by Bloomberg for one ordinary share one trading day before the relevant issue date (subject to adjustment to reflect any subdivision or consolidation of the ordinary shares) and (ii) the lowest closing bid-price as reported by Bloomberg for an ordinary share from the three consecutive trading days ending on the day prior to the date of service of the relevant conversion notice (or if such conversion notice is served after 4.35pm on any such date, then the three consecutive trading days ending on the day such conversion notice is served). In no event shall the conversion price be less than the nominal value of an ordinary share.
- A holder will not be permitted to submit a conversion notice in respect of the CLNs if the total ordinary shares held by the holder following the execution of such conversion notice would exceed 29.9% of the Company's total ordinary shares.
- If the Company commits an "event of default" then the notes could be redeemed at 114-120% of the principal amount of the convertible loan at the option of the holder.
- The Company also has the ability to redeem the CLNs under certain circumstances at 114% of their principal amount.
- Subject to limited exceptions, the CLNs are not transferable.
- Prior to conversion, the CLNs do not entitle the holder to any voting rights in the Company.

The Company has agreed to pay a fee of 5% of the aggregate principal value of the CLNs issued to the arranger for the Financing Facility, payable in shares, subject to the Directors having the necessary shareholder authorities in place to issue such new shares and such issue not requiring the publication of a prospectus by the Company, and otherwise payable in cash. 7,741,935 shares were allotted as an arrangement fee to the arranger of the Financing Facility for the first tranche of funding.

To date, Mint has converted loan notes with principal value of £2,500,000 into shares, leaving convertible loan notes to a value of £9,500,000 outstanding. A conversion notice for a further £900,000 in principal value of loan notes was received from Mint on 23 April 2021 and the corresponding shares will be allotted on or around 4 May 2021, after publication of this report, leaving convertible loan notes to a value of £8,600,000 outstanding.

#### **Scientific Advisory Board & Board Update**

I have chaired the Scientific Advisory Board since September 2017 and have worked with the Company to widen its expertise and to bring in advisers that can specifically help at each stage to which the Company's product development has advanced.

Our Scientific Advisory Board, under my Chairmanship, brings together experienced experts with extensive biotech and large pharma drug development experience and their calibre is a reflection of the potential opportunity that our therapies present.

There were no changes to the composition of the Board during 2020. The Board has continued to demonstrate its confidence in the ongoing success of the business throughout the period under review and post-period end. I have elected to receive most of my remuneration in share options and collectively we remain confident that the Company's shares should deliver significant shareholder return over the long term.

#### Conclusion

In all, the Company has made impressive progress in 2020 and into 2021, particularly considering its highly efficient use of capital and small but talented scientific advisory and research team. As the Company

approaches its next phase of growth, the investment rationale is stronger than ever. Careful application of the team's expertise and ingenuity have given the Company a strong portfolio of complementary product candidates that reduce reliance on any one initiative and give it multiple material opportunities for success. Together, these treatments aim to provide an end-to-end solution to removing the need for dangerous bone marrow transplant conditioning regimens and eliminating the need for bone marrow donors, and now have potential applicability to a range of blood and autoimmune disease as well as viral infections. The Company's patent protections are growing, and it has continuing recognition in the form of collaborations with some of the largest and most respected groups in cutting-edge biopharmaceutical development.

Shareholders may have confidence that the Company's prospects remain excellent. My fellow directors and I continue to look forward to the realisation of Hemogenyx Pharmaceuticals' great potential to deliver rewards both to shareholders in the form of increased value and to our target patients and society at large as a life-saving company.

Prof Sir Marc Feldmann AC, FRS
MB BS, PhD, FRCP, FRCPath, FAA, F Med Sci
Chairman

30 April 2021



#### BOARD OF DIRECTORS AND SENIOR MANAGEMENT

## Professor Sir Marc Feldmann – Non-Executive Director & Chairman – appointed 9 April 2018

Professor Sir Marc Feldmann is a pre-eminent 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 (Tumour 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.

This has led to much scientific recognition, for example election to the Royal Society and Academy of Medical Sciences in London, the National Academy of Sciences USA and the Australian Academy of Science, and multiple major International prizes including the Crafoord Prize of the Royal Swedish Academy of Sciences, the Albert Lasker Clinical Research Award (NY), the Ernst Schering Prize, the Paul Janssen Award for Biomedical Research, and the Canada-Gairdner Award. He was also the first recipient in biology or medicine of the EU/European Patent Office Inventor of the Year Award in the Lifetime Achievement category. In addition, Sir Marc has advised more than 20 of the largest pharmaceutical and biotech companies in the world and has mentored some of the most successful scientists, many of whom have become senior figures in the commercial pharmaceutical world. Sir Marc was knighted in the 2010 Queen's Birthday Honours, and was honoured in Australia with the

knighthood equivalent, the Companion of the Order of Australia.

Sir Marc has been at the forefront of promoting effective scientific-medical-pharmaceutical interactions. He has built up a huge network of friends and collaborators who meet regularly in Oxford and who will help Hemogenyx Pharmaceuticals to grow and enter clinical trials.

## Dr Vladislav Sandler – Chief Executive Officer – appointed 4 October 2017

Dr Vladislav Sandler is the Co-Founder and CEO of Hemogenyx Pharmaceuticals 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. In particular, Dr Sandler has extensive experience developing novel methods of direct reprogramming of somatic cells into functional and engraftable hematopoietic stem cells, as well as developing novel sources of pluri- and multi-potent cells.

Dr Sandler has conducted his research in Russia, Israel, Canada and the United States, including at the Children's Hospital at 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 Hemogenyx Pharmaceuticals in order to further pursue this significant scientific discovery and his dedication to the translation of science into clinical practice.

Dr Sandler has published numerous peer-reviewed papers and has received a number of awards and fellowships for his scientific research. Dr Sandler received his PhD from the University of British Columbia. He is a member of the International Society for Stem Cell Research.

#### BOARD OF DIRECTORS AND SENIOR MANAGEMENT

## Alexis Sandler – Non-Executive Director appointed 4 October 2017

Alexis M. Sandler is the co-founder of Hemogenyx Pharmaceuticals, 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 appointed 4 October 2017

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



The Directors present their Strategic Report of Hemogenyx Pharmaceuticals plc for the year ended 31 December 2020.

#### Introduction

This Strategic Report comprises a number of sections, namely: the Group's objectives, the Group's strategy and business model, a review of the Group's business using key performance indicators, and the principal risks and uncertainties facing the business. The disclosures under s172 of the Companies Act 2006 are included in the Governance Report.

#### **Objectives**

The Group's objective is to develop breakthrough therapies for the treatment of blood and autoimmune diseases.

#### Strategy and Business Model

The Group's long-term strategy is to create a suite of products to address current problems associated with the treatment of blood disorders such as cancers and autoimmune diseases, with viral infections, and with bone marrow, or hematopoietic stem cell, transplants. The latter represents an important part of the solution to treating blood-related diseases, with the opportunity to improve outcomes through reduced blood stem cell transplant rejection and relapse, and if successful potentially provides long-term cures for these diseases.

The Group's business model aims to advance its therapies through clinical proof-of-concept, taking them towards a final stage of development. A goal is the licensing of one or more of its therapies to partners in return for potential upfront payments, research funding support, success milestone and royalty payments.

#### **Operational Review and Outlook**

The operational review and outlook are set out in the Chairman's Statement.

#### **Financial Review**

The Group incurred a loss for the year to 31 December 2020 of £2,095,023 (31 December 2019 – loss of £1,453,144).

In the year to 31 December 2020 the loss mainly

arose from operational expenses pursuing the Group's objectives listed above as well as salaries, consulting and professional fees, and general administration expenses. These expenses have been met from the proceeds of the issue of convertible loans and equity placings. The Group received other income of £85,237 (2019 - £213,126) from collaborations with partners.

#### Cash flow and cash position

Cash used in operations totalled £1,798,404 (31 December 2019: £1,199,873).

As at 31 December 2020, the Group had a cash balance of £1,812,299 (31 December 2019: £498,679).

#### **Key Performance Indicators**

The Directors have identified the KPIs below that they feel are the most vital measurements for the Group to monitor given its current stage of development. KPIs are monitored on an annual basis to ensure that the remain the most important and relevant measure of performance and progress.

#### Cash management

In addition to the revenues from collaborations with partners mentioned above, the Group continued to draw on the cash provided by the convertible loan facilities from Orgenesis Inc. for a maximum of US\$2,000,000. As at 31 December 2020 the total available facility of US\$2,000,000 (£1,465,076) had been paid over to the Company. This was supplemented by proceeds totalling £3,148,200 before expenses from two placings that took place in the year and from the conversion of warrants for a further contribution of £35,070. The cash position at 31 December 2020 was £1,812,299 (31 December 2019: £498,679).

The Group carefully plans expenditure with rolling cash flow forecasts and tight financial control. The Group takes a collaborative cost sharing approach with business partners and avoids long-term commitments as far as possible.

#### Intellectual property

The Group will focus on developing new conditioning treatments, drugs and cell therapy products for blood and autoimmune diseases, HSC/BM transplantation, and



viral infections. The Group, or its licensors, has applied for patents to protect its proprietary technology and future products, which are in varying stages of development.

The success of the Group will depend largely on the Group's ability to implement successful drug development programmes, obtain the required regulatory approvals (in various territories), protect and exploit its own intellectual property and know-how, and the intellectual property and know-how licensed to it, and to generate a cash flow in accordance with the strategy of the Group. Intellectual property is protected by the Group through taking a proactive approach to filing patents over its products and technologies, as well as the diligent maintenance and protection of such patents and licences.

The Group patent portfolio currently includes:

#### CDX bi-specific antibodies

The patent application relating to CDX bi-specific antibodies was filed by Hemogenyx Pharmaceuticals LLC in the USA on 4 April 2016 ("CDX Patent"). The invention summarised in the patent application is a method of eliminating hematopoietic stem cells/hematopoietic progenitors ("HSC"/"HP") in a patient using bi-specific antibodies specifically binding to a protein predominantly expressed on the surface of HSC/HP and to a protein uniquely expressed on a surface of immune cells. The bound bi-specific antibodies redirect immune cells to eliminate HSC/HP. The invention relates to the required conditioning of a patient prior to a BM/HSC transplant. In this respect, the invention serves two main purposes:

- it provides adequate immunosuppression of the patient and clears sufficient niche space in the bone marrow for the transplant of HSC. This allows transplanted cells to engraft in the recipient; and
- it could potentially help to eradicate the source of malignancy.

The provisional patent application is converted to a PCT application and broadened to cover the composition of matter (in this case, novel sequences of antibodies). On April 4 2017, a PCT (Patent Cooperation Treaty) application was filed by Hemogenyx Pharmaceuticals which includes additional claims that extend the CDX Patent set out in the provisional patent application. These claims protect specific sequences of several high-quality

clones discovered and validated by the Group. The claim extension transforms the original "method" provisional patent application into a "composition of matter" PCT application.

In July 2019 the Group filed an additional composition of matter patent application in relation to newly-discovered monoclonal antibodies against a target protein expressed on the surface of hematopoietic stem cells/hematopoietic progenitors and a number of leukaemias, such as AML. It also covers a method of application of the Group's bi-specific CDX antibodies for conditioning patients for bone marrow transplantation.

An additional composition of matter patent application (covering novel sequences of the antibodies discovered and validated by the Company in collaboration with GlobalCo) is expected to be filed following completion of the GlobalCo collaboration agreement.

#### **Hu-PHEC** cell therapy

The patent relating to Hu-PHEC was filed by Cornell University ("Cornell Patent") in several jurisdictions on 13 November 2014. The patent was approved and issued in the United States of America on 25 February 2020 and published by the European Patent Office on 13 May 2020. The invention summarises a method of isolation and identification of post-natal hemogenic endothelial cells, as well as the provision of substantially purified populations of post-natal hemogenic endothelial cells, compositions of post-natal endothelial cells and methods to utilise post-natal hemogenic endothelial cells to regenerate the hematopoietic system in a patient.

#### Advanced Hematopoietic Chimeras

The provisional patent application relating to the Group's proprietary humanised mouse model, the Advanced Hematopoietic Chimera, is an application filed by Dr Sandler and Dr Rita Simone in the USA on 20 February 2018 ("AHC Patent"). The invention summarised in the patent application is mice whose hematopoietic system is at least 40% humanised and methods for preparing the same. The patent was assigned to the Group's subsidiary Immugenyx LLC on 24 May 2018. In June 2019 the Group announced that Immugenyx LLC has further refined its work to develop the Advanced peripheral blood Hematopoietic Chimera ("ApbHC") as a research and development tool. The major advantage of the ApbHC

compared to other humanised mouse models known to the Group is the absence of Graft versus Host Disease, a disease that complicates and often renders impossible the efficient use of peripheral blood mononuclear cells in transplanted mice. The ApbHC can potentially be used for testing multi-specific antibodies, including its own bispecific CDX antibody, as well as for the development and testing of new cell therapies involving immune cell programming such as CAR-T. ApbHC can also potentially be used for the modeling of autoimmune diseases, such as Systemic Lupus Erythematosus (aka Lupus), with a goal of developing fundamentally new treatments for those diseases. Furthermore, ApbHC can be used as a tool for the rapid development and/or isolation of human antibodies against previously unknown human-specific pathogens (bioprotection/biodefence applications), known in biosecurity circles as "Disease X," such as the novel coronavirus.

#### **Product development**

The Group develops therapies to transform bone marrow and blood stem cell transplant procedures. These therapies aim to replace the need for existing methods of preparation of patients for transplantation, such as chemotherapy and radiation treatments, and at the same time address the problem of finding matching stem cell donors whilst reducing the risk of blood stem cell rejection after transplantation.

The Group's key products, CDX antibodies, CAR-T therapy, the CBR platform, and Hu-PHEC cell therapy, are currently in preclinical development. In addition, the Group's AHC product is currently the subject of collaborations with other pharmaceutical companies to evaluate AHCs' effectiveness as platforms for disease modelling and drug discovery.

The Directors monitor product development through pre-clinical results. The CDX and CAR-T products have been successfully evaluated in the Group's proprietary humanised mouse model, achieving proof of concept. Furthermore, we have achieved a notable demonstration of CDX's activity versus AML cells *in vitro* and *in vivo*. If successful, the Company may be able to use the CDX and/or CAR-T products to eliminate R/R AML in patients who qualify for bone marrow transplantation. The Company is also investigating the possibility of using its CDX antibodies in combination with other treatments for

AML to increase their effectiveness.

#### **Diversity**

Hemogenyx Pharmaceuticals is committed to workplace diversity which includes but is not limited to gender, age, ethnicity and cultural background.

Hemogenyx Pharmaceuticals' Diversity Policy defines initiatives which assist the Company in maintaining and improving the diversity of its workforce. The table below highlights the proportion of women engaged by the Group:

	Men	Women
Organisation as a whole	6	6
Executive management team	2	-
Board	3	1

#### **Board of Advisors**

The Group engages the services of a Board of Advisors who are highly experienced in both the clinical development of treatments and regulatory processes to commercialisation. In addition to Professor Sir Marc Feldmann, who runs the Board of Advisors in addition to his role as Chairman, the advisors are:

## Dr H. Michael Shepard, Ph.D. SCIENTIFIC ADVISOR

- Led the discovery and development of many successful cancer treatments including Herceptin/trastuzumab annual sales exceed \$6.5 billion worldwide
- Received Harvard Medical School's prestigious Warren Alpert Prize in recognition of contributions to the field of cancer treatment research
- Founded NewBiotics, Inc., acquired by Kiadis Pharma
- · Founded BioLogix, acquired by Symphogen

## Dr Koen van Besien M.D. CLINICAL ADVISOR

- Professor of Medicine and Director of the Stem Cell Transplant Program at NYP-Weill Cornell College of Medicine
- Developed novel methods of transplantation for those patients who lack matching donors

- >200 publications in peer reviewed journals
- Editor in Chief of the journal Leukemia and Lymphoma

#### **Corporate Responsibility**

We have defined the scope of our Group's responsible business practices as falling within the following key focus areas:

- Health and Safety ensuring the safety and wellbeing of our staff
- Environment managing our environmental impact areas of waste, energy and water
- Employees supporting our people to develop and flourish within the business
- Community positive interaction with the communities in which we operate
- Ethical Standards operating to the highest ethical standards

We remain committed to ensuring these activities become embedded in how we operate and contribute towards the success of our business. This includes not only identifying and managing business risk but exploring opportunities to add value to the business.

#### **Greenhouse Gas Emissions**

Given the nature of its activities, there is limited scope for the Group to have a major impact on environmental matters. Nevertheless, the Directors are mindful of their responsibilities in this regard and strive to seek opportunities where improvements may be made; these are generally concentrated in areas of energy conservation, recycling and waste control.

#### **Principal Risks and Uncertainties**

The Group operates in an uncertain environment and is subject to a number of risk factors. The Directors have carried out a robust assessment of the principal risks facing the Group, including those that threaten its business model, future performance, solvency or liquidity. They consider the following risk factors are of particular relevance to the Group's activities and to any investment in the Group. It should be noted that the list is not exhaustive and that other risk factors not presently known or currently deemed immaterial may apply.

The risk factors are summarised below:

#### Risks relating to the Group's business strategy

#### The Group's business is relatively undeveloped

The operations of Hemogenyx Pharmaceuticals are at a relatively early stage and, to date, no commercial sales of its products have been made. The ability of the Group to achieve commercialisation is dependent on a number of factors, many of which are outside of the Group's control. Examples of factors outside of the Group's control are the impact of Brexit, capital market conditions, FDA approval and competition.

#### **Business strategy of the Group**

The development of clinical products for new medical treatments is inherently uncertain, with high failure rates in clinical studies for both early and late stage development products and such clinical studies can be expensive, time-consuming and complicated and there is no certainty as to the outcome of such studies. Even once clinical studies have been successfully carried out, later phase trials may not successfully replicate or improve on such outcomes.

#### Staffing and key personnel

The Group is reliant on a number of the key personnel, in particular Dr Vladislav Sandler who is the founder of Hemogenyx Pharmaceuticals (refer to Corporate Governance Report for further detail). Whilst the Group has endeavoured to ensure that it has contractual arrangements which include non-compete restrictions in place with such persons to lessen the risk of them ceasing to be involved with the Group, in the event that the Group was to lose the services of such individuals, its results could be adversely affected.

#### **Costs of commercialisation**

The ability of the Group to bring its products to first commercial sale will be dependent in part on the overall costs of manufacturing and the costs involved could be significant and there is no guarantee that the sale prices achievable for its products will be viable and sustainable.

#### Clinical studies and timelines risk

Hemogenyx Pharmaceuticals is currently progressing its product candidates through preclinical development. Although encouraging results have been achieved so far, there can be no certainty that these results can be reproduced in clinical trials. The monies raised in the Placings and Subscriptions, as well as the Organesis and Mint Capital convertible loans, are intended to support those preclinical development activities.

