27 September 2024

Hemogenyx Pharmaceuticals plc

("Hemogenyx Pharmaceuticals" or the "Company")

Half-year Report

Interim Results for the period ended 30 June 2024

Hemogenyx Pharmaceuticals plc (LSE: HEMO), the biopharmaceutical group developing therapies designed to transform blood disease treatment, whose shares are admitted to the equity shares (transition) category of the Official List, announces its unaudited interim results for the six-month period ended 30 June 2024.

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

Key Highlights

- The U.S. Food and Drug Administration (“FDA”) lifted the clinical hold on the Investigational New Drug (“IND”) application for HEMO-CAR-T.
- Raised £3.325 million to advance HEMO-CAR-T towards Phase I clinical trials.
- Phase I clinical trials expected to begin shortly at M.D. Anderson Cancer Center ("MD Anderson") in Texas.
- Continuing to make advancements with the Company’s Chimeric Bait Receptor (“CBR”) and bispecific antibody (“CDX”) programmes.

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

Interim Management Report

We are pleased to present Hemogenyx Pharmaceuticals' half year report for the period ending 30 June 2024. The past six months have been a time of significant progress and strategic advancement for our company as we continue to develop novel therapies inter alia for the treatment of serious blood diseases.

During the first half of 2024, the Company has been mainly focussed on getting its lead product, HEMO-CAR-T, into clinical trials, while continuing to progress its other main product candidates, CBR and CDX.

HEMO-CAR-T

In February 2024, the FDA lifted the clinical hold on the IND application for HEMO-CAR-T, our treatment for acute myeloid leukemia ("AML"), which had been imposed in June 2023. The FDA confirmed that we have satisfactorily addressed all issues identified in its prior clinical hold letter, allowing us to proceed with the Phase I clinical study of HEMO-CAR-T. Following the reopening of the IND, we successfully raised £3.325 million (before expenses) at 2p per share, issuing 166,250,000 ordinary shares, to advance HEMO-CAR-T into Phase I clinical trials.

The trials are expected to begin shortly at MD Anderson in Texas, one of the leading cancer treatment centers in the U.S. As shareholders know, we have been collaborating with the University of Pennsylvania Medical Center ("Penn") to conduct the trials at their facility. While Penn remains supportive and wishes to participate, several issues have delayed their proposed schedule. Fortunately, we connected with MD Anderson regarding their participation in the trials. MD Anderson is a large and highly reputable centre for cancer treatment, including AML, and they are confident in maintaining a consistent and reliable flow of trial candidates. It is important to note that every patient from the very first one treated in the HEMO-CAR-T clinical study will produce valuable data regarding the safety and potentially efficacy of the treatment.

We are now in the final stages of the opening a clinical site at MD Anderson and expect to treat the first patient soon. Penn remains eager to participate in the trials at a later stage, and we hope they will do so, though likely not until 2025.

While we have been discussing partnerships with potential hospital collaborators, we have made significant progress with HEMO-CAR-T during the period under review. We have evaluated its potential to treat pediatric AML and a subset of pediatric acute lymphoblastic leukemia ("ALL") in young patients. An amendment to include pediatric AML in our clinical protocol has been reviewed by independent experts, and we will extend the protocol accordingly. If approved as expected, we plan to initiate clinical trials for pediatric AML and a subset of ALL at MD Anderson. These indications are of particular concern because current treatments are risky and have low success rates. There is an urgent need for effective therapies, and we believe HEMO-CAR-T can provide a valuable solution.

In addition, the Company recently announced that it has successfully completed the development of a clinical-grade assay for use in HEMO-CAR-T clinical trials, a project the Company has been working on for some time. This assay is designed to assess and ensure the proper identification and recruitment of suitable patients for the clinical trials.

We are continuing our collaboration with Prevail Infoworks, the contract research organization that will manage and oversee the planning and execution of our clinical trials. Currently, they are working closely with us to bring HEMO-CAR-T into the clinic. When the trials commence, we will manufacture the HEMO-CAR-T cells at our New York facility for use in each individual patient. Prevail Infoworks will coordinate the logistical aspects of the trials, including patient enrolment, data management, regulatory compliance, and overall trial monitoring, ensuring that the studies are conducted efficiently and effectively.

Although we had hoped to start the trials sooner, we have used this time to further advance development of the HEMO-CAR-T program, which will make the execution and assessment of the trials easier. Developing the clinical-grade assay and focusing on pediatric opportunities are

significant steps forward. These advancements will help us carry out the clinical trials more effectively and broaden the potential use of HEMO-CAR-T to additional leukaemia patients who currently have very limited treatment options.

CBR and CDX

As we have been waiting for the HEMO-CAR-T clinical trials to commence, we have been able to apply more effort to progress our other product candidates, in particular the CBR and the CDX programs.

