



29 September 2022

Hemogenyx Pharmaceuticals plc

("Hemogenyx Pharmaceuticals" or the "Company")

Half-year Report

Interim Results for the period ended 30 June 2022

Hemogenyx Pharmaceuticals plc (LSE: HEMO), the Standard Listed biopharmaceutical group developing therapies designed to transform blood disease treatment, announces its unaudited interim results for the six-month period ended 30 June 2022.

All financial amounts are stated in GBP British pounds unless otherwise indicated.

Key Highlights

- In final stages of preparation for filing an Investigational New Drug ("IND") application to commence clinical trials for HEMO-CAR-T, following positive feedback from the US Federal Drug Administration
- Continuing development of CDX antibody and Chimeric Bait Receptor antiviral/biodefence platform
- Bolstered the scientific team in preparation for clinical trials and cell manufacturing with two key appointments
- Following the period end, moved into state-of-the-art new laboratory facilities in Manhattanville, New York, with clean rooms and equipment enabling in-house cell manufacturing
- On track and on budget for initiating phase I clinical trials of HEMO-CAR-T, subject to approval

Fuller details of these developments are contained in the Interim Management Report below.

Commenting on the outlook for Hemogenyx Pharmaceuticals, Sir Marc Feldmann, Chairman, said: *"The Board is delighted with the continued high quality work of the Company and in particular with the steps taken to ensure that the difficult task of submitting a comprehensive IND application for HEMO-CAR-T is delivered efficiently. We anticipate taking HEMO-CAR-T, and indeed the Company, to their next phase of development, entering the clinical stage. At the same time, the Company's roster of other cutting-edge assets gives confidence that Hemogenyx Pharmaceuticals will make further important contributions to healthcare. We look forward to providing shareholders with more news as we gear up to becoming a clinical-stage company."*

Interim Management Report

We are pleased to provide an update on the Company's activities over the six-month period ended 30 June 2022.

The six months concerned were a period of steady but very definite progress. This has been aided by our move to a state-of-the-art purpose-built laboratory facility which enables us to undertake research and manufacturing processes that we were previously unable to carry out in-house, and more importantly to progress our three main programmes, in particular HEMO-CAR-T. During the period under review, work also continued both on our CDX bi-specific antibody and Chimeric Bait Receptor ("CBR") platform.

HEMO-CAR-T

HEMO-CAR-T, a CAR-T therapy targeting Acute Myeloid Leukaemia ("AML"), is our lead product candidate, the intellectual property and development of which are in the Company's sole control. We have been working toward completing the necessary IND application for HEMO-CAR-T, having held detailed discussions with the US Federal Drug Administration ("FDA") during the period and received constructive feedback through a pre-IND submission that confirmed our development process and our proposals for clinical trials. Most of the data required for the IND application has been compiled and the components for manufacturing HEMO-CAR-T have been produced. We are now engaged in the final stages of establishing the production of HEMO-CAR-T cells for the treatment of patients. We are confident of completing the IND application in the near future and are working on detailed protocols for carrying out clinical trials.

The work is necessarily very detailed as the main concern in the process is to ensure patients' safety, which requires great care on the FDA's part and of course ours. We have been working with a group of Key Opinion Leaders in the treatment of acute leukaemias that has helped us to hone our approach to clinical trials. We are now in the process of finalising our trial protocol, which will involve a relationship with at least one major hospital, likely to include the University of Pennsylvania with whom we already have a working arrangement.

CDX Antibody

With the help of Selexis SA, we are in the process of establishing a CDX master cell line and a research cell bank ("RCB") which are necessary for the manufacturing of CDX for both IND-enabling studies and clinical trials. On 20 July, following the end of this reporting period, the Company's existing intellectual property protection for CDX was further strengthened by the China National Intellectual Property Administration granting patent number 201780034711.2, titled Method of Eliminating Hematopoietic Stem Cells/Hematopoietic Progenitors (HSC/HP) In a Patient Using Bi-specific Antibodies. This patent joins patents previously granted in the US for CDX and monoclonal antibodies used for the development of CDX and HEMO-CAR-T. The Company is exploring partnership options for taking CDX through final IND-enabling studies and into clinical trials.