The development of clinical products for new medical treatments is inherently uncertain, with high failure rates in clinical studies for both early- and late-stage development products. Furthermore, such clinical studies (Phase 1, Phase 2a/2b, Phase 3) are typically expensive, complex, can take considerable time to complete and have uncertain outcomes.

Furthermore, as a result of adverse, undesirable, unintended or inconclusive results from any testing or clinical trials (which have yet to be designed), the future progress, planning and potential treatment outcome of the products and clinical programmes may be affected and may potentially prevent or limit the commercial use of one, many or all of the Company's products. In addition, later phase clinical trials may fail to show the desired safety and efficacy obtained in earlier studies, and a successful completion of one stage of clinical development of an investigational clinical product does not ensure that subsequent stages of clinical development will be successful.

Failure can occur at any stage of clinical development and, as a result, enforced delays to the clinical development plan could delay or prevent commercialisation of the Company's product candidates. Various factors associated with the potential failure or delay in completing a clinical programme include, but are not limited to:

- Delays in securing clinical investigators or clinical study sites;
- Delays in securing any regulatory authority, hospital ethics committee, or institutional review board approval or approvals necessary to commence a clinical study;
- Delays or failure to recruit a sufficient number of clinical study participants in accordance with the clinical study protocol;

- Difficulty or inability to monitor subjects adequately during or after treatment;
- Inability to replicate in Phase 3 controlled studies any safety and efficacy data obtained from controlled Phase 2a/2b clinical studies;
- Difficulty or inability to secure clinical investigator compliance to follow the approved clinical study protocol; and
- Unexpected adverse events or any other safety or related issues.

#### Research and development risk

The Group operates in the biotechnology and biopharmaceutical development sectors and carries out complex scientific research. If the research or preclinical testing or clinical trials of any of Hemogenyx Pharmaceuticals' product candidates fail, meaning that these candidates will not be licensed or marketed, this would result in a complete absence of revenue from these failed candidates. Positive results from preclinical and early clinical studies do not guarantee positive results from clinical trials required to permit application for regulatory approval. Furthermore, the Group may discontinue the development of candidates if results are not positive or unlikely to further its progress towards a meaningful outcome or collaboration.

#### Intellectual property (IP) infringement

The Group may be subject to future litigation concerning its own IP and the IP of others. Adverse judgements in relation to its IP would likely have negative outcomes for its results of operations.

#### Intellectual property (IP) control

The Group is partially reliant on an exclusive, world-wide licence of a patent from Cornell University for its Hu-PHEC line of business. The exclusivity and exploitable territory for this licence depend on the Group meeting various developmental milestones.

#### **Environmental and other regulatory requirements**

The event of a breach with any environmental or regulatory requirements may give rise to reputational, financial or other sanctions against the Group, and therefore the Board considers these risks seriously and designs, maintains and reviews its policies and processes

so as to mitigate or avoid these risks. Whilst the Board has a good record of compliance, there is no assurance that the Group's activities will always be compliant.

#### **Financing**

The Group's ability to develop its product through to commercial sale will depend upon the Group's ability to obtain financing primarily through a further raising of new equity capital. Although the Group has been successful in raising new equity capital, there can be no guarantee that it will be able to do so in the future. The Group may not be successful in procuring the requisite funds on terms which are acceptable to it (or at all) and, if such funding is unavailable, would raise questions over its ability to further develop its products through to commercialisation. Further, Shareholders' holdings of Ordinary Shares may be materially diluted if debt financing is not available.

#### **Market conditions**

Market conditions, including general economic conditions and their effect on exchange rates, interest rates and inflations rates, may impact the ultimate value of the Group regardless of its operating performance. The Group also faces competition from other organisations, some of which may have greater resources or be more established in a particular territory. The Board considers and reviews all market conditions to try and mitigate any risks that may arise from these.

#### Political and country risk – UK departure from the EU

The Company is quoted in the United Kingdom (UK) and operates in the UK and European Union (EU), in addition to other territories. Since a significant proportion of the regulatory framework in the UK applicable to the Group's business and its product candidates is derived from EU directives and regulations, Brexit and any ultimate trade deals struck between the UK and EU could materially impact the regulatory regime with respect to the development, manufacture, importation, approval and commercialisation of the Group's product candidates in the UK or the EU. For example, as a result of the uncertainty surrounding Brexit, the EMA relocated to Amsterdam from London. Following the Transition Period, the UK is no longer covered by the centralised procedures for obtaining EU-wide marketing authorisation from the EMA and, unless a specific agreement is entered into, a separate process for authorisation of drug products,

including the Company's drug candidates, will be required in the UK, the potential process for which is currently unclear. Moreover, in the US, tariffs on certain US imports have recently been imposed, and the EU and other countries have responded with retaliatory tariffs on certain US exports. In addition, the Group may be required to pay taxes or duties or be subjected to other hurdles in connection with the importation of the Group's candidates into the EU, or the Group may incur expenses in establishing a manufacturing facility in the EU in order to circumvent such hurdles. Any further changes in international trade, tariff and import/export regulations as a result of Brexit or otherwise may impose unexpected duty costs or other non-tariff barriers on the Group. As a result, given the ongoing uncertainty surrounding the situation, the Company is monitoring matters and seeking advice as to how to mitigate the risks arising.

#### Pandemic and business disruption risk

The Company may be affected by disruptions to its operations in one or more locations, particularly in the near future in light of responses to the novel coronavirus or other potential pandemics. The Company's New York operations are classed as an essential business and have not been subject to closure, and work has continued to date with prudent hygiene and distancing measures in place including limited work in the laboratory on rota and work from home. All laboratory staff have been fully vaccinated. The Company is allowing for extended delivery times for some supplies, and for slower progress with collaboration partners. The Board and UK management continue to operate remotely, as usual. At present the Company believes that there should be no significant material disruption to its work, but the Board continues to monitor these risks and the Company's business continuity plans.

Approved by the Board on 30 April 2021

Dr Vladislav Sandler CEO

The Directors present their report with the audited financial statements of the Group for the year ended 31 December 2020.

The Company's Ordinary Shares were admitted to listing on the London Stock Exchange under the name Silver Falcon plc, on the Official List pursuant to Chapters 14 of the Listing Rules, which sets out the requirements for Standard Listings, on 9 November 2015.

On 4 October 2017 the Company's shareholders voted in favour of acquiring the biotechnology company Hemogenyx Pharmaceuticals Limited, with shares being readmitted to trading on 5 October 2017 under the name Hemogenyx Pharmaceuticals plc.

#### **Principal Activity**

The Group's principal activity is the discovery, development and commercialisation of a suite of products to address current problems associated with the treatment of blood disorders such as cancers and autoimmune diseases, with viral infections, and with bone marrow, or hematopoietic stem cell, transplants. The company's leading technologies aim to change the way in which bone marrow/hematopoietic stem cell ("BM"/"HSC") transplants are performed and improve their efficacy. Hemogenyx Pharmaceuticals' distinct

and complementary products include immunotherapy product candidates for the treatment of AML and other blood malignancies and patient conditioning – the CDX bi-specific antibody and CAR-T therapy, and a cell therapy product for BM/HSC transplantation – the Hu-PHEC. Each of these products holds the potential to revolutionise the way BM/HSC transplants are being performed or diseases of the blood are treated, offering solutions that mitigate the dangers and limitations associated with the current standard of care.

The Group has three companies that are located outside of the UK. The principal laboratory of the Group is located in Brooklyn, New York, USA. The Group also has a subsidiary in Liège, Belgium.

#### **Results and Dividends**

The Consolidated Statement of Comprehensive Income set out on page 50 shows a loss for the year amounting to £2,095,023 (2019: loss of £1,453,144). The Directors do not propose a dividend in respect of the year ended 31 December 2020 (31 December 2019: nil).

#### **Directors and Directors' Interests**

The Directors who held office during the year were as follows:

	Date Appointed	Date Resigned
Professor Sir Marc Feldmann	9 April 2018	-
Dr Vladislav Sandler	4 October 2017	-
Alexis Sandler	4 October 2017	-
Peter Redmond	29 July 2015	-

The Directors of the Company who held office at 31 December 2020 had the following beneficial interests in the Ordinary shares of the Company at 31 December 2020 according to the register of directors' interests:

Director	At 31 December 2020	At 31 December 20219
Professor Sir Marc Feldmann	-	-
Peter Redmond*	5,596,270	5,040,714
Dr Vladislav Sandler	41,544,677	41,544,677
Alexis Sandler	75,090,685	75,090,685

<sup>\*</sup>Peter Redmond holds the majority of these shares through Catalyst Corporate Consultants Ltd of which he is the sole shareholder.

At the date of this report, there have been no further changes to the Directors' beneficial interest in the Ordinary shares of the Company as disclosed in the table above.

According to the Register of Directors' Interests, no rights to subscribe for shares in or debentures of Group companies were granted to any of the Directors or their immediate families, or exercised by them, during the financial year except as indicated below (see Note 20 for detail on option plans):

	OPTIONS			
Date of grant	Number of options at start of year	Options granted or acquired during year	Options lapsed during year	Number of options at end of year
9 Apr 2018	18,002,568	-	-	18,002,568
	18,002,568	-	-	18,002,568
20 August 2020	-	5,000,000	-	5,000,000
	-	5,000,000	-	5,000,000
13 July 2020	-	2,200,000	-	2,200,000
	-	2,200,000	-	2,200,000
	9 Apr 2018 20 August 2020	Date of grant         Number of options at start of year           9 Apr 2018         18,002,568           18,002,568         18,002,568           20 August 2020         -           -         -           13 July 2020         -	Date of grant         Number of options at start of year         Options granted or acquired during year           9 Apr 2018         18,002,568         -           18,002,568         -           20 August 2020         -         5,000,000           13 July 2020         -         2,200,000	Date of grant         Number of options at start of year         Options granted or acquired during year         Options lapsed during year           9 Apr 2018         18,002,568         -         -           18,002,568         -         -         -           20 August 2020         -         5,000,000         -           13 July 2020         -         2,200,000         -

#### **Qualifying Third Party Indemnity Provision**

At the date of this report, the Company has a third-party indemnity policy in place for all Directors.

#### **Substantial Shareholders**

As at 31 December 2020, the total number of issued Ordinary Shares with voting rights in the Company was 433,636,255 (now: 494,343,020). The Company has been notified of the following interests of 3 per cent or more in its issued share capital as at the date of approval of this report.

Party Name	Number of Ordinary Shares	% of Share Capital
Alexis Sandler	75,090,685	15.19
Vladislav Sandler	41,544,677	8.80
Craig Auringer	23,837,250	4.82
Samantha Bauer	17,082,201	3.46

#### **Relationship Agreement**

In accordance with Listing Rule 9.8.4(14)R, the Company has set out below a statement describing the relationship agreement entered into by the Company with its principal shareholder.

On 8 September 2017, the Company entered into a Relationship Agreement with Dr Vladislav Sandler and Alexis Sandler (the "Controlling Parties"), which came into force at the Company's re-admission. The principal purpose of the Relationship Agreement is to ensure that the Company is capable at all times of carrying on its business independently of the Controlling Parties.

If the Company ceases to be admitted to the Main Market of the London Stock Exchange, or the Controlling Parties (together with their associates) cease to hold 20 per cent or more of the voting rights over the Company's shares the Relationship Agreement shall terminate save for certain specified provisions.

The Relationship Agreement provides that the Controlling Parties undertake to use all reasonable endeavours to procure that they and their associates shall:

- conduct all transactions with the Company on an arm's length basis and on a normal commercial basis;
- not take any action that would have the effect of preventing the Company from complying with its obligations under the Listing Rules or the corporate governance principles adopted by the Group;

- not propose or procure the proposal of a shareholder resolution which is intended to, or appears to be intended to, circumvent the proper application of the Listing Rules; and
- not take any actions which is intended to, or appears to be intended to, breach or circumvent the proper application of the Relationship Agreement, the Listing Rules or the corporate governance principles adopted by the Group.

The Directors believe that the terms of the Relationship Agreement enable the Company to carry on its business independently from the Controlling Parties and their affiliates and ensure that all transactions and relationships between the Company and the Controlling Parties are, and will be, at arm's length and on a normal commercial basis. The Company has and, in so far as it is aware, the Controlling Parties and their associates have, complied with the independence provisions set out in the Relationship Agreement from the date of the agreement, through the relevant period under review. The ordinary shares owned by the Controlling Parties rank pari passu with the other ordinary shares in all respects.

#### **Share Capital**

Details of the issued share capital, together with details of the movement in issued share capital during the year, are shown in Note 18 to the financial statements.

#### **Financial Instruments**

Details of the use of the Company's financial risk management objectives and policies as well as exposure to financial risk are contained in the Accounting policies and Note 25 of the financial statements.

## Future Developments and Events Subsequent to the Year End

Further details of the Group's future developments and events subsequent to the year end are set out in the Chairman's Statement and Strategic Report.

#### **Corporate Governance**

The Corporate Governance report forms part of the Directors' Report and is disclosed on pages 28-34.

#### **Going Concern**

The Company's business activities, together with facts likely to affect its future operations and financial and liquidity positions are set out in the Chairman's Statement and Directors' Strategic Report. In addition, Note 25 to the financial statements discloses the Company's capital risk management policy and Note 2 details further considerations made by the Directors in respect of going concern, including an assessment of the possible impact on the Company arising from COVID-19.

The Directors, having made due and careful enquiry, are of the opinion that the Company has access to sufficient funding in order to execute its operations over the next 12 months. The Directors therefore have made an informed judgment, at the time of approving the financial statements, that there is a reasonable expectation that the Company has adequate resources to continue in operational existence for the foreseeable future. As a result, the Directors have adopted the going concern basis of accounting in the preparation of the annual financial statements.

#### **Political Donations**

The Group made no political donations during the year (2019: £nil).

#### **Charitable Donations**

There were no charitable donations made by the Group in the current or prior year.

#### Greenhouse gas emissions

Greenhouse gas emissions, energy consumption and energy efficiency disclosures have not been provided because the Company has consumed less than 40,000 kWh of energy during the period.

#### **Auditors**

The auditors, PKF Littlejohn LLP, have expressed their willingness to continue in office and a resolution to reappoint them will be proposed at the Annual General Meeting.

#### **Statement of Directors' Responsibilities**

The Directors are responsible for preparing the Annual Report and the financial statements in accordance with applicable law and regulations.

Company law requires the Directors to prepare financial statements for each financial year. Under that law the Directors have elected to prepare the financial statements in accordance with international accounting standards in conformity with the Companies Act 2006.

Under Company law the Directors must not approve the financial statements unless they are satisfied that they give a true and fair view of the state of affairs of the Company and of the profit or loss of the Company for that year.

In preparing these financial statements, the Directors are required to:

- Select suitable accounting policies and then apply them consistently;
- Make judgments and accounting estimates that are reasonable and prudent;
- State whether applicable international accounting standards in conformity with the Companies Act 2006 have been followed, subject to any material departures disclosed and explained in the financial statements; and
- Prepare the financial statements on the going concern basis unless it is inappropriate to presume that the Company will continue in business.

The Directors are responsible for keeping adequate accounting records that are sufficient to show and

explain the Group and parent company's transactions and disclose with reasonable accuracy at any time the financial position of the Group and parent company and enable them to ensure that the financial statements and the Directors' remuneration report comply with the Companies Act 2006 and, as regards the group financial statements, international financial reporting standards adopted pursuant to Regulation (EC) No.1606/2002 as it applies in the European Union. They are also responsible for safeguarding the assets of the Group and parent company and hence for taking reasonable steps for the prevention and detection of fraud and other irregularities. They are also responsible to make a statement that they consider that the annual report and accounts, taken as a whole, is fair, balanced, and understandable and provides the information necessary for the shareholders to assess the Group and parent company's position and performance, business model and strategy.

The Directors are responsible for the maintenance and integrity of the corporate and financial information included on the Company's website. Legislation in the United Kingdom governing the preparation and dissemination of the financial statements may differ from legislation in other jurisdictions.

#### Directors' Responsibility Statement Pursuant to Disclosure and Transparency Rules

Each of the Directors, whose names and functions are listed on page 3, confirms that, to the best of their knowledge and belief:

 the group and company financial statements have been prepared in accordance with international financial reporting standards adopted pursuant to Regulation (EC) No.1606/2002 as it applies in the European Union, and give a true and fair view of the assets, liabilities, financial position and loss of the Group and parent company; and  the Annual Report and financial statements, including the Business review, includes a fair review of the development and performance of the business and the position of the Group and parent company, together with a description of the principal risks and uncertainties that they face.

#### **Disclosure of Information to Auditors**

So far as the Directors are aware, there is no relevant audit information of which the Company's auditors are unaware, and each Director has taken all the steps that he ought to have taken as a Director in order to make himself aware of any relevant audit information and to establish that the Company's auditors are aware of that information.

Approved by the Board on 30 April 2021

Dr Vladislav Sandler CEO

#### Introduction

The Company recognises the importance of, and is committed to, high standards of Corporate Governance. The Company has voluntarily applied the main and supporting principles set out in the UK Code of Corporate Governance published by the Financial Reporting Council in 2018 ("the Code"). The Code has been followed to the extent practicable for a company of its size and nature. The Code can be found at frc.org. uk/our-work/publications/Corporate-Governance. The ways in which the Company has applied the Code are explained below:

- The Code requires that a smaller company should have at least two Independent Non-Executive Directors. As at 31 December 2020 the Board consisted of an Executive Director and three Non-Executive Directors. The Non-Executive Directors are interested in either ordinary shares in the Company, options over ordinary shares in the Company, or both, and cannot therefore be considered fully independent under the Code. The remuneration of the Non-Executive Directors includes options and this is contrary to best practice, and thus the Company is not in full compliance. However, the Directors consider the present structure and arrangements to be adequate given the size and stage of development of the Company, and all are considered to be independent in character and judgement.
- Directors appointed by the Board are subject to election by shareholders at the Annual General Meeting of the Company following their appointment and thereafter are subject to re-election in accordance with the Company's articles of association. The terms and conditions of appointment of Non-Executive Directors will be made available upon written request.

The Board has voluntarily adopted a code for Directors' dealings based on the Model Code contained in the Listing Rules of the UK Listing Authority that was previously in force. The Board will be responsible for taking all proper and reasonable steps to ensure compliance with the code by the Directors. Compliance with the code is being undertaken on a voluntary basis and the FCA will not have the authority to (and will not) monitor the Company's voluntary compliance with it, nor to impose sanctions in respect of any failure by the Company to so comply. In addition, the Company will take all proper and

reasonable steps to ensure compliance by the Founders with the Code for dealings in the Ordinary Shares.

The Company is small with a modest resource base. The Company has a clear mandate to optimise the allocation of limited resources to support its development plans. As such, the Company strives to maintain a balance between conservation of limited resources and maintaining robust corporate governance practices. As the Company evolves, the Board is committed to enhancing the Company's corporate governance policies and practices deemed appropriate for the size and maturity of the organisation.

