



28 September 2023

Hemogenyx Pharmaceuticals plc

("Hemogenyx Pharmaceuticals" or the "Company")

Half-year Report

Interim Results for the period ended 30 June 2023

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 2023.

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

Key Highlights

- Applied for Investigational New Drug ("IND") status for the Company's lead product HEMO-CAR-T with the U.S. Food and Drug Administration ("FDA").
- IND application placed on clinical hold, with the FDA later accepting the Company's plan for resolving outstanding issues.
- Continuing development of Chimeric Bait Receptor ("CBR") antiviral/biodefence platform.
- Following the period end, the Company received a strategic investment of US\$833,000 from Prevail Partners, LLC ("Prevail Partners") at a large premium to share price.
- Entered into agreement with Prevail InfoWorks Inc. ("Prevail InfoWorks") to provide clinical services and technologies for the Company's upcoming Phase I clinical trial of HEMO CAR-T.

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

Commenting on the outlook for Hemogenyx Pharmaceuticals, Vladislav Sandler, Chief Executive Officer, said:

"While the placing of HEMO-CAR-T on clinical hold was a setback, we are clear on the particular area in which additional information is required, and we are encouraged by the FDA's response to our plans to resolve the issues. We remain confident and committed to progressing HEMO CAR-T to clinical trials as the Company's next step. We have put measures in place to allow us to achieve this milestone, including the new agreement with Prevail InfoWorks and the investment by Prevail Partners, which gives a clear signal of the project's value even at this pre-clinical phase. Meanwhile, the prospects for our other cutting-edge assets continue to be positive, and CBR in particular is beginning to attract real attention."

Interim Management Report

We are pleased to provide an update on the Company's activities over the six-month period ended 30 June 2023. Although it is not all plain sailing, we are now developing on a number of fronts which, while adding materially to operating costs, puts us into a far stronger position for further development. In particular, we are now seeing major benefits from our state-of-the-art research and manufacturing facilities and we have also made cautious but significant additions to our scientific and manufacturing team.

HEMO-CAR-T

The Company has continued to focus on its lead product candidate, HEMO-CAR-T, throughout 2023 and, as shareholders are aware, after substantial work we submitted an IND application to the FDA in May 2023. The FDA considered that in certain respects they needed additional information and therefore placed the project on clinical hold in June. We received a detailed explanation from the FDA as to the areas needing additional work and we have since then been working with our manufacturing partner, WuXi, to address FDA concerns.

We are taking great care to provide a very thorough response with the aim that the IND application, when resubmitted, is as full and complete as possible. Having responded to the FDA with a detailed plan, supported by laboratory tests, to address its comments, we were pleased earlier this month when the FDA confirmed that it accepts our plan and that this plan will satisfactorily address its comments. This will enable the agency to remove the clinical hold so that we can proceed to clinical trials. There remains work to be done on this, but we are confident of eventual success.

The reason for the clinical hold relates to a splicing that occurs during the manufacturing process of the lentivirus that is used to produce CAR-T cells. The Company has identified the source of the splicing deficiency and has already developed a method to eliminate it. The lentivirus is being remanufactured.

On 14 September, we were able to announce a very important further step towards the development of HEMO CAR-T which also represents a real validation of the product's perceived value. We received a strategic investment from Prevail Partners, a corporate investment fund investing in clinical stage therapeutics companies. Prevail Partners has agreed to invest in Hemogenyx Pharmaceuticals through a subscription to 11,066,667 new ordinary shares at a price of US\$0.075 per share (approximately £0.06) for the total sum of US\$830,000 (approximately £668,000). Such investment, at a significant premium to the Company's share price at the time, represents a vote of confidence by a specialist professional group with knowledge and experience of the pharmaceutical industry.

The investment by Prevail Partners sits alongside the agreement entered with Prevail Infoworks, a Philadelphia, PA based Contract Research Organization (CRO) and affiliate of Prevail Partners, to provide clinical services and technologies for the Company's upcoming Phase I study of its anti-FLT3 chimeric antigen receptor-redirectioned T cells ("CAR-T cells") in subjects with relapsed/refractory acute myeloid leukemia (AML). Further details may be found below in Note 10 to the financial statements titled 'Events after the reporting period'.