CBR

We have also made significant progress with CBR, a novel platform technology that constitutes a new paradigm for treating viral infections. The essence of the CBR-based approach is programming immune cells using a novel type of modifiable synthetic receptor to destroy viral pathogens. This approach can also potentially be used to programme immune cells to destroy malignant cells causing certain types of cancer. Our scientists have achieved *in vitro* proof of concept for a CBR construct that neutralises all known variants of the SARS-CoV-2 virus that causes

COVID, and have now completed preparations to test it against live replicating virus in a Biosafety Level 3 facility. The Company has filed a seminal provisional patent application protecting its rights to the intellectual property (“IP”) covering CBR.

Personnel and Establishment

While we continue to keep a tight rein on costs, our preparations for clinical trials and manufacturing of HEMO-CAR-T have been greatly enhanced through the recruitment of a Medical Director and a Director of Quality. Dr Koen van Besien, one of America’s top bone marrow transplant and oncology doctors joined us as Medical Director. Dr van Besien will oversee the development of the clinical trial programme for our HEMO-CAR-T. He is uniquely positioned to accelerate studies of HEMO-CAR-T in the clinic due to his rich experience and deep insight into the cutting-edge treatments of patients suffering from blood cancers.

We have also appointed Mr Stuart Tinch as Director of Quality. His great understanding and experience into the cutting-edge GMP manufacturing of viral vectors and cell therapies as well as his expertise in establishing and maintaining quality systems will help to accelerate Hemogenyx Pharmaceuticals’ product candidates. Stuart will help us to establish manufacturing of our lead product candidate, HEMO-CAR-T, as well as potentially other cell therapies, according to the highest standards of quality to facilitate their transition into the clinic.

Finally, following the end of this reporting period we moved into our custom-built research and manufacturing facility in the Manhattanville district of New York City. The new facility includes two clean rooms for the cGMP (“current Good Manufacturing Practice”) manufacturing of cell therapies including our own HEMO-CAR-T cells for the treatment of AML. These clean rooms have been through commissioning and validation and are ready to be certified. The new facility will allow us to take matters further in-house in areas which we previously outsourced as well as potentially to achieve significant savings.

Fundraising

During the period, the Company did not undertake any fundraising.

Financial Results

During the six months ended 30 June 2022, the Company recorded a loss of £1,300,653 (2021: £3,632,338 loss). During the six months ended 30 June 2022, the Company recorded a loss from operations of £1,143,243 (2021: £1,161,497 loss). The loss in the 2021 period includes financing related expenses of £2,650,232. The losses from operations in both the 2022 and 2021 periods were relatively consistent, reflecting the similar size of the employee base and conservative spending of our funding. The Company had cash and cash equivalents totalling £5,799,495 as at 30 June 2022.

The Company recorded no consultancy income during the period ended 30 June 2022 (2021: £98,995, relating to funds received from a third party under a research collaboration associated with humanised mice).

The Future

Hemogenyx Pharmaceuticals, aided by its commercial and scientific advisers, has continued to advance its programme of work across its portfolio while making optimal use of its financial resources. Current scientific work is focused primarily on preparations for taking HEMO-CAR-T to

clinical trials which will constitute a significant milestone for the Company. Meanwhile, the team continues to progress its CDX and CBR assets, and to seek ways to further their development.

We have made good progress on multiple fronts over the period and I thank our dedicated staff, distinguished advisory team and our directors.