Set out below are the Company's corporate governance practices for the year ended 31 December 2020.

#### **Committees**

The Company has established audit, remuneration and nomination committees.

#### **Audit Committee**

The Audit Committee has responsibility for, among other things, the monitoring of the integrity of the financial statements of the Company and its Group and the involvement of the Group's auditors in that process. It focuses in particular on compliance with accounting policies and ensuring that an effective system of external audit and financial control is maintained, including considering the scope of the annual audit and the extent of the non-audit work undertaken by external auditors and advising on the appointment of external auditors. The ultimate responsibility for reviewing and approving the annual report and accounts and the half-yearly reports remains with the Board. The Audit Committee will meet at least three times a year at the appropriate times in the financial reporting and audit cycle.

The members of the Audit Committee are Peter Redmond, who acts as chairman of the committee, and Professor Sir Marc Feldmann.

The Group's external auditor is PKF Littlejohn LLP who has served as external auditor for five years. The role of external auditor last went to tender in 2015. The Audit Committee closely monitors the level of audit and non-audit services that they provide to the Company and Group.

Having assessed the performance, objectivity and independence of the auditors, the Committee will be recommending the reappointment of PKF Littlejohn LLP as auditors to the Company at the 2021 Annual General Meeting.

During the year to 31 December 2020 the Audit Committee considered the following key issues in relation to the Financial Statements:

Issue	Action
Accounting policies	The Committee reviewed and discussed the significant accounting policies with management and the external auditor and reached the conclusion that each policy was appropriate to the Group.
Carrying value of investment in Hemogenyx Pharmaceuticals LLC	The Committee reviewed the impairment assessment report prepared by management and agreed that given the reasonable expectation that the Group will achieve its milestone targets over the next 18 months that no impairment to the value of the investment in Hemogenyx Pharmaceuticals LLC was required as at 31 December 2020.
Going Concern review	The Committee considered the ability of the Group to operate as a Going Concern considering cash flow forecasts for the next 12 months and milestone achievements. It was determined by the Committee that it was reasonable to expect that the Group has or will have access to sufficient funding in order to achieve its 12-month milestone targets and that it was appropriate for the Financial Statements to be prepared on a going concern basis.
Review of audit and non-audit services and fees	The external auditor is not engaged by the Group to carry out any non-audit work in respect of which it might, in the future, be required to express an audit opinion.
	The Committee reviewed the fees charged for the provision of audit and non-audit services and determined that they were in line with fees charged to companies of similar size and stage of development.
	The Committee considered and was satisfied the external auditor's assessment of its own independence.

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#### GOVERNANCE REPORT

#### **Remuneration Committee**

The remuneration committee reviews the performance of the Executive Directors and makes recommendations to the Board on matters relating to their remuneration and terms of employment. The committee also makes recommendations to the Board on proposals for the granting of share awards and other equity incentives pursuant to any share award scheme or equity incentive scheme in operation from time to time. The Remuneration Committee will meet at least twice a year.

The members of the Remuneration Committee are Peter Redmond, who acts as chairman of the committee, and Alexis Sandler.

#### **Nomination Committee**

The Nomination Committee is responsible for considering and making recommendations to the Board in respect of appointments to the Board, the Board committees and the chairmanship of the Board committees. It is also responsible for keeping the structure, size and composition of the Board under regular review, and for making recommendations to the Board with regard to any changes necessary, taking into account the skills and expertise that will be needed on the Board in the future. The Nomination Committee meets at least once a year.

The members of the Nomination Committee are Peter Redmond, who acts as chairman of the committee, Professor Sir Marc Feldmann, and Alexis Sandler.

#### Leadership

The Company is headed by an effective Board which is collectively responsible for the long-term success of the Company.

The role of the Board: the Board sets the Company's strategy, ensuring that the necessary resources are in place to achieve the agreed strategic priorities, and reviews management and financial performance. It is accountable to shareholders for the creation and delivery of strong, sustainable financial performance and long-term shareholder value. To achieve this, the Board directs and monitors the Company's affairs within a framework of controls which enable risk to be assessed and managed effectively. The Board also has responsibility for setting the Company's core values and standards of business

conduct and for ensuring that these, together with the Company's obligations to its stakeholders, are widely understood throughout the Company. The Board has a formal schedule of matters reserved which is provided later in this report.

Board Meetings: the core activities of the Board are carried out in scheduled meetings of the Board. These meetings are timed to link to key events in the Company's corporate calendar and regular reviews of the business are conducted. Additional meetings and conference calls are arranged to consider matters which require decisions outside the scheduled meetings. During the year, the Board met on 15 occasions.

Outside the scheduled meetings of the Board, the Directors maintain frequent contact with each other to discuss any issues of concern they may have relating to the Company or their areas of responsibility, and to keep them fully briefed on the Company's operations.

Matters reserved specifically for the Board: the Board has a formal schedule of matters reserved that can only be decided by the Board. The key matters reserved are the consideration and approval of:

- The Company's overall strategy;
- · Financial statements and dividend policy;
- Management structure including succession planning, appointments and remuneration; material acquisitions and disposal, material contracts, major capital expenditure projects and budgets;
- Capital structure, debt and equity financing and other matters;
- · Risk management and internal controls;
- The Company's corporate governance and compliance arrangements; and
- Corporate policies

Summary of the Board's work in the year: during the year, the Board considered all relevant matters within its remit, but focused in particular on the development and risk diversification of the Company.

Attendance at meetings	Number held and entitled to attend	Number attended
Dr Vladislav Sandler	15	15
Professor Sir Marc Feldmann	15	15
Alexis Sandler	15	15
Peter Redmond	15	13

The Board is pleased with the high level of attendance and participation of Directors at Board and committee meetings.

The Chairman sets the Board Agenda and ensures adequate time for discussion.

Non-Executive Directors: the Non-Executive Directors bring a broad range of business and commercial experience to the Company and have a particular responsibility to challenge independently and constructively the performance of the Executive management (where appointed) and to monitor the performance of the management team in the delivery of the agreed objectives and targets.

All directors with the exception of the CEO and Professor Sir Marc Feldmann were appointed for an initial term of 12 months. These terms were extended by mutual agreement after satisfactory performance and reelection by shareholders.

Other governance matters: all of the Directors are aware that independent professional advice is available to each Director in order to properly discharge their duties as a Director. In addition, each Director and Board committee has access to the advice of the Company Secretary.

The Company Secretary: the Company Secretary is Andrew Wright. He is responsible for the Board complying with UK procedures.

#### **Effectiveness**

For the period under review the Board comprised a Chief Executive Officer, a Non-Executive Chairman, and two independent Non-Executive Directors. Biographical details of the Board members are set out on pages 12-14 of this report.

The Directors are of the view that the Board and its committees consist of Directors with an appropriate balance of skills, experience, independence and diverse backgrounds to enable them to discharge their duties and responsibilities effectively.

Independence: the Non-Executive Directors bring a broad range of business and commercial experience to the Company. The Board considers each of the Non-Executive Directors to be independent in character and judgement.

Appointments: the Board is responsible for reviewing and the structure, size and composition of the Board and making recommendations to the board with regards to any required changes.

Commitments: all Directors have disclosed any significant commitments to the Board and confirmed that they have sufficient time to discharge their duties.

Induction: all new Directors received an induction as soon as practical on joining the Board.

Conflict of interest: a Director has a duty to avoid a situation in which he or she has, or can have, a direct or indirect interest that conflicts, or possibly may conflict with the interests of the Company. The Board had satisfied itself that there is no compromise to the independence of those Directors who have appointments on the Boards of, or relationships with, companies outside the Company. The Board requires Directors to declare all appointments and other situations which could result in a possible conflict of interest.

Board performance and evaluation: Hemogenyx Pharmaceuticals plc has a policy of appraising Board performance annually. Having reviewed various

approaches to Board appraisal, it has concluded that for a company of its current scale, an internal process in which all Board members submit answers to a questionnaire that considers the functionality of the Board and its committees is most appropriate at this stage.

#### **Accountability**

The Board is committed to providing shareholders with a clear assessment of the Company's position and prospects. This is achieved through this report and as required other periodic financial and trading statements.

Going concern: the Company's business activities, together with factors likely to affect its future operations, financial position, and liquidity position are set out in the Chairman's Statement and the principal risks and uncertainties sections of the Strategic Report. In addition, the Notes to the Financial Statements disclose the Company's financial risk management practices with respect to its capital structure, liquidity risk, interest rate risk, credit risk, and other related matters.

The Directors, having made due and careful enquiry, are of the opinion that the Company has adequate working capital to execute its operations and has the ability to access additional financing over the next 12 months. The Directors, therefore, have made an informed judgement, at the time of approving financial statements, that there is a reasonable expectation that the Company has adequate resources to continue in operational existence for the foreseeable future. As a result, the Directors have continued to adopt the going concern basis of accounting in preparing the annual financial statements.

Internal controls: the Board of Directors reviews the effectiveness of the Company's system of internal controls in line with the requirement of the Code. The internal control system is designed to manage the risk of failure to achieve its business objectives. This covers internal financial and operational controls, compliances and risk management. The Company has necessary procedures in place for the year under review and up to the date of approval of the Annual Report and financial statements. The Directors acknowledge their responsibility for the Company's system of internal controls and for reviewing its effectiveness. The Board confirms the need for an ongoing process for identification, evaluation and management of significant risks faced by the Company.

The Directors carry out a risk assessment before signing up to any commitments.

#### Workforce policies and practices

The Board is responsible for ensuring that workforce policies and practices are consistent with the Group's values and support its long term sustainable success, and that staff are able to raise any matters of concern. The Non-executive Director designated to engage with the workforce on these matters is Alexis Sandler. Ms Sandler, and in turn the Board, review the Group's policies and procedures, including anti-harassment and discrimination policies, sexual harassment reporting procedures, and procedures for reporting grievances or other concerns, and oversee the proportionate and independent investigation of any matters arising from them. These policies are provided to workers prior to the start of their work with the Group, and hard copies are posted prominently in the Group's operating premises together with other legally required notices.

#### **Relations with stakeholders**

The Company is committed to a continuous dialogue with shareholders as it believes that this is essential to ensure a greater understanding of and confidence amongst its shareholders in the medium and longer term strategy of the Group and in the Board's ability to oversee its implementation. It is the responsibility of the Board as a whole to ensure that a satisfactory dialogue takes place.

Section 172 of the Companies Act 2006 requires Directors to take into consideration the interests of stakeholders in their decision making. The Board is committed to understanding and engaging with all key stakeholder groups of the Company in order to maximise value and promote long-term Company success in line with our strategic objectives. The Board recognises its duties under Section 172 and continuously has regard to how the Company's activities and decisions will impact employees, those with which it has a business relationship, the community and environment and its reputation for high standards of business conduct. In weighing all of the relevant factors, the Board, acting in good faith and fairly between members, makes decisions and takes actions that it considers will best lead to the long-term success of the Company.

During the year, the Board assessed its current activities between the Board and its stakeholders, which demonstrated that the Board actively engages with its stakeholders and takes their various objectives into consideration when making decisions. Specifically, actions the Board has taken to engage with its stakeholders in 2020 include:

- Attended the 2020 AGM, which was a closed meeting in 2020 due to the restrictions imposed by the UK government's response to the COVID-19 pandemic, prepared to answer any questions raised by shareholders, and held an additional shareholder webinar to hear from and provide additional feedback to investors:
- Arranged meetings with certain stakeholders to provide them with updates on the Company's research and development activities and other general corporate updates;
- Made presentations at conferences and published recordings and slide decks on the Company's research and development;
- Evaluated the relationships with the Company's various collaborators through management and identified ways to strengthen relationships and arrangements with key collaborations; and
- Monitored company culture and engaged with employees on efforts to continuously improve company culture and morale.

The Board believes that appropriate steps and considerations have been taken during the year so that each Director has an understanding of the various key stakeholders of the Company. The Board recognises its responsibility to contemplate all such stakeholder needs and concerns as part of its discussions, decision-making, and in the course of taking actions, and will continue to make stakeholder engagement a top priority in the coming years.

The Board's primary shareholder contact is through Peter Redmond, the Non-Executive Director responsible for shareholder relations. The Chairman, the CEO and other Directors, as appropriate, make themselves available for contact with major shareholders and other stakeholders in order to understand their issues and concerns.

The Company plans to use the AGM as an opportunity to communicate with its shareholders. Notice of the AGM will be issued shortly and at least 21 days before the date of the meeting. To ensure compliance with the Governance Code, the Board proposes separate resolutions for each issue and proxy forms allow shareholders who are unable to attend the AGM – as may again be a particular issue this year in light of travel and meeting restrictions resulting from the COVID-19 pandemic – to vote for or against or to withhold their vote on each resolution. The results of all proxy voting will be published on the Group's web site after the AGM. Shareholders who attend the AGM will have the opportunity to ask questions.

The Group's web site at https://hemogenyx.com is the primary source of information on the Group. The web site includes an overview of the activities of the Group and all recent Group announcements.

#### Viability statement

In accordance with the UK Corporate Governance Code published in July 2018, the Directors have assessed the prospects of the Group and concluded that it is appropriate to adopt the going concern basis of accounting. The assessment of going concern is disclosed in Note 2.

The Board's assessment of the Group's current position and principal risks are disclosed in the Directors' Strategic Report on pages 15 to 21.

Dr Vladislav Sandler CEO

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### DIRECTORS' REMUNERATION REPORT

The Company has an established remuneration committee. The Committee reviews the scale and structure of the Directors' fees, taking into account the interests of shareholders and the performance of the Company and directors.

The items included in this report are unaudited unless otherwise stated.

# Statement of Hemogenyx Pharmaceutical plc's Policy on Directors' Remuneration by the Chairman of the Remuneration Committee

As Chairman of the Remuneration Committee I am pleased to introduce our Directors' Remuneration Report. One of the Remuneration Committee's aims is to provide clear, transparent remuneration reporting for our shareholders which adheres to the best practice corporate governance principles that are required for listed organisations.

The Directors' Remuneration Policy, which is set out on pages 37 to 38 of this report, will be submitted to shareholders for approval at our Annual General Meeting.

A key focus of the Directors' Remuneration Policy is to align the interests of the Directors to the long-term interests of the shareholders and aims to support a high-performance culture with appropriate reward for superior performance, without creating incentives that will encourage excessive risk taking or unsustainable company performance. This is underpinned through the implementation and operation of incentive plans.

#### **Key Activities of the Remuneration Committee**

The key activities of the Remuneration Committee are:

- to determine and agree with the Board the framework or broad policy for the remuneration of the Company's chairman, chief executive, the executive directors, the company secretary and such other members of the executive management as it is designated to consider;
- in determining such policy, take into account all factors which it deems necessary including relevant legal and regulatory requirements, the provisions and recommendations of the UK Corporate Governance Code (the "Code") and associated guidance. The objective of such policy shall be to ensure that members of the executive management of the

Company are provided with appropriate incentives to encourage enhanced performance and are, in a fair and responsible manner, rewarded for their individual contributions to the success of the Company;

- recommend and monitor the level and structure of remuneration for senior management;
- when setting remuneration policy for directors, review and have regard to the remuneration trends across the Company, and review the on-going appropriateness and relevance of the remuneration policy;
- obtain reliable, up-to-date information about remuneration in other companies. To help it fulfil its obligations the Committee shall have full authority to appoint remuneration consultants and to commission or purchase any reports, surveys or information which it deems necessary, within any budgetary restraints imposed by the Board;
- be exclusively responsible for establishing the selection criteria, selecting, appointing and setting the terms of reference for any remuneration consultants who advise the Committee;
- approve the design of, and determine targets for, any performance related pay schemes operated by the Company and approve the total annual payments made under such schemes;
- review the design of all share incentive plans for approval by the Board and shareholders. For any such plans, determine each year whether awards will be made, and if so, the overall amount of such awards, the individual awards to executive directors, company secretary and other designated senior executives and the performance targets to be used;
- ensure that contractual terms on termination, and any payments made, are fair to the individual, and the Company, that failure is not rewarded and that the duty to mitigate loss is fully recognised; and
- oversee any major changes in employee benefits structures throughout the Company.

#### **Members**

The Remuneration Committee comprises the following independent Non-Executive Directors:

Name	Position	Date of appointment
Peter Redmond	Chairman	5 October 2017
Alexis Sandler	Member	5 October 2017

#### **Remuneration Components**

The Company remunerates directors in line with best market practice in the industry in which it operates. The components of Director remuneration that are considered by the Board for the remuneration of directors in future years are likely to consist of:

- Base salaries
- Pension and other benefits
- Annual bonus
- Share incentive arrangements

The Executive Director has entered into a service agreement with the Company and the Non-Executive Directors have entered into letters of appointment with the Company.

All such contracts impose certain restrictions as regards the use of confidential information and intellectual property and the Executive Director's service contract imposes restrictive covenants which apply following the termination of the agreement.

The Executive Director Dr Vladislav Sandler is entitled to pay at a rate of £1,500 per day for time spent in the UK on the Company's business. In addition, Dr Sandler has a separate contract with Hemogenyx Pharmaceuticals LLC effective 1 September 2017 appointing him as CEO and Chief Scientific Officer of that company for an initial three-year term with automatic continuation and setting out his duties in relation to his day-to-day to work in connection with Hemogenyx Pharmaceuticals' product candidates. Pursuant to this contract, Dr Sandler is currently entitled to receive \$187,500 per annum and four weeks' holiday a year. Dr Sandler is also subject to certain non-compete and non-interference covenants in the event of its termination (subject to certain limited exceptions). Dr Sandler also has a separate contract with

Immugenyx LLC effective from 1 January 2019 appointing him as CEO and Chief Scientific Officer of that company for an initial three-year term with automatic continuation and setting out his duties in relation to his day-to-day work in connection with Immugenyx's development of its AHC. Pursuant to this contract, Dr Sandler receives \$60,000 and 10,000 ownership units in Immugenyx LLC per annum. This contract has the same non-compete and non-interference covenants in the event of its termination as his contract with Hemogenyx Pharmaceuticals LLC.

#### **Other Matters**

The Company does not currently have any annual or long-term incentive schemes or any other scheme interests in place for any of the Directors.

The Company has established a workplace pension scheme but it does not presently have any employees qualifying under the auto-enrolment pension rules who have not opted out of the scheme. It does not currently pay pension amounts in relation to Directors' remuneration. The Company has not paid out any excess retirement benefits to any Directors or past Directors. The Company has not paid any compensation to past Directors.

#### **Recruitment Policy**

Base salary levels will take into account market data for the relevant role, internal relativities, their individual experience and their current base salary. Where an individual is recruited at below market norms, they may be re-aligned over time (e.g. two to three years), subject to performance in the role. Benefits will generally be in accordance with the approved policy.