Our CBR platform is an advanced immunotherapy designed to reprogram or redirect immune cells, such as macrophages, to prevent and combat infections from both existing and emerging viral threats, as well as to eliminate specific types of cancer. Our research originally focused on the former where, for example, we established *in vitro* that CBR could treat viruses such as COVID and potentially a much wider range of viruses. More recently, we have established that it could also be used against a range of cancers. We are developing and testing multiple CBR constructs to identify the best candidates for targeting rare cancers such as epithelial ovarian carcinoma. Selected CBR candidates will undergo rigorous testing to advance them to IND enabling studies. In addition, we have established a means of delivering CBR intranasally, for treating airborne viral infections which would significantly ease the use of CBRs in the field. We have also recently made improvements in the stability of mRNA-based CBRs to further enhance the effectiveness of this treatment.

Regarding CDX, we have been advancing the studies required for an IND application. CDX is designed to prepare patients with AML for bone marrow transplants and, we believe, may also be directly capable of treating relapsed or refractory AML. Meanwhile, we have developed a new and improved version of CDX. Our scientists used bispecific pairing technology to create this version, and it has shown significantly enhanced effectiveness in the laboratory (*in vitro*) tests. Additional animal (*in vivo*) studies are currently underway.

HEMO-CAR-T and CDX offer different yet complementary approaches to treating AML. CDX is specifically designed to target AML cells and has the potential to condition patients for bone marrow transplants. By directly attacking AML and preparing patients for transplants, CDX provides a dual strategy in combating this aggressive cancer. On the other hand, HEMO-CAR-T involves modifying a patient's T-cells to seek out and destroy cancer cells. By developing both therapies, we increase our chances of success and aim to offer effective treatment options to a broader range of AML patients.

Financial Results

During the six months ended 30 June 2024, the Group recorded a loss before taxation of £2,815,604 (2023: £4,323,564 loss), including operating costs of £2,369,455 (2023: £3,896,308). For further comparison, the operating costs for the twelve months to 31 December 2023 were £5,820,165. The reduction in costs for the period ended 30 June 2024 compared to the same period in 2023 is due to two principal factors: a significant favourable movement in the UK sterling and US dollar exchange rate accounting for a variance of £1,039,436 and a reduction in research and development costs of £413,419. This is primarily due to a reduction in payments to WuXi in respect of the Company's advancement to the clinical trial phase. These costs concluded in March 2024.

The Company had cash and cash equivalents totalling £1,642,762 as of 30 June 2024.

Conclusion

We have now reached a pivotal stage where our lead product, HEMO-CAR-T, is set to enter the clinic, a development that undeniably elevates us to a clinical-stage company. Meanwhile, our other product candidates are also making significant strides forward. We are confident in our ability to finance their development through a combination of equity capital, industry partnerships, and non-dilutive funding. We look forward to bringing our potentially life-saving therapies into use and delivering positive returns to our shareholders.

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 2024.

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

26 September 2024

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.

Enquiries:

Hemogenyx Pharmaceuticals plc	https://hemogenyx.com
Dr Vladislav Sandler, Chief Executive Officer & Co-Founder	headquarters@hemogenyx.com

Peter Redmond, Director peter.redmond@hemogenyx.com

SP Angel Corporate Finance LLP Tel: +44 (0)20 3470 0470

Matthew Johnson, Vadim Alexandre, Adam Cowl

Peterhouse Capital Limited Tel: +44 (0)20 7469 0930

Lucy Williams, Duncan Vasey, Charles Goodfellow

Condensed Consolidated Interim Statement of Comprehensive Loss for the six months ended 30 June 2024

Continuing Operations	Note	**6 months to 30 June 2024 Unaudited** £	6 months to 30 June 2023 Unaudited £
Revenue		**-**	-
Administrative Expenses		**(2,369,455)**	(3,896,308)
Depreciation		**(321,685)**	(319,909)
Operating Loss		**(2,691,140)**	(4,216,217)
Finance Income		**17,328**	54,692
Finance Costs		**(141,792)**	(162,039)
Loss before Taxation		**(2,815,604)**	(4,323,564)
Loss attributable to:			
- Equity owners		**(2,812,832)**	(4,321,103)
- Non-controlling interests		**(2,772)**	(2,461)
Loss for the period		**(2,815,604)**	(4,323,564)
Other comprehensive income			
Items that may be reclassified subsequently to profit or loss:			
Translation of foreign operations		**(102,482)**	751,572
Total comprehensive income for the period		**(2,918,086)**	(3,571,992)
Total comprehensive income attributable to:			
- Equity owners		**(2,915,314)**	(3,569,531)
- Non-controlling interests		**(2,772)**	(2,461)
Basic and diluted earnings (per share)	5	**(0.002)**	(0.003)

Condensed Consolidated Interim Statement of Financial Position as at 30 June 2024