Responsibility Statement

We confirm that to the best of our knowledge:

- the Half-year Report has been prepared in accordance with International Accounting Standard 34 'Interim Financial Reporting'; and
- gives a true and fair view of the assets, liabilities, financial position and loss of the Group; and
- the Half Year Report includes a fair review of the information required by DTR 4.2.7R of the Disclosure and Transparency Rules, being an indication of important events that have occurred during the first six months of the financial year and their impact on the set of interim financial statements; and a description of the principal risks and uncertainties for the remaining six months of the year; and
- the Half Year Report includes a fair review of the information required by DTR 4.2.8R of the Disclosure and Transparency Rules, being the information required on related party transactions; there were no such transactions in the six months ended 30 June 2022.

The Half Year Report was approved by the Board of Directors and the above responsibility statement was signed on its behalf by:

Dr Vladislav Sandler
CEO

29 September 2022

Market Abuse Regulation (MAR) Disclosure

The information contained within this announcement is deemed to constitute inside information as stipulated under the Market Abuse Regulation ("MAR") (EU) No. 596/2014, as incorporated into UK law by the European Union (Withdrawal) Act 2018. Upon the publication of this announcement, this inside information is now considered to be in the public domain.

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**Condensed Consolidated Interim Statement of Comprehensive Loss
for the six months ended 30 June 2022**

Continuing Operations	Note	6 months to 30 June 2022 Unaudited £	6 months to 30 June 2021 Unaudited £
Revenue		-	-
Administrative Expenses		(1,111,010)	(1,099,320)
Depreciation		(32,233)	(62,177)
Operating Loss		(1,143,243)	(1,161,497)
Other Income	5	-	170,244
Finance Income		1,956	9,677
Finance Costs		(17)	(2,650,762)
Loss before Taxation		(1,141,304)	(3,632,338)
Loss attributable to:			
- Equity owners		(1,127,675)	(3,631,142)
- Non-controlling interests		(13,629)	(1,196)
Loss for the period		(1,141,304)	(3,632,338)
Other comprehensive income Items that may be reclassified subsequently to profit or loss:			
Translation of foreign operations		(159,349)	(300,329)
Total comprehensive income for the period		(1,300,653)	(3,932,667)
Total comprehensive income attributable to:			
- Equity owners		(1,287,024)	(3,931,471)
- Non-controlling interests		(13,629)	(1,196)
Basic and diluted earnings (per share)	6	(0.002)	(0.007)

Condensed Consolidated Interim Statement of Financial Position as at 30 June 2022

		30 June 2022 Unaudited	Year Ended 31 December 2021 Audited
	Note	£	£
<u>Assets</u>			
Non-current assets			
Property, plant and equipment	7	739,411	787,887
Security deposit		138,913	142,599
Right of use asset		1,675	9,242
Intangible asset		490,607	441,493
Total non-current assets		1,370,606	1,381,221
Current assets			
Trade and other receivables		672,058	298,220
Cash and cash equivalents		5,799,496	6,840,969
Total current assets		6,471,554	7,139,189
Total assets		7,842,160	8,520,410
<u>Equity and Liabilities</u>			
Equity attributable to shareholders			
Paid-in Capital			
Called up share capital		9,797,493	9,797,493
Share premium		16,808,647	16,808,647
Other reserves		916,305	904,226
Reverse asset acquisition reserve		(6,157,894)	(6,157,894)
Foreign currency translation reserve		(185,270)	(25,921)
Retained Earnings		(14,262,417)	(13,134,742)
Equity attributable to owners of the Company		6,916,864	8,191,809
Non-controlling interests		(37,869)	(24,240)
Total Equity		6,878,995	8,167,569
<u>Liabilities</u>			
Current liabilities			
Trade and other payables		963,165	342,689
Lease liabilities		-	10,152
Current liabilities		963,165	342,689
Trade and other payables		963,165	342,689
Lease liabilities		-	10,152
Total Current Liabilities		963,165	352,841

Total Liabilities

963,165

352,841

Total equity and liabilities

7,842,160

8,520,410

The 2021 comparatives are the audited consolidated group accounts for the year ended 31 December 2021 as published on 30 April 2022.