For external and internal appointments, the Board may agree that the Company will meet certain relocation and/ or incidental expenses as appropriate.

#### **Payment for Loss of Office**

The Committee will honour Executive Directors' contractual entitlements. Service contracts do not contain liquidated damages clauses. If a contract is to be terminated, the Committee will determine such mitigation as it considers fair and reasonable in each case. There is no agreement between the Company and its Executive Directors or employees, providing for compensation for loss of office or employment that occurs because of a takeover bid.

The Committee reserves the right to make additional payments where such payments are made in good

faith in discharge of an existing legal obligation (or by way of damages for breach of such an obligation); or by way of settlement or compromise of any claim arising in connection with the termination of an Executive Director's office or employment.

#### **Service Agreements and Letters of Appointment**

The Executive Director's service agreement had an initial term of two years and may subsequently be terminated by the Company or the Executive Director by giving 6 months' notice.

Name	Date of service agreement	Notice period by Company (months)	Notice period by Director (months)
Dr Vladislav Sandler	4 October 2017	6	6

The Non-Executive Directors of the Company do not have service contracts but are appointed by letters of appointment. Each Non-Executive Director's term of office runs for an initial period of one year unless terminated earlier upon written notice or upon their resignations.

The terms of the Non-Executive Directors' appointments are subject to their re-election by the Company's shareholders at any Annual General Meeting at which the Non-Executive Directors stand for re-election.

The details of each Non-Executive Director's current term are set out below:

Name	Date of service agreement	Current term (years)	Notice period by Company (months)	Notice period by Director (months)	Date of resignation
Alexis Sandler	4 October 2017	1	3	3	-
Peter Redmond	4 October 2017	1	3	3	-
Professor Sir Marc Feldmann	9 April 2018	3	3	3	-

#### **Executive Directors' Remuneration (audited)**

The table below sets out the remuneration received by each Executive Director for the years ended 31 December 2020 and 2019. Dr Vladislav Sandler was the highest paid Director:

Executive Directors	Basic salary 2020 £'000	Pension 2020 £'000	Total 2020 £'000
Dr Vladislav Sandler	200	5	205
Total	200	5	205

Executive Directors	Basic salary 2019 £'000	Pension 2019 £'000	Total 2019 £'000
Dr Vladislav Sandler	145	4	149
Total	145	4	149

#### **Non-Executive Directors' Remuneration**

The table below sets out the remuneration received by each Non-Executive Director during the years ended 31 December 2020 and 2019:

	Basic salary 2020 £'000	Total 2020 £'000
Alexis Sandler	27	27
Peter Redmond	42	64
Professor Sir Marc Feldmann	13	13
Total	82	104

	Basic salary 2019 £'000	Total 2019 £'000
Alexis Sandler	10	10
Peter Redmond	36	36
Professor Sir Marc Feldmann	12	12
Total	59	59

#### Relative importance of spend on pay

The table below illustrates the year-on-year change in total remuneration compared to distributions to shareholders and loss before tax for the financial years ended 31 December 2020 and 2019:

	Distributions to shareholders	Total employee pay (including stock based compensation) £	Operational cash outflow
Year ended 31 December 2020	-	1,130,763	1,798,404
Year ended 31 December 2019	-	691,992	1,199,873
Percentage change	n/a	63.4%	49.9%

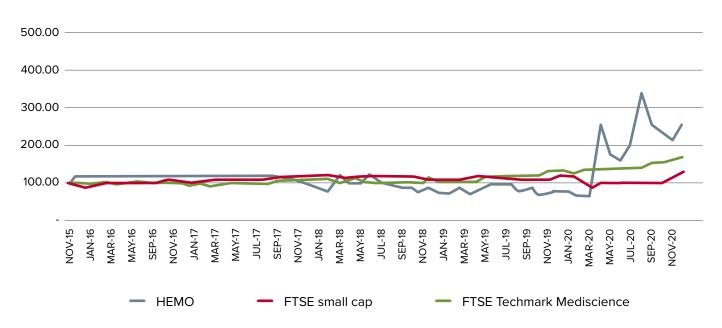
Total employee pay includes wages and salaries, social security costs, healthcare cost, 401K scheme cost and share-based payments for employees in continuing operations. Further details on Employee remuneration are provided in Note 8.

Operational cash outflow has been shown in the table above as cash flow monitoring and forecasting is an important consideration for the Remuneration Committee and Board of Directors when determining cash-based remuneration for directors and employees.

#### Historical share price performance comparison

The table below compares the share price performance (based on a notional investment of £100) of Hemogenyx Pharmaceuticals plc against the FTSE SmallCap and FTSE Techmark Mediscience for the period November 2015 to December 2020 calculated on a month end spot basis. The FTSE SmallCap has been chosen to provide a wider market comparator constituting companies of an appropriate size and the FTSE Techmark Mediscience chosen due to sector relevance:

#### **Investment Performance Comparison**



Hemogenyx Pharmaceuticals plc was listed in November 2015 (under the name Silver Falcon plc) and therefore no historical share price data exists prior to this period. There was also no data between December 2015 and October 2017 pending completion of a transaction. It is for these reasons that the historical investment performance is not reflective of the current Group.

#### Consideration of shareholder views

The Board considers shareholder feedback received and guidance from shareholder bodies. This feedback, plus any additional feedback received from time to time, is considered as part of the Company's annual policy on remuneration.

Approved on behalf of the Board of Directors.

#### **Peter Redmond**

**Director & Remuneration Committee Chairman** 

30 April 2021

#### **Opinion**

We have audited the financial statements of Hemogenyx Pharmaceuticals Plc (the 'parent company') and its subsidiaries (the 'group') for the year ended 31 December 2020 which comprise the Consolidated Statement of Comprehensive Income, the Group and Parent Company Statements of Financial Position, the Group and Parent Company Statements of Changes in Equity, the Group and Parent Company Statements of Cash Flows and Notes to the Financial Statements, including a summary of significant accounting policies. The financial reporting framework that has been applied in their preparation is applicable law and international accounting standards in conformity with the requirements of the Companies Act 2006 and as regards the parent company financial statements, as applied in accordance with the provisions of the Companies Act 2006.

In our opinion:

- the financial statements give a true and fair view of the state of the group's and of the parent company's affairs as at 31 December 2020 and of the group's and parent company's loss for the year then ended;
- the group financial statements have been properly prepared in accordance with international accounting standards in conformity with the requirements of the Companies Act 2006;
- the parent company financial statements have been properly prepared in accordance with international accounting standards in conformity with the requirements of the Companies Act 2006 and as applied in accordance with the provisions of the Companies Act 2006; and
- the financial statements have been prepared in accordance with the requirements of the Companies Act 2006 and as regard to the group financial statements, international financial reporting standards adopted pursuant to Regulation (EC) No 1606/2002 as it applies in the European Union.

#### **Basis for opinion**

We conducted our audit in accordance with International We conducted our audit in accordance with International Standards on Auditing (UK) (ISAs (UK)) and applicable law. Our responsibilities under those standards are further described in the Auditor's responsibilities for the

audit of the financial statements section of our report. We are independent of the group and parent company in accordance with the ethical requirements that are relevant to our audit of the financial statements in the UK, including the FRC's Ethical Standard as applied to listed public interest entities, and we have fulfilled our other ethical responsibilities in accordance with these requirements. We believe that the audit evidence we have obtained is sufficient and appropriate to provide a basis for our opinion.

#### Conclusions relating to going concern

In auditing the financial statements, we have concluded that the director's use of the going concern basis of accounting in the preparation of the financial statements is appropriate. Our evaluation of the directors' assessment of the group's and parent company's ability to continue to adopt the going concern basis of accounting included a review of management's assessment of the going concern basis, together with budgets and cash flow forecasts for the 12 months following the reporting date. This included a review for reasonableness of assumptions used to prepare the budget and consideration of the impact of COVID-19.

Based on the work we have performed, we have not identified any material uncertainties relating to events or conditions that, individually or collectively, may cast significant doubt on the group's or parent company's ability to continue as a going concern for a period of at least twelve months from when the financial statements are authorised for issue.

In relation to the entities reporting on how they have applied the UK Corporate Governance Code, we have nothing material to add or draw attention to in relation to the directors' statement in the financial statements about whether the director's considered it appropriate to adopt the going concern basis of accounting.

Our responsibilities and the responsibilities of the directors with respect to going concern are described in the relevant sections of this report.

#### Our application of materiality

For the purposes of determining whether the financial statements are free from material misstatement, we define materiality as the magnitude of misstatement that makes it probable that the economic decisions of a reasonably knowledgeable person, relying on the financial statements, would be changed or influenced. We also determine a level of performance materiality which we use to assess the extent of testing needed to reduce an appropriately low level the probability that the aggregate of uncorrected and undetected misstatements exceeds materiality for the financial statements as a whole.

Materiality for the group financial statements was set at £46,000 (2019: £31,000). This was calculated based on 2% of total expenses for the year. Using our professional judgement, we have determined this to be the principal benchmark within the financial statements as it will be most relevant to stakeholders in assessing the financial performance of the group in its early years of development as the group is not currently revenue generating.

Materiality for the parent company financial statements was set at £40,000 (2019: £25,000). This was calculated based on a factor of group materiality. We have determined this level of materiality for the parent company to gain sufficient coverage of expenses.

We also determine a level of performance materiality which we use to assess the extent of testing needed to reduce to an appropriately low level the probability that the aggregate of uncorrected and undetected misstatements exceeds materiality for the financial statements as a whole. Performance materiality for the group financial statements was set at £32,000 (2019: £21,700) and the parent company was set at £28,000 (2019: £17,500), being 70% of materiality for the financial statements as a whole respectively.

We agreed to report to those charged with governance all corrected and uncorrected misstatements we identified through our audit with a value in excess of  $\mathfrak{L}2,300$  and for the parent company a value in excess of  $\mathfrak{L}2,000$ . We also agreed to report any other audit misstatements below that threshold that we believe warranted reporting on qualitative grounds.

#### Our approach to the audit

The group includes the listed parent company and the US based subsidiaries. We tailored the scope of our audit to ensure that we performed enough work to be able to give an opinion on the financial statements as a whole, taking into account the structure of the group and the company, the accounting processes and controls, and the industry in which they operate.

All entities in the group were audited by a single engagement team. We did not rely on the work of any component auditors.

As part of our planning we assessed the risk of material misstatement including those that required significant auditor consideration at the component and group level. Procedures were then performed to address the risk identified and for the most significant assessed risks of material misstatement, the procedures performed are outlined below in the key audit matters section of this report.

#### **Key audit matters**

Key audit matters are those matters that, in our professional judgment, were of most significance in our audit of the financial statements of the current period and include the most significant assessed risks of material misstatement (whether or not due to fraud) we identified, including those which had the greatest effect on: the overall audit strategy, the allocation of resources in the audit; and directing the efforts of the engagement team. These matters were addressed in the context of our audit of the financial statements as a whole, and in forming our opinion thereon, and we do not provide a separate opinion on these matters.

#### **Key Audit Matter**

#### How our scope addressed this matter

#### Carrying Value of investments in and loans to subsidiary undertakings

Investments held by the parent company in Hemogenyx LLC and loans to subsidiaries are a significant balance. The subsidiary undertakings are not yet revenue generating.

There is a risk that the investments and loans are overstated if the subsidiary undertakings are unable to generate sufficient future profits or gains in the foreseeable future.

Investment: £8.0m (Note 16) Loan: £2.8m (Note 15) We undertook audit procedures which included:

- Reviewing the directors' assessment of the carrying value and their conclusions thereof.
- Review of the subsidiary's financial performance.
- The assessment of recoverability determined by the development success of new medicines and treatments.
- Review and assessment of the progress of the individual projects under development.
- We also reviewed board minutes for any indications of changes in investments held by the parent Company and also agreed ownership documents of all the subsidiaries in the group.
- We also reviewed the market capitalisation of the group on the London Stock Exchange at the date of this report as a guide and to provide further assurance of its carrying value subsequent to the year end.

Our work did not identify any issues with the carrying value of investments in and loans to subsidiary undertakings.

#### Carrying value of the intangible assets

The carrying value of the Intangible Asset recorded in the subsidiary's books is the other key risk area as these items will ultimately result in the main source of income for the group.

This asset mainly derives from an exclusive license agreement signed in January 2015, where the Company purchased the patent rights surrounding the two main products under development for \$347,500. The directors concluded that no impairment was required at this stage and amortisation will commence once these products are ready for marketing.

Intangible asset: £255k (Note 14)

We undertook audit procedures which included:

- Confirming that the cost of intangibles is correctly recorded by agreeing to the price to the supporting documentation.
- Review of the directors' assessment on the intangible assets carrying value and challenging of the underlying assumptions.
- Review of the events after the year-end for indicators of impairment.

The Directors' judgements in their assessment are reasonable and our work did not identify any impairment indicators regarding the carrying value of intangible assets.

#### Other information

The other information comprises the information included in the annual report, other than the financial statements and our auditor's report thereon. The directors are responsible for the other information contained within the annual report. Our opinion on the group and parent company financial statements does not cover the other information and, except to the extent otherwise explicitly stated in our report, we do not express any form of assurance conclusion thereon. Our responsibility is to read the other information and, in doing so, consider whether the other information is materially inconsistent with the financial statements or our knowledge obtained in the course of the audit, or otherwise appears to be materially misstated. If we identify such material inconsistencies or apparent material misstatements, we are required to determine whether this gives rise to a material misstatement in the financial statements themselves. If, based on the work we have performed, we conclude that there is a material misstatement of this other information, we are required to report that fact.

We have nothing to report in this regard.

## Opinions on other matters prescribed by the Companies Act 2006

In our opinion the part of the directors' remuneration report to be audited has been properly prepared in accordance with the Companies Act 2006.

In our opinion, based on the work undertaken in the course of the audit:

- the information given in the strategic report and the directors' report for the financial year for which the financial statements are prepared is consistent with the financial statements; and
- the strategic report and the directors' report have been prepared in accordance with applicable legal requirements.

## Matters on which we are required to report by exception

In the light of the knowledge and understanding of the group and the parent company and their environment obtained in the course of the audit, we have not identified material misstatements in the strategic report or the directors' report.

We have nothing to report in respect of the following matters in relation to which the Companies Act 2006 requires us to report to you if, in our opinion:

- adequate accounting records have not been kept by the parent company, or returns adequate for our audit have not been received from branches not visited by us; or
- the parent company financial statements and the part of the directors' remuneration report to be audited are not in agreement with the accounting records and returns; or
- certain disclosures of directors' remuneration specified by law are not made; or
- we have not received all the information and explanations we require for our audit.

#### Corporate governance statement

The Listing Rules require us to review the directors' statement in relation to going concern, longer-term viability and that part of the Corporate Governance Statement relating to the group's and parent company's compliance with the provisions of the UK Corporate Governance Statement specified for our review.

Based on the work undertaken as part of our audit, we have concluded that each of the following elements of the Corporate Governance Statement is materially consistent with the financial statements or our knowledge obtained during the audit:

- Directors' statement with regards the appropriateness of adopting the going concern basis of accounting and any material uncertainties identified;
- Directors' explanation as to its assessment of the entity's prospects, the period this assessment covers and why they period is appropriate;
- Directors' statement that they consider the annual report and the financial statements, taken as a whole, to be fair, balanced and understandable;
- Board's confirmation that it has carried out a robust assessment of the emerging and principal risks;
- The section of the annual report that describes the review of effectiveness of risk management and internal control systems; and
- The section describing the work of the audit committee.

#### Responsibilities of directors

As explained more fully in the statement of directors' responsibilites, the directors are responsible for the preparation of the group and parent company financial statements and for being satisfied that they give a true and fair view, and for such internal control as the directors determine is necessary to enable the preparation of financial statements that are free from material misstatement, whether due to fraud or error.

In preparing the group and parent company financial statements, the directors are responsible for assessing the group and the parent company's ability to continue as a going concern, disclosing, as applicable, matters related to going concern and using the going concern basis of accounting unless the directors either intend to liquidate the group or the parent company or to cease operations, or have no realistic alternative but to do so.

## Auditor's responsibilities for the audit of the financial statements

Our objectives are to obtain reasonable assurance about whether the financial statements as a whole are free from material misstatement, whether due to fraud or error, and to issue an auditor's report that includes our opinion. Reasonable assurance is a high level of assurance but is not a guarantee that an audit conducted in accordance with ISAs (UK) will always detect a material misstatement when it exists. Misstatements can arise from fraud or error and are considered material if, individually or in the aggregate, they could reasonably be expected to influence the economic decisions of users taken on the basis of these financial statements.

Irregularities, including fraud, are instances of non-compliance with laws and regulations. We design procedures in line with our responsibilities, outlined above, to detect material misstatements in respect of irregularities, including fraud. The extent to which our procedures are capable of detecting irregularities, including fraud is detailed below:

 We obtained an understanding of the group and parent company and the sector in which they operate to identify laws and regulations that could reasonably be expected to have a direct effect on the financial statements. We obtained our understanding in this regard through discussions with management, application of cumulative audit knowledge and experience of the sector.

- We determined the principal laws and regulations relevant to the group and parent company in this regard to be those arising from Companies Act 2006, LSE listing rules, Disclosure and Transparency Rules and UK Corporate Governance Code (voluntary adoption).
- We designed our audit procedures to ensure the audit team considered whether there were any indications of non-compliance by the group and parent company with those laws and regulations. These procedures included, but were not limited to:
  - · Enquiries of management
  - · Review of minutes
  - · Review of RNS publications.
- As in all of our audits, we addressed the risk of fraud arising from management override of controls by performing audit procedures which included, but were not limited to: the testing of journals; reviewing accounting estimates for evidence of bias; and evaluating the business rationale of any significant transactions that are unusual or outside the normal course of business.

Because of the inherent limitations of an audit, there is a risk that we will not detect all irregularities, including those leading to a material misstatement in the financial statements or non-compliance with regulation. This risk increases the more that compliance with a law or regulation is removed from the events and transactions reflected in the financial statements, as we will be less likely to become aware of instances of non-compliance. The risk is also greater regarding irregularities occurring due to fraud rather than error, as fraud involves intentional concealment, forgery, collusion, omission or misrepresentation.

A further description of our responsibilities for the audit of the financial statements is located on the Financial Reporting Council's website at: <a href="https://www.frc.org.uk/auditorsresponsibilities">www.frc.org.uk/auditorsresponsibilities</a>. This description forms part of our auditor's report.

#### Other matters which we are required to address

We were appointed by the audit committee on 2 March 2020 to audit the financial statements for the period ending 31 December 2020 and subsequent financial periods. Our total uninterrupted period of engagement is 6 years, covering the periods ending 31 December 2015 to 31 December 2020.