CBR

Meanwhile, we have continued to work on our other major product candidates, in particular our Chimeric Bait Receptor ("CBR") platform which, as shareholders are aware, is focussed on

developing a new approach which we believe will provide effective cures for a wide range – indeed perhaps the full range – of viral infections, including diseases for which no cures are available at present. In the wake of the COVID-19 pandemic, and facing global threats of biological warfare and the fast spreading of pandemics from previously unknown diseases, the need for proactive solutions against future infectious agents has become clear. To address this imminent threat, our CBR immunotherapy is designed to prevent and combat infection by any known or emerging virus.

We have designed a set of novel CBR constructs to programme the immune cells that are responsible for innate immunity to eliminate viral infections. Additionally, we have designed and currently test bait-macrophage engagers (“BMEs”) to redirect immune cells to fight viral infections. Our technology utilises a synthetic biology approach to advance medicine to protect society from future pandemics and even future bioweapons that may challenge the global economy and public health. Our early work concentrated on SARS-CoV-2 virus and its variants, but we also believe that CBR-based treatments will be able to deal with a much wider range of viruses.

We have strengthened our team with the recruitment of additional scientists during the period, inter alia to work on our CBR/BME platform. The project has begun to attract high-level interest from authorities. This interest is gratifying and, given our limited resources and the need to focus on our lead product HEMO-CAR-T, we have made considerable progress and plan to devote further internal resources to this project as soon as HEMO-CAR-T enters clinical trials.

CDX Antibody

CDX, our CD3-FLT3 bispecific antibody, will provide an alternative means of treating acute myeloid leukemia and of conditioning patients for bone marrow transplants when fully developed. We continue to explore potential partnership arrangements to take that forward. This remains a potentially valuable part of our portfolio and we will also work to take this forward once our lead product has moved into the clinic.

Fundraising

In January 2023, we announced that the Company had raised £4,056,250 before expenses through the placing and subscription of 162,250,000 new ordinary shares at a price of 2.5p per share.

In addition, following the period end, we raised a further US\$833,000 (£668,000) at approximately £0.06, as more fully described in the section headed “HEMO-CAR-T” above.

Financial Results

During the six months ended 30 June 2023, the Group recorded a loss before taxation of £4,323,564 (2022: £1,141,304 loss), including operating costs of £3,896,308 (2022: £1,111,010). For further comparison, the operating costs for the twelve months to 31 December 2022 were £3,433,476. The increased operating loss marks the increasing volume of work and need to engage external service providers as the Company’s assets are taken towards the crucial clinical trial stage of their development. These include significant payments to WuXi and other consultants engaged in development services, increased costs for our research and manufacturing facility and additional payroll costs as we added to our specialist scientific team. The increase in cost is an inevitable corollary of developing the Company on a broader scale and moving forward its key projects.

The Company had cash and cash equivalents totalling £3,084,852 as of 30 June 2023.

The Future

In the immediate future, we remain laser-focused on resubmitting our IND application for HEMO-CAR-T to the FDA as soon as we can, and on preparing for its move into clinical trials.

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 2023.

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

28 September 2023

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 2023

Continuing Operations	Note	6 months to 30 June 2023 Unaudited £	6 months to 30 June 2022 Unaudited £
Revenue		-	-
Administrative Expenses		(3,896,308)	(1,111,010)
Depreciation		(319,909)	(32,233)
Operating Loss		(4,216,217)	(1,143,243)
Finance Income		54,692	1,956
Finance Costs		(162,039)	(17)
Loss before Taxation		(4,323,564)	(1,141,304)
Loss attributable to:			
- Equity owners		(4,321,103)	(1,127,675)
- Non-controlling interests		(2,461)	(13,629)
Loss for the period		(4,323,564)	(1,141,304)
Other comprehensive income			
Items that may be reclassified subsequently to profit or loss:			
Translation of foreign operations		751,572	(159,349)
Total comprehensive income for the period		(3,571,992)	(1,300,653)
Total comprehensive income attributable to:			
- Equity owners		(3,569,531)	(1,287,024)
- Non-controlling interests		(2,461)	(13,629)
Basic and diluted earnings (per share)	5	(0.003)	(0.002)