**Condensed Consolidated Interim Statement of Changes in Equity
for the six months ended 30 June 2022 and 30 June 2021**

	Called up Share Capital £	Share Premium £	Other reserves £	Reverse acquisition reserve £	Foreign currency translation reserve £	Retained losses £	Non- Controlling interests £	Total Equity £
As at 1 January 2021	4,336,363	9,990,965	764,815	(6,157,894)	(7,896)	(8,035,514)	(15,158)	875,681
Loss in period	-	-	-	-	-	(3,631,142)	(1,196)	(3,632,338)
Other comprehensive income	-	-	-	-	(300,329)	-	-	(300,329)
Conversion of debt to equity (Note 9)	5,373,710	5,026,290	-	-	-	-	-	10,400,000
Prior year adj. to value of share-based payments	-	180	(318)	-	-	(1,198)	-	(1,336)
Charge recognised upon conversion of debt (Note 9)	-	1,212,475	-	-	-	-	-	1,212,475
Issue of options (Note 8)	-	-	82,833	-	-	-	-	82,833
Shares issued to arrangers of debt facility (Note 9)	87,420	578,917	-	-	-	-	-	666,337
As at 30 June 2021 (unaudited)	9,797,493	16,808,827	847,330	(6,157,894)	(308,225)	(11,667,854)	(16,354)	9,303,323
As at 1 January 2022	9,797,493	16,808,647	904,226	(6,157,894)	(25,921)	(13,134,742)	(24,240)	8,167,569
Loss in period	-	-	-	-	-	(1,127,675)	(13,629)	(1,300,653)
Other comprehensive income	-	-	-	-	(159,349)	-	-	-
Issue of options (Note 8)	-	-	12,079	-	-	-	-	12,079
As at 30 June 202 (unaudited)	9,797,493	16,808,647	916,305	(6,157,894)	(185,270)	(14,262,417)	(37,869)	6,878,995

Condensed Consolidated Interim Statement of Cash Flows for the six months ended 30 June 2022

Group	Note	6 months to 30 June 2022 Unaudited £	6 months to 30 June 2021 Unaudited £
<u>Cash flows generated from operating activities</u>			
Loss for the period		(1,141,304)	(3,632,338)
Depreciation	7	32,233	62,177
Other non-cash items, including forgiveness of PPP loan		2,205	(65,040)
Foreign exchange gain		1,058	(300,232)
Interest income		(1,956)	(9,677)
Interest expense		20	-
Finance costs		-	1,413,607
Charge recognised upon conversion of debt		-	1,212,475
Share based payments		12,079	82,833
Increase in trade and other payables		500,752	111,822
(Increase) decrease in trade and other receivables		(342,383)	19,711
Net cash outflow used in operating activities		(937,298)	(1,104,662)
<u>Cash flows generated from financing activities</u>			
Proceeds from issuance of debt securities		-	12,000,000
Repayment of convertible debt		-	(1,600,000)
Payment of debt issuance costs		-	(505,235)
Share issue costs		-	-
Proceeds from borrowings		-	-
Payment of lease liabilities		(5,441)	(19,641)
Net cash flow (used in) generated from financing activities		(5,441)	9,875,124
<u>Cash flows generated from investing activities</u>			
Interest income		1,956	9,677
Purchase of property, plant & equipment		(1,553)	(13,925)
Net cash flow generated from (used in) investing activities		403	(4,248)
Net increase in cash and cash equivalents		(942,335)	8,766,214
Effect of exchange rates on cash		(99,139)	(14,845)
Cash and cash equivalents at the beginning of the period		6,840,969	1,812,299
Cash and cash equivalents at the end of the period		5,799,496	10,563,668

Notes to the Condensed Consolidated Interim Financial Statements

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, 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 6th Floor, 60 Gracechurch Street, London, EC3V 0HR, and the Company's shares are listed on the main market of the London Stock Exchange.