We have recently become aware that, during the period of 1 May 2020 to 25 June 2020, Welbeck Associates Limited provided trust account services to Hemogenyx Pharmaceuticals Plc. The trust account was administered by a director of Welbeck Associates Limited, who is also a partner of PKF Littlejohn LLP. This service involved the use of an account held in trust to collate and transfer receipts from potential equity investors into the company relating to funds brokered by Peterhouse Capital Limited.

We are satisfied that it does not meet the definition of accounting services under the FRC Ethical Standard which would be subject to an outright prohibition under the FRC Ethical Standard. This is because they do not involve the maintenance of accounting records nor do they involve the preparation of financial statements or other subject matter. It is Peterhouse Capital Limited which maintains the accounting records relevant to this service.

Our safeguards in respect of this non-audit service have centred on the fact that the partner was not involved in the audit engagement in any capacity. The service did not involve making any judgements and as noted above, instructions were taken only from Peterhouse Capital Limited and not from Hemogenyx Pharmaceuticals Plc. We confirm that this safeguard was applied and that it enables us to conclude that our professional judgement and our audit report are not affected by the provision of the trust account service.

Our audit opinion is consistent with the additional report to the audit committee.

#### Use of our report

This report is made solely to the company's members, as a body, in accordance with Chapter 3 of Part 16 of the Companies Act 2006. Our audit work has been undertaken so that we might state to the company's

members those matters we are required to state to them in an auditor's report and for no other purpose. To the fullest extent permitted by law, we do not accept or assume responsibility to anyone, other than the company and the company's members as a body, for our audit work, for this report, or for the opinions we have formed.

**David Thompson (Senior Statutory Auditor)** For and on behalf of PKF Littlejohn LLP **Statutory Auditor** 

**15 Westferry Circus Canary Wharf** London E14 4HD

30 April 2021



## CONSOLIDATED STATEMENT OF COMPREHENSIVE INCOME

Continuing Operations	Note	Year Ended 31 December 2020 £	Year Ended 31 December 2019 £
Revenue		-	-
Administrative Expenses	6	(2,043,633)	(1,589,407)
Depreciation Expense	12	(106,753)	(94,726)
		22222	(4.00.4.400)
Operating Loss		(2,150,386)	(1,684,133)
Other Income	7	85,237	213,126
Finance Income		3,365	14,191
Finance Costs		(33,239)	(31,328)
Loss before Taxation		(2,095,023)	(1,488,144)
Income tax	10	-	35,000
Loss for the year		(2,095,023)	(1,453,144)
Loss attributable to:			
- Owners of Hemogenyx Pharmaceuticals plc		(2,082,220)	(1,450,627)
- Non-controlling interests		(12,803)	(2,517)
		(2,095,023)	(1,453,144)
Items that will be reclassified subsequently to profit or loss:			
Translation of foreign operations		(61,119)	16,176
Other Comprehensive income for the year		(61,119)	16,176
Total comprehensive income for the year		(2,156,142)	(1,436,968)
Attributable to:			
Owners of Hemogenyx Pharmaceuticals plc		(2,143,339)	(1,434,451)
Non-controlling interests		(12,803)	(2,517)
Total comprehensive loss for the year		(2,156,142)	(1,436,968)
Basic and diluted loss per share attributable to the equity owners of the Company	11	(0.005)	(0.004)



# CONSOLIDATED STATEMENT OF FINANCIAL POSITION

Group	Note	31 December 2020 £	31 December 2019 £	
Assets				
Non-current assets				
Property, plant and equipment	12	222,858	123,922	
Right of use asset	13	45,885	109,442	
Deferred financing costs	28	223,615	-	
Intangible asset	14	254,955	262,050	
Total non-current assets		747,313	495,414	
Current assets				
Trade and other receivables	17	104,972	55,804	
Cash and cash equivalents		1,812,299	498,679	
Total current assets		1,917,271	554,483	
Total assets		2,664,584	1,049,897	
Equity and Liabilities				
Equity attributable to shareholders				
Paid-in Capital				
Called up share capital	18	4,336,363	3,612,429	
Share premium	19	9,990,965	7,699,789	
Other reserves	20	764,815	399,229	
Reverse asset acquisition reserve	4	(6,157,894)	(6,157,894)	
Foreign currency translation reserve		(7,896)	53,223	
Retained Earnings		(8,035,514)	(5,953,294)	
Equity attributable to owners of the Company		890,838	(346,518)	
Non-controlling interests		(15,158)	(2,517)	
Total Equity		875,680	(349,035)	
Liabilities				
Non-current liabilities				
Lease liabilities	13	10,028	73,192	
Borrowings	23	-	1,144,167	
Total non-current liabilities		10,028	1,217,359	
Current liabilities				
Trade and other payables	22	160,771	141,677	
Borrowings	23	1,579,378	-	
Lease liabilities	13	38,726	39,896	
Total Current Liabilities		1,778,875	181,573	
Total Liabilities		1,788,903	1,398,932	
Total equity and liabilities		2,664,584	1,049,897	

This report was approved by the Board and authorised for issue on 30 April 2021 and signed on its behalf by: Dr Vladislav Sandler, CEO

## COMPANY STATEMENT OF FINANCIAL POSITION

Company	Note	31 December 2020 £	31 December 2019 £
Assets			
Non-current assets			
Loan to subsidiaries	15	2,766,051	1,570,839
Deferred financing costs	28	213,472	-
Investment in subsidiary	16	8,000,000	8,000,000
Total non-current assets		10,979,523	9,570,839
Current assets			
Trade and other receivables	17	61,448	6,282
Cash and cash equivalents		1,036,214	14,505
Total current assets		1,097,662	20,787
Total assets		12,077,185	9,591,626
Equity and Liabilities			
Equity attributable to shareholders			
Paid-in Capital			
Called up share capital	18	4,336,363	3,612,429
Share premium	19	9,990,965	7,699,789
Other reserves	20	749,767	386,662
Retained Earnings		(3,136,290)	(2,205,815)
Total Equity		11,940,805	9,493,065
Liabilities			
Current liabilities			
Trade and other payables	22	136,380	98,561
Total Current Liabilities		136,380	98,561
Total Liabilities		136,380	98,561
Total equity and liabilities		12,077,185	9,591,626

Hemogenyx Pharmaceuticals plc has used the exemption granted under s408 of the Companies Act 2006 that allows for the non-disclosure of the Income Statement of the parent company. The after-tax loss attributable to Hemogenyx Pharmaceuticals plc for the year ended 31 December 2020 was £930,475 (2019: £486,048).

This report was approved by the Board and authorised for issue on 30 April 2020 and signed on its behalf by: Dr Vladislav Sandler, CEO

# CONSOLIDATED STATEMENT OF CHANGES IN EQUITY

Group	Called up Share Capital	Share Premium	Other reserves	Reverse acquisition reserve	Foreign currency translation reserve	Retained earnings	Non- Controlling interests	Total Equity
	£	£	£	£	£	£	£	£
As at 1 January 2019	3,601,762	7,340,267	686,851	(6,157,894)	37,047	(4,548,867)	-	959,166
Loss in year	-	-	-	-	-	(1,450,627)	(2,517)	(1,453,144)
Other Comprehensive Income	-	-	-	-	16,176	-	-	16,176
Total comprehensive income for the year	-	-	-	-	16,176	(1,450,627)	(2,517)	(1,436,968)
Issue of shares – exercise of warrants	10,667	21,333	-	-	-	-	-	32,000
Embedded derivate on convertible note	-	-	6,280	-	-	-	-	6,280
Issue of options	-	-	90,487	-		-	-	90,487
Writeback of options lapsed	-	-	(46,200)	-		46,200	-	-
Write-back of warrants exercised	-	338,189	(338,189)	-	_	-	-	-
As at 31 December 2019	3,612,429	7,699,789	399,229	(6,157,894)	53,223	(5,953,294)	(2,517)	(349,035)
Loss in year	-	-	-	-	-	(2,082,220)	(12,803)	(2,095,023)
Other Comprehensive Income	-	-	-	-	(61,119)	-	-	(61,119)
Total comprehensive income for the year	-	-	-	-	(61,119)	(2,082,220)	(12,803)	(2,156,142)
Issue of shares, net	717,254	2,262,786	-	-	-	-	-	2,980,040
Exercise of warrants	6,680	28,390	-	-	-	-	-	35,070
Embedded derivate on convertible note	-	-	2,482	-	-	-	-	2,482
Issue of options	-	-	363,104	-	-	-	-	363,104
Purchase of subsidiary shares	-	-	-	-	-	-	162	162
As at 31 December 2020	4,336,363	9,990,965	764,815	(6,157,894)	(7,896)	(8,035,514)	(15,158)	875,681

# COMPANY STATEMENT OF CHANGES IN EQUITY

Company	Called up Share Capital	Share Premium	Other reserves	Retained earnings/(loss)	Total Equity
	£	£	£	£	£
As at 1 January 2019	3,601,762	7,340,267	680,564	(1,765,967)	9,856,626
Loss in year	-	-	-	(486,048)	(486,048)
Other Comprehensive Income	-	-	-	-	-
Total comprehensive income for the year	-	-	-	(486,048)	(486,048)
Issue of shares – exercise of warrants	10,667	21,333	-	-	32,000
Issue of options	-	-	90,487	-	90,487
Write-back of options lapsed	-	-	(46,200)	(46,200)	-
Write-back of warrants exercised	-	338,189	(338,189)	-	-
As at 31 December 2019	3,612,429	7,699,789	386,662	(2,205,815)	9,493,065
Loss in year	-	-	-	(930,475)	(930,475)
Other Comprehensive Income	-	-	-	-	-
Total comprehensive income for the year	-	-	-	(930,475)	(930,475)
Issue of shares	717,254	2,262,786	-	-	2,980,040
Exercise of warrants	6,680	28,390	-	-	35,070
Issue of options	-	-	363,105	-	363,105
As at 31 December 2020	4,336,363	9,990,965	749,767	(3,136,290)	11,940,805

## CONSOLIDATED STATEMENT OF CASH FLOWS

Group	Note	Year Ended 31 December 2020 £	Year Ended 31 December 2019 £
Cash flows generated from operating activities			
Loss before income tax		(2,095,023)	(1,453,144)
Depreciation	12	106,753	94,726
Other Non-cash items		172	-
Interest income		(3,365)	(14,191)
Interest expense		33,239	31,328
Compensation settled in shares		· .	32,000
Share based payments	20	363,104	90,487
Foreign exchange gain/(loss)		(146,772)	20,745
(Decrease) in trade and other payables		(35,738)	(17,880)
(Increase)/decrease in trade and other receivables		(21,397)	16,056
Prepaid and deposits		623	· -
Net cash outflow used in operating activities		(1,798,404)	(1,199,873)
Cash flows generated from financing activities			
Proceeds from issuance of equity securities		3,148,200	_
Proceeds from exercise of warrants		35,070	_
	23		-
Proceeds from borrowings Share issue costs	23	461,776	-
		(168,160)	-
Deferred financing costs	40	(223,615)	-
Payment of lease liabilities	13	(41,249)	(39,393)
Net cash flow generated from (used in) financing activities	_	3,212,022	(39,393)
Cash flows generated from investing activities			
Interest income		3,365	14,191
Purchase of property, plant & equipment		(173,047)	(11,918)
Net cash flow generated from (used in) investing activities		(169,682)	2,273
Net increase /(decrease) in cash and cash equivalents		1,243,936	(1,236,993)
Effect of exchange rates on cash		69,684	(26,756)
Cash and cash equivalents at the beginning of the period		498,679	1,762,428
Cash and cash equivalents at the end of the period		1,812,299	498,679

## COMPANY STATEMENT OF CASH FLOWS

Company	Note	Year Ended 31 December 2020	Year Ended 31 December 2019
		£	£
Cash flows generated from operating activities			
Loss before income tax	_	(930,475)	(486,048)
Foreign exchange (gain)		26,508	48,621
Interest income		-	(76)
Compensation settled in shares		-	32,000
Share based payments	20	363,105	90,487
(Decrease) in trade and other payables		(13,153)	(35,524)
Decrease in trade and other receivables		(4,195)	69,692
Net cash outflow used in operating activities		(558,210)	(280,848)
Cash flows generated from financing activities			
Proceeds from issuance of equity securities	_	3,148,200	-
Proceeds from exercise of warrants		35,070	-
Share issue costs		(168,160)	-
Deferred financing costs		(213,472)	-
Net cash flow generated from financing activities		2,801,638	-
Cash flows generated from investing activities			
Interest income	_	_	76
Loan to related parties		(1,221,678)	(151,914)
Net cash flow generated from investing activities		(1,221,678)	(151,838)
Net (Decrease)/increase in cash and cash equivalent		1,021,750	(432,686)
Effect of exchange rates on cash		(41)	(13,812)
Cash and cash equivalents at the beginning of the period		14,505	461,003
Cash and cash equivalents at the end of the period		1,036,214	14,505

#### 1. General information

The Group's business is preclinical-stage biotechnology focused on the discovery, development and commercialisation of innovative treatments relating to bone marrow/hematopoietic (blood-forming) stem cell (BM/HSC) transplants for blood diseases, including leukaemia, lymphoma and bone marrow failure, autoimmune disease, and viral infections. The products under development are designed to address a range of problems that occur with current standard of care treatments.

The Company's registered office is located at 5 Fleet Place, London EC4M 7RD, and it is listed on the London Stock Exchange.

#### 2. Summary of significant accounting policies

The principal accounting policies applied in the preparation of these financial statements are set out below. These policies have been consistently applied to all the years presented, unless otherwise stated.

#### **Basis of preparation**

The financial statements have been prepared in accordance with international accounting standards in conformity with the Companies Act 2006 and international financial reporting standards adopted pursuant to Regulation (EC) No.1606/2002 as it applies in the European Union. The financial statements have been prepared under the historical cost convention.

#### **Basis of consolidation**

The consolidated financial statements comprise the financial statements of Hemogenyx Pharmaceuticals plc and its subsidiaries as at 31 December 2020. The financial statements of the subsidiaries are prepared for the same reporting period as the parent company, using consistent accounting policies.

All intra-group balances, transactions, income and expenses and profits and losses resulting from intra-group transactions that are recognised in assets, are eliminated in full.

Subsidiaries are fully consolidated from the date of acquisition, being the date on which the Group obtains control, and continue to be consolidated until the date

that such control ceases. Hemogenyx Pharmaceuticals plc owns the majority of the shareholdings and has operational control over all its subsidiaries. Please refer to Note 4 for information on the consolidation of Hemogenyx Pharmaceuticals LLC.

Hemogenyx Pharmaceuticals plc has used the exemption grated under s408 of the Companies Act 2006 that allows for the non-disclosure of the Income Statement of the parent company. The after-tax loss attributable to Hemogenyx Pharmaceuticals plc for the year ended 31 December 2020 was £930,475 (2019: £486,048).

#### Research and development expenditure

#### Research and development

Expenditure on research activities, undertaken with the prospect of gaining new scientific or technical knowledge and understanding, is expensed in profit or loss as incurred. Development activities involve a plan or design for the production of new or substantially improved products and processes. Development expenditures are capitalised only if development costs can be measured reliably, the product or process is technically and commercially feasible, future economic benefits are probable, and the Company intends to, and has sufficient resources to, complete development and to use or sell the asset. No development costs have been capitalised to date.

#### ii. Clinical trial expenses

Clinical trial expenses are a component of the Company's research and development costs. These expenses include fees paid to contract research organisations, clinical sites, and other organisations who conduct development activities on the Company's behalf. The amount of clinical trial expenses recognised in the period related to clinical agreements is based on estimates of the work performed using an accrual basis of accounting. These estimates incorporate factors such as patient enrolment, services provided, contractual terms, and prior experience with similar contracts.

#### iii. Government grants

Government grants relate to financial grants from governments, public authorities, and similar local, national or international bodies. These are recognised when there is a reasonable assurance that the Company will comply with the conditions attaching to them, and

that the grant will be received. Government grants relating to research and development are off-set against the relevant costs.

#### **Intangibles**

#### Research and development

Research expenditure is written off as incurred. Development costs are capitalised only if the expenditure can be measured reliably, the product or process is technically and commercially feasible, future economic benefits are probable, the Group intends to and has sufficient resources to complete development and to use or sell the asset, and it is able to measure reliably the expenditure attributable to the intangible asset during its development.

The Group's view is that capitalised assets have a finite useful life and to that extent they should be amortised over their respective unexpired periods with provision made for impairment when required. Assets capitalised are not amortised until the associated product is available for use or sale. Amortisation is calculated using the straight-line method to allocate the costs of development over the estimated useful economic lives. Estimated useful economic life is assessed by reference to the remaining patent life and may be adjusted after taking into consideration product and market characteristics such as fundamental building blocks and product life cycle specific to the category of expenditure.

#### Intellectual property (IP)

IP assets (comprising patents, know-how, copyright and licences) acquired by the Group as a result of a business combination are initially recognised at fair value or as a purchase at cost and are capitalised.

Internally generated IP costs are written off as incurred except where IAS 38 criteria, as described in research and development above, would require such costs to be capitalised.

The Group's view is that capitalised IP assets have a finite useful life and to that extent they should be amortised over their respective unexpired periods with provision made for impairment when required. Capitalised IP assets are not amortised until the Group is generating an economic return from the underlying asset and as such no amortisation has been incurred to date as the products to which they relate are not ready to be sold on the open market. When the trials are completed and the products attain the necessary accreditation and clearance from the regulators, the Group will assess the estimated useful economic like and the IP will be amortised using the straight-line method over their estimated useful economic lives.

#### **Fixed assets**

All property, plant and equipment are stated at historical cost less accumulated depreciation or impairment value. Cost includes the original purchase price and expenditure that is directly attributable to the acquisition of the items to bring the asset to its working condition. Depreciation is provided at rates calculated to write off the cost less estimated residual value of each asset over its expected useful economic life. Right of Use assets are depreciated over their expected useful economic life on the same basis as owned assets, or where shorter, the lease term. Assets are reviewed for impairment when events or changes in circumstances indicate that the carrying amount may not be recoverable.

#### The following rates are used:

Computer equipment	33%	Straight-line
Property, plant & equipment	20% - 50%	Straight-line

#### Impairment of non-financial assets

The Group is required to review, at least annually, whether there are indications (events or changes in circumstances) that non-financial assets have suffered impairment and that the carrying amount may exceed the recoverable amount. If there are indications of impairment then an impairment review is undertaken. An impairment charge is recognised within operating costs for the amount by which the carrying amount exceeds its recoverable amount. The recoverable amount is the higher of the asset's fair value less costs to sell and the value-in-use. In the event that an intangible asset will no longer be used, for example, when a patent is abandoned, the balance of unamortised expenditure is written off.

Impairment reviews require the estimation of the recoverable amount based on value-in-use calculations. Non-financial assets relate typically to investments in related parties and in-process development and patents, and require broader assumptions than for developed technology. Key assumptions taken into consideration relate to technological, market and financial risks and include the chance of product launch taking into account the stage of development of the asset, the scale of milestone and royalty payments, overall market opportunities, market size and competitor activity, revenue projections, estimated useful lives of assets (such as patents), contractual relationships and discount rates to determine present values of cash flows.