	Note	As at 30 June 2024 Unaudited	As at 31 December 2023 Audited
Assets		£	£
Non-current assets			
Property, plant and equipment	6	**854,335**	966,423
Security deposit		**166,165**	153,668
Right of use asset	9	**2,152,630**	2,346,015
Intangible asset		**472,503**	470,173
Total non-current assets		**3,645,633**	3,936,279
Current assets			
Trade and other receivables		**827,867**	922,013
Cash and cash equivalents		**1,642,762**	1,247,601
Total current assets		**2,470,629**	2,169,614
Total assets		**6,116,262**	6,105,893
Equity and Liabilities			
Equity attributable to shareholders			
Paid-in Capital			
Called up share capital	7	**13,418,160**	11,755,660
Share premium	7	**21,436,546**	19,938,556
Other reserves		**1,164,637**	1,164,637
Reverse asset acquisition reserve		**(6,157,894)**	(6,157,894)
Foreign currency translation reserve		**(179,978)**	(77,496)
Retained Earnings		**(26,617,566)**	(23,804,734)
Equity attributable to owners of the Company		**3,063,905**	2,818,729
Non-controlling interests		**(40,495)**	(37,723)
Total Equity		**3,023,410**	2,781,006
Liabilities			
Non-current liabilities			
Lease liabilities	9	**2,528,588**	2,672,802
		2,528,588	2,672,802
Current liabilities			
Trade and other payables		**308,660**	379,001
Lease liabilities	9	**255,604**	273,084
Total Current Liabilities		**564,264**	652,085

Total Liabilities	**3,092,852**	3,324,887
Total equity and liabilities	**6,116,262**	6,105,893

The 2023 comparatives are the audited consolidated group accounts for the year ended 31 December 2023 as published on 25 April 2024.

Condensed Consolidated Interim Statement of Changes in Equity for the six months ended 30 June 2024 and 30 June 2023

	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 2023	9,797,493	16,808,647	921,801	(6,157,894)	(980,563)	(17,114,056)	(31,908)	3,243,520
Loss in period	-	-	-	-	-	(4,321,103)	(2,461)	(4,323,564)
Other comprehensive income	-	-	-	-	751,572	-	-	751,572
Total comprehensive income for the year	-	-	-	-	751,572	(4,321,103)	(2,461)	(3,571,992)
Issue of options	-	-	40,473	-	-	-	-	40,473
Issue of shares (Note 7)	16,225	4,040,025	-	-	-	-	-	4,056,250
Cost of capital (Note 7)	-	(138,344)	-	-	-	-	-	(138,344)
As at 30 June 2023 (unaudited)	9,813,718	20,710,328	962,274	(6,157,894)	(228,991)	(21,435,159)	(34,369)	3,629,907
As at 1 January 2024	**11,755,660**	**19,938,556**	**1,164,637**	**(6,157,894)**	**(77,496)**	**(23,804,734)**	**(37,723)**	**2,781,006**
Loss in period	**-**	**-**	**-**	**-**	**-**	**(2,812,832)**	**(2,772)**	**(2,815,604)**
Other comprehensive income	**-**	**-**	**-**	**-**	**(102,482)**	**-**	**-**	**(102,482)**
Total comprehensive income for the period	**-**	**-**	**-**	**-**	**(102,482)**	**(2,812,832)**	**(2,772)**	**(2,918,086)**
Issue of shares (Note 7)	**1,662,500**	**1,662,500**	**-**	**-**	**-**	**-**	**-**	**3,325,000**
Cost of capital (Note 7)	**-**	**(164,510)**	**-**	**-**	**-**	**-**	**-**	**(164,510)**
As at 30 June 2024 (unaudited)	**13,418,160**	**21,436,546**	**1,164,637**	**(6,157,894)**	**(179,978)**	**(26,617,566)**	**(40,495)**	**3,023,410**

Condensed Consolidated Interim Statement of Cash Flows for the six months ended 30 June 2024

Group	Note	6 months to 30 June 2024 Unaudited	6 months to 30 June 2023 Unaudited
		£	£
Cash flows generated from operating activities			
Loss for the period		**(2,815,604)**	(4,323,564)
Depreciation	6, 9	**321,685**	319,909
Foreign exchange gain		**(14,630)**	197,148
Interest income		**(17,328)**	(54,692)
Interest expense		**141,792**	162,039
Share based payments	8	**-**	40,473
(Decrease) in trade and other payables		**(65,400)**	136,578
(Increase)/decrease in trade and other receivables		**(17)**	5,600
Decrease/(Increase) in prepaid and deposits		**98,682**	(25,866)
Net cash outflow used in operating activities		**(2,350,820)**	(3,542,375)
Cash flows generated from financing activities			
Proceeds from issuance of shares, net of direct costs	7	**3,160,490**	3,917,906
Payment of lease liabilities	9	**(317,872)**	(318,079)
Net cash flow generated from financing activities		**2,842,618**	3,599,827
Cash flows generated from investing activities			
Interest income		**17,328**	54,692
Purchase of property, plant & equipment	6	**-**	(13,161)
Net cash flow generated from investing activities		**17,328**	41,531
Net increase in cash and cash equivalents		**509,126**	98,983
Effect of exchange rates on cash and cash equivalents		**(113,965)**	453,111
Cash and cash equivalents at the beginning of the period		**1,247,601**	2,532,758
Cash and cash equivalents at the end of the period		**1,642,762**	3,084,852