2. Interim financial information

The condensed consolidated interim financial statements are for the six month period ended 30 June 2022. The condensed consolidated interim financial statements do not include all the information required for full annual financial statements and should be read in conjunction with the consolidated financial statements of the Group for the year ended 31 December 2021, which were prepared under International Financial Reporting Standards (IFRS).

The condensed consolidated interim financial statements have not been audited nor have they been reviewed by the Group's auditors under ISRE 2410 of the Auditing Practices Board. These condensed consolidated interim financial statements do not constitute statutory accounts as defined in Section 434 of the Companies Act 2006. The Group's statutory financial statements for the year ended 31 December 2020 prepared under IFRS have been filed with the Registrar of Companies. The auditor's report on those financial statements was unqualified and did not contain a statement under Section 498(2) of the Companies Act 2006.

3. Basis of preparation and changes to the Group's Accounting Policies

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

Basis of Preparation

The condensed consolidated interim financial statements have been prepared in accordance with IAS 34 'Interim Financial Reporting'. The accounting policies adopted in this report are consistent with those of the annual financial statements for the year to 31 December 2021 as described in those financial statements. A number of new or amended standards became applicable for the current reporting period, but they did not have any impact on the group's accounting policies and did not require retrospective adjustments.

Going Concern

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

The Company did not raise any outside funding during the six months ended 30 June 2022. The Company had cash and cash equivalents totalling £5,799,495 as at 30 June 2022.

The Directors, having made due and careful enquiry, are of the opinion that the Company has adequate working capital to execute its operations for the present time 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 these 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.

Should the Company elect to raise additional capital within the next year, it cannot be certain that such additional funding will be available on acceptable terms, or at all. To the extent that the Company raises additional funds by issuing equity securities, the Company's stockholders may experience dilution. Any debt financing, if available, may involve restrictive covenants. If the Company is unable to raise additional capital when required or on acceptable terms, it may have to (i) significantly delay, scale back or discontinue the development and/or commercialisation of one or more product candidates; (ii) seek collaborators for product candidates at an earlier stage than otherwise would be desirable and on terms that are less favourable than might otherwise be available; or (iii) relinquish or otherwise dispose of rights to technologies, product candidates or products that it would otherwise seek to develop or commercialise on unfavourable terms.

Segmental Reporting

The Group's operations are located in New York, USA, with the head office located in the United Kingdom. The main assets of the Group, cash and cash equivalents, are held in the United States to support the operating business.

The Group currently has one reportable segment: a biotechnology business 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 and treatment of blood diseases such as AML and autoimmune diseases, and viral infections.

Accounting Policies

The accounting policies, presentation and methods of computation applied by the Group in these condensed interim financial statements are the same as those applied by the Group in its consolidated financial information in its 2021 Annual Report and Accounts. The new standards, described below, will be adopted by the Group when effective, and have had no impact on these half yearly results.

New and amended accounting standards and interpretations

On 12 February 2021 the IASB issued an amendment to IAS 1 concerning accounting policy disclosures, and an amendment to IAS 8 concerning the definition of accounting estimates. On 7 May 2021 the IASB issued an amendment to IAS 12 concerning deferred tax related to assets and liabilities arising from a single transaction. The Company does not expect any material impact from the application of these two amendments, which are effective for annual reporting periods beginning on or after 1 January 2023. The Company will not early adopt these amendments.

On 23 January 2020 the IASB issued 'Classification of Liabilities as Current or Non-current', an amendment to IAS 1. On 14 May 2020 the IASB issued 'Reference to the Conceptual Framework', an amendment to IFRS 3; 'Proceeds before Intended Use', an amendment to IAS 16; 'Onerous Contracts – Cost of Fulfilling a Contract', an amendment to IAS 37; and 'Annual Improvements to IFRS standards 2018-2020'. The Company does not expect a material impact from those amendments, which are effective for annual reporting periods beginning on or after 1 January 2022. The Company adopted these amendments as required, and the impact was not material.