#### Investments

Equity investments in subsidiaries are held at cost, less any provision for impairment. As there is no quoted price in an active market, fair value cannot be reliably measured.

#### Going concern

The preparation of financial statements requires an assessment on the validity of the going concern assumption.

The Directors have given particular thought to the impact on the Group that may result from the novel coronavirus and any other potential pandemics that may arise. The Group's New York operations are classed as an essential business and are not subject to closure, and so work has continued with prudent hygiene and

distancing measures in place including limited work in the laboratory on rota and work from home. The Group is allowing for extended delivery times for some supplies, and for slower progress with collaboration partners. The Board and UK management continue to operate remotely, as usual. At present the Group believes that there should be no material disruption to its work, but the Board continues to monitor these risks and the Group's business continuity plans.

The Directors have reviewed projections for a period of at least 12 months from the date of approval of the financial statements. The financial statements have been prepared on the going concern basis. The Group's forecasts and projections, taking account of reasonably possible changes in trading performance, show that the Group will not require further funding in the next 12 months. As discussed in Note 28, the Group has entered into a financing agreement which will provide up to £60 million of financing to the Group over the next few years. The Directors therefore believe that the Group has or will have access to sufficient funding in order to execute its operations over the next 12 months. Therefore, the Directors consider the going concern basis appropriate.

#### Trade and other receivables and payables

Trade and other receivables are amounts due from customers for services performed in the ordinary course of business. If collection is expected in one year or less (or in the normal operating cycle of the business if longer), they are classified as current assets. If not, they are presented as non-current assets.

Trade and other receivables are recognised initially at fair value, and subsequently measured at amortised cost using the effective interest method, less provision for impairment.

Other liabilities measured at amortised cost are obligations to pay for goods or services that have been acquired in the ordinary course of business from suppliers. The liabilities are classified as current liabilities if payment is due within one year or less (or in the normal operating cycle of the business if longer). If not, they are presented as non-current liabilities.

The liabilities are recognised initially at fair value, and subsequently measured at amortised cost using the effective interest method.

#### Foreign currencies

#### Functional and presentation currency

The Company's presentation currency is the British Pound Sterling ("£"). The functional currency for the Company, being the currency of the primary economic environment in which the Company operates, is the British Pound Sterling. The individual financial statements of each of the Company's wholly owned subsidiaries are prepared in the currency of the primary economic environment in which it operates (its functional currency).

The financial statements of Hemogenyx Pharmaceuticals LLC, Immugenyx LLC and Hemogenyx-Cell SPRL have been translated in to Pound Sterling in accordance with IAS 21 *The Effects of Changes in Foreign Exchange Rates*. This standard requires that assets and liabilities be translated using the exchange rate at period end, and income, expenses and cash flow items are translated using the rate that approximates the exchange rates at the dates of the transactions (i.e. the average rate for the period). The foreign exchange differences on translation of Hemogenyx Pharmaceuticals LLC, Immugenyx LLC and Hemogenyx-Cell SPRL are recognised in other comprehensive income (loss).

#### Foreign currency transactions

Foreign currency transactions are translated into the functional currency using the exchange rates prevailing on the dates of the transactions. Foreign exchange gains and losses resulting from the settlement of such transactions and from the translation at periodend exchange rates of monetary assets and liabilities denominated in foreign currencies are recognised in profit and loss.

#### Share capital

Ordinary Shares are classified as equity. Equity instruments issued by the Hemogenyx Pharmaceuticals Group are recorded at the proceeds received, net of direct issue costs.

#### Cash

Cash consists of cash bank deposit balances.

#### **Deferred Financing Costs**

Deferred financing costs represent direct expenditures made by the Company for the financing transaction

completed in January 2021. These costs will be offset against the proceeds received in 2021 from the financing transactions.

#### Share based payments

The Group has applied the requirements of IFRS 2 Share-based Payment for all grants of equity instruments.

The Group operates an equity-settled share option plan to certain shareholders. The fair value of the service received in exchange for the grant of options and warrants is recognised as an expense. Equity-settled sharebased payments are measured at fair value (excluding the effect of non-market based vesting conditions) at the date of grant. The fair value determined at the grant date of equity-settled share-based payment is expensed on a graded vesting basis over the vesting period, based on the Group's estimate of shares that will eventually vest and adjusted for the effect of non-market based vesting conditions.

Fair value is measured by use of the Black-Scholes model. The expected life used in the models has been adjusted, based on management's best estimate, for the effects of non-transferability, exercise restrictions, and behavioural considerations.

In addition, the Group issues equity-settled share-based payments to the directors, senior management and employees ("Employee Share Options"), to corporate finance advisers for assistance in raising private equity, and to its Scientific Advisory Board members ("Nonemployee Share Options"). Equity-settled share-based payments are measured at fair value at the date of grant for Employee Share Options and the date of service for Non-employee Share Options. The fair value determined at the grant date or service date, as applicable, of the equity-settled share-based payments is expensed, with a corresponding credit to equity, on a straight-line basis over the vesting period, based on the Group's estimate of shares that will eventually vest. At each subsequent reporting date, the Group calculates the estimated cumulative charge for each award having regard to any change in the number of options that are expected to vest and the expired portion of the vesting period. The change in this cumulative charge since the last reporting date is expensed with a corresponding credit being made to equity. Once an option vests, no further adjustment is

made to the aggregate amount expensed.

The fair value is calculated using the Black Scholes method for both Employee and Non-employee Share Options as management views the Black Scholes method as providing the most reliable measure of valuation. The expected life used in the model has been adjusted, based on management's best estimate, for the effects of non-transferability exercise restrictions and behavioural considerations. The market price used in the model is the issue price of Company shares at the last placement of shares immediately preceding the calculation date. The fair values calculated are inherently subjective and uncertain due to the assumptions made and the limitation of the calculations used.

#### **Taxation**

#### Current tax

Current taxation is based on the results for the year as adjusted for items that are non-assessable or disallowed. It is calculated using rates that have been enacted, or substantially enacted, by the balance sheet date. Current income tax assets and liabilities are measured at the amount expected to be recovered from or paid to the relevant taxation authorities.

#### Deferred tax

Deferred income tax is recognised on all temporary differences arising between the tax bases of assets and liabilities and their carrying amounts in the financial statements, with the following exceptions:

- where the temporary difference arises from the initial recognition of goodwill or of an asset or liability in a transaction that is not a business combination and, at the time of the transaction, affects neither accounting nor taxable profit or loss;
- in respect of taxable temporary differences associated with investment in subsidiaries, associates and joint ventures, where the timing of the reversal of the temporary differences can be controlled and it is probable that the temporary differences will not reverse in the foreseeable future; and
- deferred income tax assets are recognised only to the extent that it is probable that taxable profit will be available against which the deductible temporary differences, carried forward tax credits or tax losses can be utilised.

Deferred income tax assets and liabilities are measured on an undiscounted basis at the tax rates that are expected to apply when the related asset is realised or liability is settled, based on tax rates and laws enacted or substantively enacted at the statement of financial position date.

The carrying amount of deferred income tax assets is reviewed at each statement of financial position date. Deferred income tax assets and liabilities are offset, only if a legally enforcement right exists to set off current tax assets against current tax liabilities, the deferred income taxes related to the same taxation authority and that authority permits the Company to make a single net payment.

Income tax is charged or credited directly to equity if it relates to items that are credited or charged to equity. Otherwise income tax is recognised in the statement of comprehensive income.

#### **Financial Assets and Liabilities**

Financial assets and liabilities are recognised in the Company's statement of financial position when the Company becomes a party to the contractual provisions of the instrument. The Company currently does not use derivative financial instruments to manage or hedge financial exposures or liabilities.

Loans and receivables are non-derivative financial assets with fixed or determinable payments that are not quoted in an active market. They are included in current assets, except for maturities greater than 12 months after the end of the reporting period. These are classified as non-current assets. The Company's loans and receivables comprise Trade and Other Receivables and Cash and Cash Equivalents in the Statement of Financial Position.

#### **Impairment of Financial Assets**

The Company and Group assesses at each reporting date whether a financial asset is impaired and will recognise the impairment loss immediately through the consolidated statement of comprehensive loss.

#### **Interest Bearing Loans and Borrowings**

Borrowings are initially recognised at the fair value of consideration received less directly attributable transaction costs. After initial recognition, borrowings

are subsequently measured at amortised cost using the effective interest rate method. Where borrowings are provided by shareholders at an interest rate discounted to market rates, the difference on initial fair value is taken to equity as a capital contribution.

Where the Group has entered into a hybrid instrument whereby there is a debt instrument and an embedded derivative financial liability, the fair value of the debt instrument less the fair value of the derivative financial liability is equal to loan recognised on initial measurement.

#### IFRS 15, Revenue from Contracts with Customers

The Company follows IFRS 15, which establishes principles for reporting useful information to users of financial statements about the nature, amount, timing, and uncertainty of revenue and cash flows arising from an entity's contracts with customers. The standard establishes a five-step principle-based approach for revenue recognition and is based on the concept of recognising an amount that reflects the consideration for performance obligations only when they are satisfied, and the control of goods or services is transferred.

The majority of the Group's revenue is derived from fees related to collaboration agreements.

Management reviewed contracts where the Group received consideration in order to determine whether or not they should be accounted for in accordance with IFRS 15. To date, Hemogenyx Pharmaceuticals has entered into few transactions that meet the scope of IFRS 15. Instead, most income has been generated through collaboration agreements and grants with counterparties that do not meet the definition of a customer, and therefore the contracts fall outside the scope of IFRS 15 and have been accounted for in accordance with IAS 20.

Income is recognised at either a point-in-time or over time, depending on the nature of the services and existence of acceptance clauses.

#### IFRS 16, Leases

IFRS 16 requires lessees to recognise a lease liability reflecting future lease payments and a 'right-of-use asset' for virtually all lease contracts. IFRS 16 includes an optional exemption for certain short-term leases and

leases of low-value assets; however, this exemption can only be applied by lessees. For lessors, the accounting remains substantially unchanged. IFRS 16 provides updated guidance on the definition of a lease (as well as the guidance on the combination and separation of contracts); under IFRS 16, a contract is, or contains, a lease if the contract conveys the right to control the use of an identified asset for a period of time in exchange for consideration.

The right-of-use asset and lease liability are both based on the present value of lease payments due over the term of the lease, with the asset being depreciated in accordance with IAS 16 *Property, Plant and Equipment* and the liability increased for the accretion of interest and reduced by lease payments.

Note 13 sets out the key impacts on the Consolidated Statement of Comprehensive Loss and the Consolidated Statement of Financial Position of the adoption of the standard.

#### Segmental reporting

The Group's operations are located in New York, USA and in Liège, Belgium with the head office located in the United Kingdom. The main assets of the Group, cash and cash equivalents, are held in the United Kingdom, Belgium and the United States. The Board ensures that adequate amounts are transferred internally to allow all companies to carry out their operations on a timely basis.

The Group currently has one reportable segment – a biotechnology company focused on the discovery, development and commercialisation of innovative treatments relating to bone marrow/hematopoietic (blood-forming) stem cell (BM/HSC) transplants for blood disease.

## New Accounting Standards and Interpretations issued and applied in the Financial Statements

Amendments to References to the Conceptual Framework in IFRS Standards: included are revised definitions of an asset and a liability as well as new guidance on measurement and derecognition, presentation and disclosure.

Amendment to IFRS 3: Business Combinations: the amendments clarify that to be considered a business,

an acquired set of activities and assets must include, at a minimum, an input and a substantive process that together significantly contribute to the ability to create outputs. The definition removes the reference to an ability to reduce costs, and the assessment of whether market participants are capable of replacing any missing inputs or processes and continuing to produce outputs. An optional concentration test that permits a simplified assessment of whether an acquired set of activities and assets is not a business has been included as part of the amendments.

Amendments to IAS 1 and IAS 8: *Definition of Material:* the amendments clarify the definition of material and how it should be applied. The amendments ensure that the definition of material is consistent across all IFRS Standards.

Adoption of the above standards did not have a material impact on the consolidated financial statements.

## New Accounting Standards and Interpretations in issue but not applied in the Financial Statements

The standards and interpretations that are issued, but not yet effective, up to the date of issuance of the financial statements are listed below. The Group and Company intend to adopt these standards, if applicable, when they become effective. These are summarised below:

Amendments to IAS 1: Classification of Liabilities as Current or Non-current: the amendments clarify that the classification of liabilities as current or non-current should be based on rights that are in existence at the end of the reporting period, and refer to the "right" to defer settlement by at least twelve months. They make explicit that only rights in place "at the end of the reporting period" should affect the classification of a liability. The amendments clarify that classification is unaffected by expectations about whether an entity will exercise its right to defer settlement of a liability, and clarify that settlement refers to the transfer to the counterparty of cash, equity instruments, other assets or services. Issued 23 January 2020, applies to accounting periods beginning on or after 1 January 2022, subject to EU endorsement.

Amendment to IAS 1: Classification of Liabilities as Current or Non-current – Deferral of Effective Date: the amendment defers the effective date of the January 2020 amendments to IAS 1 by one year to annual reporting periods beginning on or after 1 January 2023. Issued 15 July 2020, applies to accounting periods beginning on or after 1 January 2023 with early application of the January 2020 amendments permitted, subject to EU endorsement.

Amendments to IFRS 3: Business Combinations - reference to the Conceptual Framework: The changes in Reference to the Conceptual Framework (Amendments to IFRS 3) update IFRS 3 so that it refers to the 2018 Conceptual Framework instead of the 1989 Framework. They also add to IFRS 3 a requirement that, for transactions and other events within the scope of IAS 37 or IFRIC 21, an acquirer applies IAS 37 or IFRIC 21 (instead of the Conceptual Framework) to identify the liabilities it has assumed in a business combination. Lastly, they add to IFRS 3 an explicit statement that an acquirer does not recognise contingent assets acquired in a business combination. Issued 14 May 2020, applies for annual periods beginning on or after 1 January 2020, with early application permitted if an entity also applies all other updated references at the same time or earlier, subject to EU endorsement.

Annual Improvements to IFRS Standards 2018-2020: The pronouncement contains amendments to four International Financial Reporting Standards (IFRSs) as result of the IASB's annual improvements project:

- IFRS 1 First-time Adoption of International Financial Reporting Standards: subsidiary as a first-time adopter
   The amendment permits a subsidiary that applies paragraph D16(a) of IFRS 1 to measure cumulative translation differences using the amounts reported by its parent, based on the parent's date of transition to IFRSs.
- IFRS 9 Financial Instruments fees in the '10 per cent' test for derecognition of financial liabilities
   The amendment clarifies which fees an entity includes when it applies the '10 per cent' test in IFRS 9 in assessing whether to derecognise a financial liability. An entity includes only fees paid or received between the entity (the borrower) and the lender, including fees paid or received by either the entity or the lender on the other's behalf.

IFRS 16 Leases - Lease incentives - the amendment to Illustrative Example 13 accompanying IFRS 16 removes from the example the illustration of the reimbursement of leasehold improvements by the lessor in order to resolve any potential confusion regarding the treatment of lease incentives that might arise because of how lease incentives are illustrated in that example. Issued 14 May 2020, applicable for annual periods beginning on or after 1 January 2022 with early application permitted in respect of IFRS 1, IFRS 9, and IAS 41. The amendment to IFRS 16 only regards an illustrative example, so no effective date is stated. All subject to EU endorsement.

The Group has not early adopted any of the above standards and the directors are assessing the impact on future financial statements. There are no other IFRS or IFRIC interpretations that are not yet effective that would be expected to have a material impact on the Group.

#### 3. Significant accounting judgements, estimates and assumptions

The preparation of the financial statements in conformity with International Financial Reporting Standards requires the use of certain critical accounting estimates. It also requires management to exercise its judgement in the process of applying the Company's accounting policies.

Estimates and judgements are continually evaluated, and are based on historical experience and other factors, including expectations of future events that are believed to be reasonable under the circumstances. The estimates and assumptions that have a significant risk of causing a material adjustment to the carrying amounts of assets and liabilities within the next financial year are discussed below.

The principal areas in which judgement is applied are as follows:

#### Fair value disclosure

The embedded derivative elements of the convertible notes are measured using a risk-based pricing model. The computed fair value was not significant in 2020 and 2019.

#### Valuation of stock options

Management uses the Black Scholes model to value the share options. The model requires use of assumptions regarding volatility, risk free interest rate and a calculation of the value of the option at the time of the grant. Please see Note 20 for details.

#### Intangible assets impairment

When there is an indicator of a significant and permanent reduction in the value of intangible assets, an impairment review is carried out. The impairment analysis is principally based on estimated discounted future cash flows. The determination of the assumptions is subjective and requires the exercise of considerable judgement about the outcome of research and development activity, probability of technical and regulatory success, amount and timing of projected future cash flow or changes in market conditions. Any changes in key assumptions could materially affect whether an impairment exists. See Note 14 for further details.

#### 4. Reverse acquisition and LSE listing

On 4 October 2017, the Company acquired the entire issued share capital of Hemogenyx Pharmaceuticals LLC, a private company incorporated in the United States, by way of a share for share exchange. In substance, the shareholders of Hemogenyx Pharmaceuticals LLC acquired a controlling interest in the Company and the transaction has therefore been accounted for as a reverse acquisition. Following the completion of the transaction the Company changed its name to Hemogenyx Pharmaceuticals plc.

The reverse acquisition reserve that arose from the reverse takeover is \$6,157,894 at December 31, 2020 and 2019 and is made up of the following:

	Components
	£
As at start of year	-
Pre-acquisition losses of Hemogenyx Pharmaceuticals plc <sup>1</sup>	
	(799,763)
Hemogenyx Pharmaceuticals LLC issued capital at acquisition <sup>2</sup>	
	1,010,849
Investment in Hemogenyx Pharmaceuticals LLC <sup>3</sup>	
	(8,000,000)
Reverse acquisition expense <sup>4</sup>	1,631,020
As at December 31, 2020 and 2019	(6,157,894)

The movements on the Reverse acquisition reserve are as follows:

- These consolidated financial statements present the legal capital structure of the Company. However, under reverse acquisition accounting rules, the Company was not acquired until 4 October 2017 and therefore the entry above is required to eliminate the initial retained losses of the Company.
- 2. Hemogenyx Pharmaceuticals LLC had issued share capital of equivalent to £1,010,849 as at 4 October 2017. As these financial statements present the capital structure of the parent entity, the issue of equity by Hemogenyx Pharmaceuticals LLC has been recorded in this reserve.
- 3. The Company issued 228,571,428 shares at £0.035 each, totalling £8,000,000 for the entire issued capital of Hemogenyx Pharmaceuticals LLC. The above entry is required to eliminate the balance sheet impact of this transaction.
- 4. The entry above represents the difference between the value of the equity issued by the Company, and the deemed consideration given by Hemogenyx Pharmaceuticals LLC to acquire the Company.