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 the 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 2024. 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 2023, 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 2023 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 2023 as described in those financial statements. Several 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 successfully raised £3,325,000 (before expenses) through the allotment and issue of 166,250,000 new ordinary shares at 2 pence per share during the period to 30 June 2024. The proceeds raised were used to enable the Company to progress towards the testing of HEMO-CAR-T in patients in Phase I clinical trials and to provide continuing working capital for the Company's operations. A small portion of the funds were used for the development of the Company's other product candidates, including the necessary maintenance and prosecution of the Company's patent applications.

Substantial funding will be required by the Company to progress through Phase I clinical trials over the next two years. To the extent that the Company raises additional funds by issuing equity securities, the Company's shareholders 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 will 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. There can be no assurance that either the funding shortfall will be addressed in whole or in part, neither is there an assurance that the Group will have access to any financing on terms which are acceptable, or at all, in which case the Group's product development activities would have to cease and the Company would no longer be adequately capitalised.

At present, the Company has insufficient working capital for its foreseeable requirements over the 12 months from the date of issuing these interim results. However, the Directors believe that the Company can access additional financing. The Directors, therefore, have made an informed judgment, at the time of approving these financial statements that the Company will be able to raise sufficient funds to continue in operation for the foreseeable future.

Segmental Reporting

The Group's operations are located in New York, USA,; the parent company is a British public company which is administered in the United Kingdom. The main assets of the Group, cash and cash equivalents, are held primarily in the United Kingdom and the United States, while the fixed assets and right of use assets are held in 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 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 suchas 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 2023 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

The International Accounting Standards Board (IASB) issued various amendments and revisions to International Financial Reporting Standards and IFRIC interpretations. The amendments and revisions were applicable for the period ended 30 June 2024 but did not result in any material changes to the financial statements of the Company.

4. 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. 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 2023.

5. Earnings per share

Basic and fully diluted earnings per share are calculated by dividing the loss for the six months from continuing operations of £2,918,086 (six months to 30 June 2023: £3,571,992 loss) attributable to equity owners of the Group by the weighted average number of ordinary shares in issue during those periods of 1,226,900,920 and 1,042,923,486 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 2024 and six months to 30 June 2023, there is no dilutive effect from the subsisting share options.

6. Property, Plant and Equipment

During the six months ended 30 June 2024, the Group did not acquire any PPE assets (six months ended 30 June 2023: £13,161) and incurred depreciation expense of £116,804 (six months ended 30 June 2023: £109,769).

7. Issued capital

	Shares	Called up share capital £	Share premium £
As at 31 December 2023	**1,175,565,988**	**11,755,660**	**19,938,555**
Issue of shares	166,250,000	1,662,500	1,662,500
Share issuance costs	-	-	(164,510)
As at 30 June 2024	**1,341,815,988**	**13,418,160**	**21,436,545**

During the six months ending 30 June 2024, the Company sold 166,250,000 shares of ordinary stock at a price of 2p per share as part of a private placement of its securities.

8. Share-based payments

Options

During the six months to 30 June 2024, no options were issued to directors or employees and 7,501,070 options lapsed during the six months to 30 June 2024.

A schedule of options granted since inception for all plans as at 30 June 2024 is shown below:

	Number of options
Members of the Scientific Advisory Board	12,481,912
Employees, including directors	104,326,986
Total	**116,808,898**

For the six months ended 30 June 2024, the Company did not recognise any share-based payment expense in the statement of profit or loss (30 June 2023: £40,473).

9. Right of use assets and leases

The Group follows IFRS 16 with respect to its leases, whereby the Group recognises right-of-use assets and lease liabilities for all leases on its balance sheet. One of the US subsidiaries has an agreement for the lease of laboratory facilities to which IFRS 16 has been applied.

During the six months ended 30 June 2024, the Group incurred a right of use asset depreciation expense of £204,881 (six months ended 30 June 2023: £210,140), incurred lease liability interest expense of £141,689 (six months ended 30 June 2023: £165,202) and made lease payments in the amount of £369,982 (six months ended 30 June 2023: £318,079).

10. Events after the reporting date

There were no events after the reporting date.