4. Significant accounting judgments, 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. Actual results may differ from these estimates.

In preparing these condensed interim financial statements, the significant judgements made by management in applying the Group's accounting policies and the key sources of estimation uncertainty were the same as those applied to the consolidated financial statements for the year ended 31 December 2021.

5. Other income

Other income during the period ended 30 June 2022 was £0 (H1 2021: £170,244, comprising £71,249 arising from the forgiveness of a US governmental loan programme – the Payroll Protection Program – and £98,995 received from a third party under a research collaboration programme relating to humanised mice).

6. Earnings per share

Basic and fully diluted earnings per share are calculated by dividing the loss for the six months from continuing operations of £1,300,653 (six months to 30 June 2021: £3,631,142) attributable to equity owners of the Group by the weighted average number of ordinary shares in issue during those periods of 979,749,321 and 546,669,219 respectively.

Diluted loss per Ordinary Share equals basic loss per Ordinary Share as, due to the losses incurred in the six months to 30 June 2022 and six months to 30 June 2021, there is no dilutive effect from the subsisting share options.

7. Property, Plant and Equipment

During the six months ended 30 June 2022, the Group acquired assets with a cost of £1,553 (six months ended 30 June 2021: £13,925).

8. Share-based payments

Options

During the six months to 30 June 2022 no options were issued to directors or employees and 712,085 options lapsed during the period.

A schedule of options granted as at 30 June 2022 is shown below:

	Number of options
Employees, including directors	30,132,229
Members of the Scientific Advisory Board	14,237,192
Total	44,369,421

For the six months ended 30 June 2022, the Company recognised share-based payment expense in the statement of profit or loss of £12,079 (30 June 2021: £82,833).

9. Events after the reporting period

Opening of new facility

The Company opened its new custom-engineered laboratory at the Mink Building in West Harlem's Manhattanville Factory District of New York City, adjacent to Columbia University and City College. The Company's state-of-the-art research facility includes approximately 10,000 rentable square feet of purpose-built lab space including two clean rooms for cell therapy manufacturing. In addition to continuing and expanding its research, the Company is now able to manufacture cells in-house, accelerating and simplifying the commercialisation of its major cell therapy product candidates. The Company will first use its clean rooms to produce its HEMO-CAR-T cell therapy for the treatment of acute myeloid leukaemia.

Issuance of patent

The China National Intellectual Property Administration has issued to the Company a Notification to Grant Patent Right for the patent application entitled METHOD OF ELIMINATING HEMATOPOIETIC STEM CELLS/HEMATOPOIETIC PROGENITORS (HSC/HP) IN A PATIENT USING BI-SPECIFIC ANTIBODIES. The grant was issued on 20 July 2022 under Patent Application Number 201780034711.2. This patent covers a method of use of a bi-specific antibody ("CDX") for conditioning patients for bone marrow/hematopoietic stem cell ("BM/HSC") transplantation. It also covers composition of matter (a subset of sequences) of monoclonal antibodies against target proteins existing on the surface of hematopoietic stem cells/hematopoietic progenitors ("HSC/HP"), and/or a number of leukemias such as acute myeloid leukemia ("AML") as well as a

protein that exists on the surface of immune cells (T cells).

Appointments

Hemogenyx Pharmaceuticals strengthened its scientific team through the appointment of two new team members to key roles. Dr Koen van Besien, a renowned bone marrow transplant and oncology physician, has joined the Company as Medical Director, in which role he will oversee the development of the clinical trial programme for HEMO-CAR-T. Mr Stuart Tinch has been appointed as Director of Quality, bringing his experience of Good Medical Practice manufacturing of viral vectors and cell therapies and expertise in establishing and maintaining quality systems to the HEMO-CAR-T project and the Company's other product candidates.