#### 5. Segment Information

The Group has one reportable segment, the development of breakthrough therapies for the treatment of blood diseases, and administrative functions in the United Kingdom, and therefore the segmental information is the same as that presented in the primary statements.

The following tables present expenditure and certain asset information regarding the Group's geographical segments for the year ended 31 December 2020 and 2019:

	Year Ended 31 December 2020	Year Ended 31 December 2019
Revenue	٤	£
SEGMENT ASSETS		
United Kingdom		
<ul> <li>Non-current</li> </ul>	348,472	-
Current	1,097,662	20,787
United States		
<ul> <li>Non-current</li> </ul>	533,841	495,414
Current	798,515	513,729
Belgium		
Non-current	-	<u>-</u>
<ul> <li>Current</li> </ul>	21,094	19,967
Total		
<ul> <li>Non-current</li> </ul>	882,313	495,414
• Current	1,917,271	554,483
CAPITAL EXPENDITURE		
United Kingdom	-	-
United States	173,047	11,918
Belgium		<u>-</u> _
	173,047	11,918

Capital expenditure consists of the purchase of property, plant and equipment.

#### 6. Expenses by nature

	Group	Group
	Year Ended 31 December 2020	Year Ended 31 December 2019
	£	£
Laboratory expenses	83,662	21,246
Consumable equipment and supplies	267,057	400,571
Contractors & consultants	(1,459)	47,666
Travel	4,218	33,505
Staff Costs	1,130,764	691,992
Insurance	39,303	50,499
Other	80,187	74,815
Legal and professional fees	505,812	256,092
Foreign exchange loss / (gain)	(65,910)	13,021
Total Administrative Expenses	2,043,633	1,589,407

#### 7. Other income

Other income of £85,237 during the year to 31 December 2020 (2019: £213,126) relates to funds received from a third party under a research collaboration programme.

#### 8. Employees

	Group Year Ended 31 December 2020	Group Year Ended 31 December 2019	Company Year Ended 31 December 2020	Company Year Ended 31 December 2019
	£	£	£	£
Wages and salaries	713,788	547,127	208,750	118,251
Social security	37,732	40,667	2,506	-
Share based payments	363,105	90,487	363,105	90,487
Pension contributions	16,138	13,711	250	-
	1,130,763	691,992	574,611	208,738

Average number of people (including Executive Directors) employed:

Current Tax charge

	Group	Group	Compar	ny Company
	Year Ended 31 December 2020	Year Ended 31 December 2019	Year Ende 31 December 202	
Research & development	5	5		
Administration	3	2		2 2
-	8	7		2 2
9. Auditor's remuneration				
			Company	Company
		Ye. 31 Decemb	ar Ended oer 2020	Year Ended 31 December 2019
			3	3
Fees payable to the Comp	any auditor:		'	
Audit of the financial stater and Company	ments of the Group		45,090	45,000
, ,	_		45,090	45,000
10. Income tax				
			Company	Company
		Ye 31 Decemb	ar Ended oer 2020	Year Ended 31 December 2019
			£	£
Current Tax:				
New York City Biotech tax	credit – prior years		-	35,000
Tax on loss on ordinary act	ivities		-	35,000
Loss on ordinary activities	before tax	(2,0	095,023)	(1,453,144)
Analysis of charge in the y	/ear:			
Loss on ordinary activities	multiplied by			
weighted average tax rate 23.10% (2019: 26.16%)	for the group of	(	483,950)	(380,142)
Disallowed items			116	23,137
Timing differences			68,990	-
New York City Biotech tax	credit		-	35,000
Tax losses carried forward			(414,844)	(357,005)

35,000

Weighted average tax rate is calculated by reference to the tax rates effective in each of the jurisdictions. The tax rates effective at 31 December 2020 are 19%, 26% and 29% in the UK, the USA and Belgium respectively.

The Group has accumulated tax losses arising in the UK of approximately £1,447,000 (Dec 2019: £880,391) that should be available, under current legislation, to be carried forward against future profits. No deferred tax asset has been recognised against these losses. The Group has tax losses carried forward in the US of approximately £3,145,000 available under current rules until 2037. No deferred tax asset has been recognised against these losses.

#### 11. Earnings per share

The calculation of the basic and fully diluted earnings per share is calculated by dividing the loss for the year from continuing operations attributable to equity owners of the Group of  $\pounds(2,082,220)$  (2019:  $\pounds(1,450,627)$ ) by the weighted average number of ordinary shares in issue during the year of 414,833,093 (2019: 360,719,748).

Dilutive loss per Ordinary Share equals basic loss per Ordinary Share as, due to the losses incurred in 2020 and 2019, there is no dilutive effect from the subsisting share options. See Note 20 for details of stock options and warrants outstanding.

#### 12. Property, plant and equipment

	Property, plant & equipment	Computer equipment	Total
Group	£	£	£
Cost			
31 December 2018	274,877	-	274,877
Additions	6,355	5,563	11,918
Foreign exchange movement	(11,118)	(184)	(11,302)
31 December 2019	270,114	5,379	275,493
Additions	167,007	6,040	173,047
Foreign exchange movement	(12,013)	(462)	(12,475)
31 December 2020	425,108	10,957	436,065
Accumulated depreciation and impairmen	nt losses		
31 December 2018	100,934	-	100,934
Depreciation	55,464	1,284	56,748
Foreign exchange movement	(6,062)	(49)	(6,111)
31 December 2019	150,336	1,235	151,571
Depreciation	67,499	2,360	69,859
Foreign exchange movement	(8,052)	(171)	(8,223)
31 December 2020	209,783	3,424	213,207
Carrying amounts			
31 December 2018	173,943		173,943
31 December 2019	119,778	4,144	123,922
31 December 2020	215,325	7,533	222,858

#### 13. Leases

The Group adopted IFRS 16 using the modified retrospective approach with the effect of applying this standard at the date of initial recognition of 1 January 2019.

As a lessee, the Group has previously classified leases as operating or finance leases based on whether the lease transferred significantly all of the risks and rewards incidental to the ownership of the underlying asset. Under IFRS 16, the Group recognises right-of-use assets and lease liabilities for all leases on its balance sheet. Each of the two US subsidiaries has an agreement for the lease of laboratory facilities to which IFRS 16 has been applied.

The key impacts on the Statement of Comprehensive Income and the Statement of Financial Position are as follows:

	Right of use asset	Lease liability	Income statement
Group & Company	£	£	£
Balance on transition	-	-	-
Additions	145,923	(145,923)	-
Depreciation	(37,978)	-	(37,978)
Interest	-	(6,830)	(6,830)
Lease payments	-	39,393	-
Foreign exchange movements	1,497	272	-
Carrying value at 31 December 2019	109,442	(113,088)	(44,808)
Depreciation	(36,894)	-	(36,894)
Revaluation	(23,777)	32,031	-
Interest	-	(3,637)	(3,637)
Lease payments	-	39,431	-
Foreign exchange movements	(2,886)	(3,491)	-
Carrying value at 31 December 2020	45,885	(48,754)	(40,531)

#### 14. Intangible assets

On 15 January 2015, the Company entered into an Exclusive License Agreement with Cornell University to grant to the Company patent rights to patent PCT/US14/65469 entitled *Post-Natal Hematopoietic Endothelial Cells and Their Isolation and Use* and rights to any product or method deriving therefrom. The Company paid Cornell University USD \$347,500 for such licence rights.

Cost	Intellectual Property
	£
31 December 2018	272,753
Exchange movements	(10,703)
31 December 2019	262,050
Exchange movements	(7,095)
31 December 2020	254,955

The carrying value of intangible assets is reviewed for indications of impairment whenever events or changes in circumstances indicate that the carrying value may exceed the recoverable amount. The products to which they relate are not ready to be sold on the open market. When the trials are completed and the products attain the necessary accreditation and clearance from the regulators, the Group will assess the estimated useful economic life and the IP will be amortised using the straight-line method over their estimated useful economic lives. The directors are of the view that no impairment is required as the test results to date have been very positive and these products are now being moved on towards the clinical trial phase. Accordingly, the directors continue to believe that the products will eventually attain the necessary accreditation and clearance from the regulators and so no impairment has been considered necessary.

Amortisation will be charged to operating costs in the Statement of Comprehensive Income when the Group achieves product sales.

#### 15. Loan to subsidiary

	Company Year Ended 31 December 2020	Company Year Ended 31 December 2019
	£	£
Loan to Hemogenyx Pharmaceuticals LLC	2,766,051	1,570,839
	2,766,051	1,570,839

Hemogenyx Pharmaceuticals plc has made cumulative loans to Hemogenyx Pharmaceuticals LLC of US\$3,769,332 (£2,766,051) as at 31 December 2020 (Dec 2019: (US\$2,096,915 (£1,570,839)). The loans are interest free and will be repaid when Hemogenyx LLC's operational cash flow allows. Management has undertaken an impairment assessment of the loan as at 31 December 2020 and has determined that that there was no impairment required. The interest rate and impairment assessment are reviewed on an annual basis.

#### 16. Investment in subsidiary

Name	Address of the registered office	Nature of business	Proportion of ordinary shares held directly by parent (%)	Proportion of ordinary shares held ultimately by parent (%)
Hemogenyx UK Limited	5 Fleet Place, London, UK EC4M 7RD	Holding Company	100	-
Hemogenyx Pharmaceuticals LLC	9 East Lookerman Street, Suite 3A, Dover, Kent, Delaware, USA, 19901	Biomedical sciences	-	100
Immugenyx LLC	c/o Corporation Service Company 251 Little Falls Drive, Wilmington, Delaware, USA, 19808	Biomedical sciences	-	95.79%
Hemogenyx-Cell SPRL	Avenue du Parc Industriel 89, 4041 Milmort, Belgique	Biomedical sciences	-	100

The remaining shares in Immugenyx LLC are held by Dr Vladislav Sandler and by an employee, Carina Sirochinsky, as part of their compensation under their respective roles as CEO and Director of Operations. Dr Sandler and Ms Sirochinsky receive 10,000 and 1,000 shares respectively for each year of employment from January 2019. At 31 December 2020, Hemogenyx Pharmaceuticals LLC, Dr Sandler and Ms Sirochinsky each owns 500,000, 20,000 and 2,000 shares in Immugenyx LLC, respectively.

#### 17. Trade and other receivables

	Group	Group	Company	Company
	Year Ended 31 December 2020	Year Ended 31 December 2019	Year Ended 31 December 2020	Year Ended 31 December 2019
	£	£	£	£
VAT receivable	50,971	2,237	50,971	2,237
Trade & other receivables	5,297	30,075	-	-
Prepayments	48,704	23,492	10,477	4,045
Total trade and other receivables	104,972	55,804	61,448	6,282

There are no material differences between the fair value of trade and other receivables and their carrying value at the year-end. No receivables were past due or impaired at the year-end.

#### 18. Called up share capital

Company	Number of shares	£
As at 31 December 2018	360,176,184	3,601,762
Issue of shares 28 June 2019	1,066,667	10,667
As at 31 December 2019	361,242,853	3,612,429
Issue of shares – placement	71,725,402	717,254
Issue of shares – warrant exercise	668,000	6,680
As at 31 December 2020	433,636,255	4,336,363

During 2020, the Company raised £648,200 before expenses through a placing and subscription of 36,011,116 ordinary shares at a price of 1.8p per share. The Company also raised £2,500,000 before expenses through a placing and subscription of 35,714,286 ordinary shares at a price of 7p per share. The Company received £35,070 from the exercise of 668,000 warrants at an exercise price of 5.25p per share.

#### 19. Share premium

Group & Company	£
As at 31 December 2018	7,340,267
Issue of shares 28 June 2019	21,333
Writeback of value of placement warrants lapsed	338,189
As at 31 December 2019	7,699,789
Issue of shares – placement	2,430,946
Share issuance costs	(168,160)
Issue of share – warrant exercise	28,390
As at 31 December 2020	9,990,965

#### 20. Other reserves

Group	Year Ended 31 December 2020	Year Ended 31 December 2019	
	£	£	
As at start of year	399,229	686,851	
Charge for the year - employees	363,104	90,487	
Fair value of warrants lapsed	-	(338,189)	
Fair value of options lapsed	-	(46,200)	
Convertible Note embedded derivative	2,482	6,280	
As at end of year	764,815	399,229	
Company	Year Ended 31 December 2020	Year Ended 31 December 2019	
	£	£	
As at start of year	386,662	680,564	
Charge for the year - employees	363,105	90,487	
Fair value of warrants lapsed	-	(338,189)	
Fair value of options lapsed	<u>-</u>	(46,200)	
As at end of year	749,767	386,662	

The expense recognised for employee and non-employee services during the year is shown in the following table:

Group and Company	Year Ended 31 December 2020	Year Ended 31 December 2019
	£	£
Expense arising from equity-settled share-based payment transactions	363,105	90,487
Total expense arising from share-based payment transactions	363,105	90,487

#### **Employee Plan**

Under the Employee Plan ("EMP") share options are granted to directors and employees at the complete discretion of the Company. The fair value of the options is determined by the Company at the date of the grant. Options granted vest in tranches on each of the following events/dates:

- i. Admission to the LSE ("Admission");
- ii. On the date falling six (6) months after Admission;
- iii. On the date falling twelve (12) months after Admission; and
- iv. On the date falling twenty-four (24) months after Admission

On the provision that the option holder remains an employee of the Group.

Options granted to most other option holders from 4 January 2018 onwards vest in equal tranches of 12.5% every three months from the date of grant, until fully vested.

The fair value of the options is determined using the Black Scholes method as stated in Note 2. The contractual life of each option granted is between two and five years. There are no cash settlement alternatives.

Options are settled when the Company receives a notice of exercise and cash proceeds from the option holder equal to the aggregate exercise price of the options being exercised.

### Non-Employee Plan

Under the Non-Employee Plan ("NEMP") share options are granted to non-employees at the complete discretion of the Company. The exercise price of the options is determined by the Company at the date of the grant. The options vest at the date of the grant.

The fair value of the options is determined using the Black Scholes method as stated in Note 2 and not the value of services provided as this is deemed the most appropriate method of valuation. In all cases non-employee option holders received cash remuneration in consideration for services rendered in accordance with agreed letters of engagement. The contractual life of each option granted ranges from two to five years. There are no cash settlement alternatives. Volatility was determined by calculating the volatility for three similar listed companies and applying the average of the four volatilities calculated.

Options are settled when the Company receives a notice of exercise and cash proceeds from the option holder equal to the aggregate exercise price of the options being exercised.

A schedule of options granted is below:

	Number options
Employees, including directors*	31,319,036
Members of the Scientific Advisory Board	11,146,751
Total	42,465,787

<sup>\*</sup> Details of options held by individual directors are disclosed in the Directors' Report.

Group & Company	2020 Number	2020 Weighted Average Exercise Price pence	2019 Number	2019 Weighted Average Exercise Price pence
Outstanding at the beginning of the year	30,553,076	3.5	36,071,741	3.5
Granted during the year	11,912,711	7.4	712,085	3.5
Lapsed during the year	-	-	(6,230,750)	3.5
Cancelled during the year	-	-	-	-
Outstanding at end of year	42,465,787	4.6	30,553,076	3.5
Exercisable at end of year	36,812,610	4.5	22,428,934	3.5

The weighted average remaining contractual life for the share options outstanding as at 31 December 2020 is 2.52 years (2019: 2.84). The weighted average fair value of options granted during the year was 0.042 pence (2019: 0.007). The weighted average exercise price for options outstanding at the end of the year was 4.5 pence (2019: 3.5).

The following table lists the inputs to the models used for the two plans for the years ended 31 December 2020 and 31 December 2019:

	July-Aug-2020 (EMP)	Jan-2019 (EMP)
Expected volatility %	64-75	52.12
Risk-free interest rate %	0.52-1.0	0.956
Expected life of options (years)	5	5
WAEP - pence	7.4	3.5
Expected dividend yield	-	-
Model used	Black Scholes	Black Scholes

#### **Warrants**

The share placement that completed on 4 October 2017 with the issue of 57,142,857 shares at £0.035 carried 1 for 2 warrants for qualifying shareholders over 62,021,429 new ordinary shares at £0.04 per share. In order to qualify for these warrants the shareholder must have retained the shares for a period of 60 days after admission. The warrants expired on 4 October 2019. Warrants were also issued to the brokers who raised funds for that share placement. The warrants were equal in value to 2% of the total number of new shares issued for the funds raised by each broker, exercisable at £0.0525 per warrant for a term of three years from the date of the placing, as prescribed in the Company's 2017 prospectus. Optiva exercised 668,000 warrants in May 2020. No warrants were issued in 2020.

#### 21. Capital and reserves

The nature and purpose of equity and reserves are as follows:

Share capital comprises the nominal value of the ordinary issued share capital of the Company.

Share premium represents consideration less nominal value of issued shares and costs directly attributable to the issue of new shares.

Other reserves represents the value of options in connection with share-based payments, warrants connected with share placements issued by the Company, and the value of the deemed embedded derivative connected with the Convertible Note liability.

Reverse asset acquisition reserve is the reserve created in accordance with the acquisition of Hemogenyx Pharmaceuticals LLC on 5 October 2017.

Foreign currency translation reserve is used to recognise the exchange differences arising on translation of the assets and liabilities of foreign branches and subsidiaries with functional currencies other than Pounds Sterling, as well as the revaluation of intercompany loans.

Retained earnings represent the cumulative retained losses of the Company at the reporting date.