Condensed Consolidated Interim Statement of Financial Position as at 30 June 2023

	Note	As at 30 June 2023 Unaudited £	As at 31 December 2022 Audited £
<u>Assets</u>			
Non-current assets			
Property, plant and equipment	6	926,643	1,023,252
Security deposit		140,821	140,821
Right of use asset	9	2,550,017	2,892,261
Intangible asset		441,493	441,493
Total non-current assets		4,058,974	4,497,827
Current assets			
Trade and other receivables		80,105	62,024
Cash and cash equivalents		3,084,852	2,532,758
Total current assets		3,164,957	2,594,782
Total assets		7,223,931	7,092,609
<u>Equity and Liabilities</u>			
Equity attributable to shareholders			
Paid-in Capital			
Called up share capital	7	9,813,718	9,797,493
Share premium	7	20,710,328	16,808,647
Other reserves		962,274	921,801
Reverse asset acquisition reserve		(6,157,894)	(6,157,894)
Foreign currency translation reserve		(228,991)	(980,563)
Retained Earnings		(21,435,159)	(17,114,056)
Equity attributable to owners of the Company		3,664,276	3,275,428
Non-controlling interests		(34,369)	(31,908)
Total Equity		3,629,907	3,243,520
<u>Liabilities</u>			
Non-current liabilities			
Lease liabilities	9	2,817,216	3,100,678
		2,817,216	3,100,678
Current liabilities			
Trade and other payables		328,969	426,254
Lease liabilities	9	447,839	322,157
Total Current Liabilities		776,808	748,411

Total Liabilities

3,594,024

3,849,089

Total equity and liabilities

7,223,931

7,092,609

The 2022 comparatives are the audited consolidated group accounts for the year ended 31 December 2022 as published on 27 April 2023.

**Condensed Consolidated Interim Statement of Changes in Equity
for the six months ended 30 June 2023 and 30 June 2022**

	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 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)	(1,141,304)
Other comprehensive income	-	-	-	-	(159,349)	-	-	(159,349)
Total comprehensive income for the year	-	-	-	-	(159,349)	(1,127,675)	(13,629)	(1,300,653)
Issue of options (Note 8)	-	-	12,079	-	-	-	-	12,079
As at 30 June 2022 (unaudited)	9,797,493	16,808,647	916,305	(6,157,894)	(185,270)	(14,262,417)	(37,869)	6,878,995
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 period	-	-	-	-	751,572	(4,321,103)	(2,461)	(3,571,992)
Issue of options (Note 8)	-	-	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 203 (unaudited)	9,813,718	20,710,328	962,274	(6,157,894)	(228,991)	(21,435,159)	(34,369)	3,629,907

Condensed Consolidated Interim Statement of Cash Flows for the six months ended 30 June 2023

Group	Note	6 months to	6 months to
		30 June 2023	30 June 2022
		Unaudited	Unaudited
		£	£
<u>Cash flows generated from operating activities</u>			
Loss for the period		(4,323,564)	(1,141,304)
Depreciation	6	319,909	32,233
Other non-cash items, including forgiveness of PPP loan		-	2,205
Foreign exchange gain		197,148	1,058
Interest income		(54,692)	(1,956)
Interest expense		162,039	20
Share based payments	8	40,473	12,079
Changes in right of use asset and lease liability, net		314,611	-
(Decrease)/increase in trade and other payables		(20,727)	500,752
Decrease/(increase) in trade and other receivables		5,600	(342,383)
Increase in prepaid and deposits		(25,866)	-
Net cash outflow used in operating activities		(3,385,069)	(937,298)
<u>Cash flows generated from financing activities</u>			
Proceeds from issuance of shares, net of direct costs	7	3,917,906	-
Payment of lease liabilities	9	(318,079)	(5,441)
Net cash flow generated from/(used in) financing activities		3,599,827	(5,441)
<u>Cash flows generated from investing activities</u>			
Interest income		54,692	1,956
Purchase of property, plant & equipment	6	(13,161)	(1,553)
Net cash flow generated from investing activities		41,531	403
Net increase (decrease) in cash and cash equivalents		256,289	(942,335)
Effect of exchange rates on cash and cash equivalents		295,805	(99,139)
Cash and cash equivalents at the beginning of the period		2,532,758	6,840,969
Cash and cash equivalents at the end of the period		3,084,852	5,799,496

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 2023. 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 2022, 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 2022 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 2022 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 £4,056,250 (before expenses) through the allotment and issue of 162,250,000 new ordinary shares at 2.5 pence per share during the period to 30 June 2023 and a further \$830,000 (£668,000) through the allotment and issue of 11,066,667 Ordinary Shares, after the period end. These proceeds were raised in order to facilitate the progression of the Company's HEMO-CAR-T product candidate into clinical trials and to enable the Company to continue development of product candidates for the treatment of viral infections based on its CBR platform.