#### 22. Trade and other payables

	Group	Group Group		Company	
	Year Ended 31 December 2020	Year Ended 31 December 2019	Year Ended 31 December 2020	Year Ended 31 December 2019	
	£	£	£	£	
Trade and other payables	113,241	61,407	88,853	34,561	
Accruals and deferred income	47,530	80,270	47,527	64,000	
Total	160,771	141,677	136,380	98,561	
Current liabilities	160,771	141,677	136,380	98,561	
Non-current liabilities	-	-	-	-	

#### 23. Borrowings

The borrowings are comprised of borrowings and convertible notes. The Group follows IFRS 9, and as a result, where the instruments contained liability classified embedded derivatives, an election was taken to fair value the entire financial instrument through profit or loss rather than split out the embedded derivative. At 31 December 2019 all borrowings were classified as long-term due to their maturity being more than 12 months from the balance sheet date. At 31 December 2020, all borrowings were classified as current due to their maturity being less than 12 months from the balance sheet date. The notes payable consists of the following:

Group & Company	Year Ended 31 December 2020	Year Ended 31 December 2019	
	£	£	
Borrowings			
Balance at 1 January		583,269	
Drawdowns	191,146	-	
Interest expense	15,206	12,743	
Value of embedded derivative transferred to Other Reserves	(1,033)	(6,280)	
Foreign exchange movement	(23,230)	(18,104)	
Balance at 31 December	753,717	571,628	
Convertible Notes	_		
Balance at 1 January	572,539	589,557	
Drawdowns	191,161	-	
Interest expense	15,272	11,755	
Value of embedded derivative transferred to Other Reserves	(941)	(6,040)	
Foreign exchange movement	(24,966)	(22,733)	
Balance at 31 December	753,065	572,539	
Payroll Protection Loan borrowing	79,469	-	
Foreign exchange movement	(6,873)		
Balance at 31 December	72,596	-	
Total Borrowings at 31 December	1,579,378	1,144,167	

A summary of the debt facilities is as follows:

During 2018 Orgenesis entered in to two debt facility agreements with the Group, one each with Hemogenyx Pharmaceuticals LLC and Immugenyx LLC:

1) On 7 November 2018 the Group entered into a loan agreement with Orgenesis Inc., an organisation with which the Group has an existing collaboration agreement. The loan amount was for not less than US\$1,000,000 with the proceeds of the loan to be used solely for the development of the cell therapy technology in accordance with the plan of the collaboration agreement. As at reporting

date drawdowns totalling US\$1,000,000 (£692,901) had been made with Hemogenyx Pharmaceuticals LLC receiving the funds. The loan carries an interest rate of 2% and has a term of three years. Orgenesis has the option to convert both principal and accrued interest into equity in Hemogenyx-Cell at any time prior to maturity. Hemogenyx-Cell SPRL ("Hemo-Cell") is a wholly owned Belgian entity and was incorporated in April 2019 at which point this loan facility was treated as a borrowing in accordance with the provisions of IAS39.

2) On 7 November 2018 the Group entered into a loan agreement, through its wholly owned subsidiary

Immugenyx LLC, with Orgenesis Inc., an organisation with which the Group has an existing collaboration agreement. The loan amount was for not less than US\$1,000,000 with the proceeds of the loan to be used solely for the development of the cell therapy technology in accordance with the plan of the collaboration agreement. As at reporting date drawdowns totalling US\$1,000,000 (£753,065) had been made. The loan carries an interest rate of 2% and has a term of three years. Orgenesis has the option to convert both principal and accrued interest into equity in Immugenyx LLC at any time prior to maturity. This loan has been treated in accordance with treated in accordance with the provisions of IAS39.

#### **Paycheck Protection Program Loan**

On 1 May 2020, the Company received loan proceeds in the amount of approximately \$99,000 under the Paycheck Protection Program ("PPP"). The PPP, established as part of the Coronavirus Aid, Relief and Economic Security Act, as amended ("CARES Act"), provides for loans to qualifying businesses for amounts up to 2.5 times of the average monthly payroll expenses of such qualifying business. The loans and accrued interest are forgivable after certain time periods further defined in the CARES Act (the "Covered Period") as long as the borrower uses the loan proceeds for eligible purposes, including payroll, benefits, rent and utilities, and maintains its payroll levels. The amount of loan forgiveness will be reduced if the borrower terminates employees or reduces salaries during the Covered Period.

Any unforgiven portion of the PPP loan would be payable over two years at an interest rate of 1%, with a deferral of payments for the first six months. The Company used the proceeds for purposes consistent with the PPP and the loan was forgiven in its entirety in April 2021. The outstanding balance at 31 December 2020, prior to loan forgiveness, is included in short term borrowings.

### 24. Related party disclosures

There were no related party disclosures other than Directors' remuneration as disclosed in the Remuneration Report section of the Directors' Report. There are no key management personnel other than the Directors and the Company Secretary.

#### 25. Financial instruments

The Group's financial instruments consist of cash,

amounts receivable, accounts payable and accrued liabilities and deferred payment.

#### Fair value of financial assets and liabilities

Fair values have been determined for measurement and/or disclosure purposes based on the following methods. When applicable, further information about the assumptions made in determining fair values is disclosed in the notes specific to that asset or liability.

The carrying amount for cash, accounts receivable, and accounts payable and accrued liabilities on the statement of financial position approximate their fair value because of the limited term of these instruments. The fair value of deferred payment approximates its fair value. The investment is carried at cost as it is not traded on an active market.

#### Fair value hierarchy

Financial instruments that are measured subsequent to initial recognition at fair value are grouped in Levels 1 to 3 based on the degree to which the fair value is observable:

- Level 1 fair value measurements are those derived from quoted prices (unadjusted) in active markets for identical assets or liabilities; and
- Level 2 fair value measurements are those derived from inputs other than quoted prices included within level 1 that are observable for the asset or liability, either directly (i.e. as prices) or indirectly (i.e. derived from prices); and
- Level 3 fair value measurements are those derived from valuation techniques that include inputs for the asset or liability that are not based on observable market data (unobservable inputs).

The Group did not have any financial instruments in Level 1, 2 and 3.

#### Financial risk management objectives and policies

The Company has exposure to the following risks from its use of financial instruments:

- Credit risk
- · Liquidity and funding risk
- Market risk

The following table sets out the amortised costs categories of financial instruments held by the Company as at the year ended 31 December 2020 and year ended 31 December 2019:

	Group	Group	Company	Company
	Year Ended 31 December 2020	Year Ended 31 December 2019	Year Ended 31 December 2020	Year Ended 31 December 2019
	£	£	£	£
Assets				
Trade and other				
receivables, except				
prepayments	56,267	32,312	50,971	2,237
Cash and cash equivalents	1,812,299	498,679	1,036,214	14,505
	1,868,566	640,433	1,087,185	16,742
Liabilities				
Trade and other payables	(113,241)	(61,407)	(88,853)	(34,561)
Lease liabilities	(48,754)	(113,088)	-	-
Borrowings	(1,579,378)	(1,144,167)	-	
	(1,707,741)	(1,318,662)	(88,853)	(34,561)

Group	1 January 2019	Cash flows	Non-cash changes			31 December 2019
			Share repayment	Foreign exchange movements	Interest charge	
Long-term borrowings	1,172,826	-	-	(53,157)	24,498	1,144,167
Short-term borrowings	-	-	-	-	-	-
Total	1,172,826	-	-	(53,157)	24,498	1,144,167

Group	1 January 2020	Cash flows	Non-cash changes			31 December 2020
			Share repayment	Foreign exchange movements	Interest charge	
Short-term borrowings (1)	1,144,167	461,776	(1,891)	(54,949)	30,275	1,579,378
Long-term borrowings	-	-		-	-	-
Total	1,144,167	461,776	(1,891)	(54,949)	30,275	1,579,378

(1) Borrowings reclassified to short term since all balance are due within twelve months of December 31, 202

#### a) Credit risk

The Group had receivables of £3,668 owing from customers (31 December 2019: £28,279). All bank deposits are held with Financial Institutions with a minimum credit rating of AAA.

#### b) Liquidity and funding risk

The Group regularly reviews its major funding positions to ensure that it has adequate financial resources in meeting its financial obligations. The Group takes liquidity risk into consideration when deciding its sources of funds. The principle liquidity risk facing the business is the risk of going concern which has been discussed in Note 2.

#### c) Market risk

#### Interest rate risk

Interest rate risk is the risk that the value of financial instruments will fluctuate due to changes in market interest rates. The Group's income and operating cash flows are substantially independent of changes in market interest rates as the Group has no significant interest-bearing assets. The borrowings issued at fixed

rates expose the Group to fair value interest rate risk. The Company's management monitors the interest rate fluctuations on a continuous basis and acts accordingly.

The Company has floating rate financial assets in the form of deposit accounts with major banking institutions; however, it is not currently subjected to any other interest rate risk.

Based on cash balances as above as at the statement of financial position date, a rise in interest rates of 1% would not have a material impact on the profit and loss of the Company and such is not disclosed.

The interest rates on the Convertible Notes are fixed and hence a rise in interest rates of 1% would not have a material impact on the profit and loss of the Group and such is not disclosed.

In relation to sensitivity analysis, there was no material difference to disclosures made on financial assets and liabilities.

At the reporting date the interest rate profile of interestbearing financial instruments was:

	Group	Group	Company	Company
	Year Ended 31 December 2020	Year Ended 31 December 2019	Year Ended 31 December 2020	Year Ended 31 December 2019
	£	£	£	£
Financial Assets				
Cash and cash equivalents	1,812,299	498,679	1,036,214	14,505
Financial Liabilities				
Borrowings	(1, 579,378)	(1,144,167)		

#### Foreign currency risk

The Group operates internationally and has monetary assets and liabilities in currencies other than the functional currency of the operating company involved.

The Group seeks to manage its exposure to this risk by ensuring that where possible, the majority of expenditure and cash of individual subsidiaries within the Group are denominated in the same currency as the functional currency of that subsidiary.

The Group has not entered into any derivative instruments to manage foreign exchange fluctuations.

The following table shows a currency of net monetary assets and liabilities by functional currency of the underlying companies for the years ended 31 December 2020 and 31 December 2019:

#### **31 December 2019**

#### **Functional Currency**

Currency of net monetary assets (liabilities)	Pound Sterling £	US Dollars £	Euro £	Total £
Pound Sterling	13,354	-	-	13,354
US Dollars	1,151	(679,961)	(571,628)	(1,250,438)
Euros	-	-	19,967	19,967
Total	14,505	(679,961)	(551,661)	(1,217,117)

#### **31 December 2020**

#### **Functional Currency**

Currency of net monetary assets (liabilities)	Pound Sterling £	US Dollars £	Euro £	Total £
Pound Sterling	1,024,010	-	-	1,024,010
US Dollars	12,204	(70,670)		(58,466)
Euros	-	-	(753,623)	(753,623)
Total	1,036,214	(70,670)	(732,623)	232,920

#### Capital risk management

The Group defines capital as the total equity of the Company. The Group's objectives when managing capital are to safeguard the Group's ability to continue as a going concern in order to provide returns for shareholders and benefits for other stakeholders and to maintain an optimal capital structure to reduce the cost of capital.

In order to maintain or adjust the capital structure, the Group may adjust the amount of dividends paid to shareholders, return capital to shareholders, issue new shares or sell assets to reduce debt.

#### Fair value of financial assets and liabilities

There are no material differences between the fair value of the Group's financial assets and liabilities and their carrying values in the financial statements.

#### 26. Commitments

#### Licence

Milestone and royalty payments that may become due under the licence agreement are dependent on, among other factors, clinical trials, regulatory approvals and ultimately the successful development of a new drug, the outcome and timing of which are uncertain.

The Group's minimum future payments contingent upon meeting certain development, regulatory and commercialisation milestones total £780,484 (\$1,035,000) plus £377,045 (\$500,000) on receipt of marketing approval from each additional market excluding the United States of America and the European Union. Upon commencement of commercial production, the Group will pay a royalty between 2 to 5% on all net sales. In addition, the Group pays an annual licence maintenance fee of up to £56,557 (\$75,000) until the commercial sales are achieved.

#### 27. Ultimate controlling party

The Directors have determined that there is no controlling party as no individual shareholder holds a controlling interest in the Company

#### 28. Subsequent events

In November 2020, Mint Capital Limited ("Mint") and the Company entered into a Financing Facility agreement

("Financing Facility") whereby Mint has conditionally agreed to subscribe for up to £60 million in aggregate principal amount of Convertible Loan Notes pursuant to an agreement entered into with the Company (the "Subscription Agreement"). The shareholders of the Company approved the facility in January 2021 and a prospectus was published on 29 January 2021.

The key terms of the Convertible Loan Notes include:

- A principal amount of up to £60,000,000, split into denominations of £50,000 per Convertible Loan Note.
   The Convertible Loan Notes will be subscribed for at par.
- The Convertible Loan Notes are to be issued in up to nine tranches. The first tranche of £12,000,000 in principal amount was issued on 3 February 2021. The subsequent eight tranches are issuable at the sole discretion of, and in the amounts determined by, the Company at respective intervals of 90 days after the Initial Issue Date. The aggregate maximum principal amount of the Convertible Loan Notes is limited to £60,000,000.
- No interest is payable on the Convertible Loan Notes.
- · The Convertible Loan Notes are unsecured.
- Each tranche of Convertible Loan Notes issued is redeemable at par on the date falling 36 months after the relevant Issue Date (the "Maturity Date").
- Each of the Convertible Loan Notes is convertible into ordinary shares of £0.01 (1 pence) each in the capital of the Company ("Ordinary Shares") at any time during the period commencing on the fifth business day following the relevant Issue Date and ending at 5.00 p.m. London time on the business day immediately prior to the relevant Maturity Date (the "Conversion Period").
- The price used for the conversion (the "Conversion Price") will be equal to a 10 per cent discount to the lesser of (i) 125 per cent. of the closing-bid price as reported by Bloomberg for one Ordinary Share one trading day before the relevant Issue Date (subject to adjustment to reflect any sub-division or consolidation of the Ordinary Shares) and (ii) the lowest closing bid-price as reported by Bloomberg for an Ordinary Share from the three consecutive trading days ending on the day prior to the date of service of the relevant

conversion notice (or if such conversion notice is served after 4.35pm on any such date, then the three consecutive trading days ending on the day such conversion notice is served. In no event shall the Conversion Price be less than the nominal value of an Ordinary Share.

- A holder will not be permitted to submit a conversion notice in respect of the Convertible Loan Notes if the total Ordinary Shares held by the holder following the execution of such conversion notice would exceed 29.9% of the Company's total Ordinary Shares.
- If the Company commits an "event of default" then the notes could be redeemed at 114-120% of the principal amount of the convertible loan at the option of the holder.
- The Company also has the ability to redeem the convertible loan under certain circumstances at 114% of the principal amount of the convertible loan.
- Subject to limited exceptions, the Convertible Loan Notes will not be transferable.
- Prior to conversion, the Convertible Loan Notes do not entitle the holder to any voting rights in the Company.

#### **Arrangement fee**

The Company agreed to pay a fee of 5% of the aggregate principal value of the Convertible Loan Notes issued to the arranger for the Facility (the "Arranger"). Such fee was paid by the allotment and issue of new Ordinary Shares.

#### **Draw down**

The Company received £12,000,000 from the first drawn down of the Financing Facility agreement in February 2021. The price of the conversion of the convertible loan notes issued under the Financing Facility agreement into common shares of the Company, as defined by the Financing Facility agreement will be the lesser of (i) 8.4375p and (ii) 90% of the lowest closing bid price as reported on Bloomberg from the three closing bid prices immediately preceding a conversion.

The company issued 7,741,935 shares in February 2021 as an arrangement fee to the arranger of the Financing Facility.

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## NOTES TO THE FINANCIAL STATEMENTS

The Company received a conversion notice from Mint in respect of £650,000 in principal amount of Convertible Loan Notes and issued 13,131,313 shares to Mint in March 2021. Further conversion notices were received from Mint in respect of £900,000 and £950,000 in principal amount of Convertible Loan Notes. The Company issued a further 14,285,714 shares to Mint in March 2021, and 24,547,803 shares in April 2021; both of these allotments of shares were admitted to trading on the London Stock Exchange's main market in April 2021. To date, Mint has converted loan notes with principal value of £2,500,000 into shares, leaving convertible loan notes to a value of £9,500,000 outstanding. A conversion notice for a further £900,000 in principal value of loan notes was received from Mint on 23 April 2021 and the corresponding shares will be allotted on or around 4 May 2021, after publication of this report, leaving convertible loan notes to a value of £8,600,000 outstanding.

#### **Deferred financing costs**

Group costs of £223,615 were incurred prior to the year end in connection with the setting up of the Financing Facility. These costs were deferred pending the first draw down under the Financing Facility and will be amortised through profit and loss from that date.

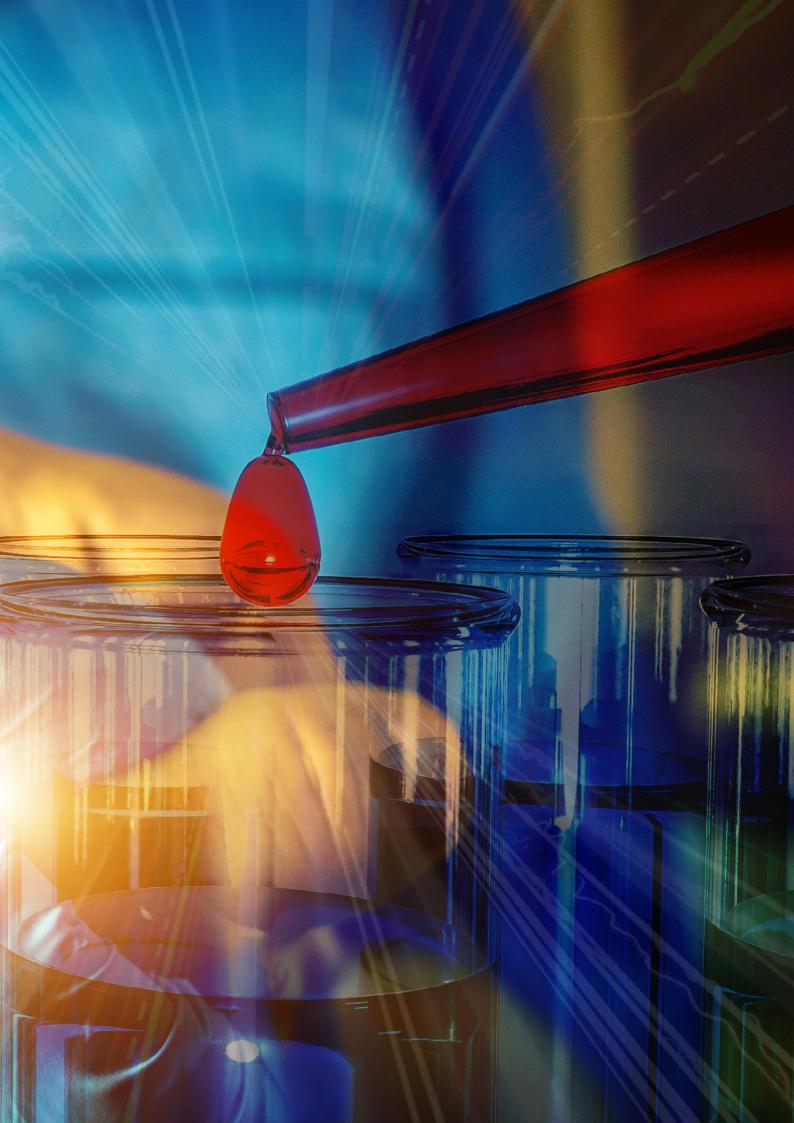
#### **Paycheck Protection Program**

The loan from the U.S. Small Business Administration under the Paycheck Protection Program (described in Note 23 to the financial statements above) was forgiven in April 2021.

#### 29. Copies of the annual report

Copies of the annual report will be available on the Company's web site at https://hemogenyx.com and from the Company's registered office, 5 Fleet Place London EC4M 7RD.







## HEMOGENYX PHARMACEUTICALS PLC