Substantial funding will be required by the Company during the clinical trial phase and further funding will be sought by the Company prior to the commencement of the Phase I clinical trials.

The Company 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.

However, the Directors are of the opinion that the Company has adequate working capital to execute its operations for the present time and is confident in its 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.

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 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 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 2022 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 a 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 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 2022.

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 £3,571,992 (six months to 30 June 2022: £1,141,304 loss) attributable to equity owners of the Group by the weighted average number of ordinary shares in issue during those periods of 1,042,923,486 and 773,952,166 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 2023 and six months to 30 June 2022, there is no dilutive effect from the subsisting share options.

6. Property, Plant and Equipment

During the six months ended 30 June 2023, the Group acquired assets with a cost of £13,161 (six months ended 30 June 2022: £1,553) and incurred depreciation expense of £109,769 (six months ended 30 June 2022: £32,233).

7. Issued capital

	Shares	Called up share capital £	Share premium £
As at 31 December 2022	979,749,321	9,797,493	16,808,647
Issue of shares	162,250,000	16,225	4,040,025
Share issuance costs	-	-	(138,344)
As at 30 June 2023	1,141,999,321	9,813,718	20,710,328

During the six months ending 30 June 2023, the Company sold 162,250,000 shares of ordinary stock at a price of 2.5p per share as part of a private placement of its securities.

8. Share-based payments

Options

During the six months to 30 June 2023, 22,839,986 options with an exercise price of 2.5p per ordinary share and 34,259,980 options with an exercise price of 2.875p per ordinary share were issued under the Company's 2021 Equity Incentive Plan. The first tranche of 22,839,986 options vests over 5 years and the second tranche of 34,259,980 options vests contingent upon authorisation by the FDA to commence clinical trials of HEMO-CAR-T. No options lapsed during the six months to 30 June 2023.

A schedule of options granted since inception for all plans as at 30 June 2023 is shown below:

	Number of options
Members of the Scientific Advisory Board	12,481,912
Employees, including directors	104,326,986
Total	116,808,897

For the six months ended 30 June 2023, the Company recognised share-based payment expense in the statement of profit or loss of £40,473 (30 June 2022: £12,079).

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 2023, the Group incurred a right of use asset depreciation expense of £210,140 (six months ended 30 June 2022: £4,968), incurred lease liability interest expense of £165,202 (six months ended 30 June 2022: £45) and made lease payments in the amount of £318,079 (six months ended 30 June 2022: £5,441).

10. Events after the reporting period

On 10 July 2023, the Company announced that it had received a full review letter from the FDA regarding the IND application for the Company's product candidate CAR T-cells for the treatment of AML to the effect that HEMO-CAR-T be put on clinical hold.

On 7 September 2023, the Company's patent under application number "WO2023168292 Chimeric Bait Receptors and Uses Thereof" was published by the World Intellectual Property Organization. It remains to be reviewed and approved by national patent authorities.

On 14 September 2023, the Company announced that the FDA has accepted its plan to address the FDA's concerns that resulted in a clinical hold of the HEMO-CAR-T IND application.

On 18 September 2023, the Company finalised a funding arrangement with investment fund Prevail Partners, LLC, which agreed to invest in the Company through a subscription to 11,066,667 ordinary shares at a price of US\$0.075 per share (approximately £0.06) for the total sum of US\$830,000 (approximately £668,000).

On the same date, the Company also announced that its wholly owned subsidiary, Hemogenyx Pharmaceuticals LLC, has signed a Master Service and Technology Agreement ("MSTA") with Prevail InfoWorks, Inc., an affiliate of Prevail Partners. Under the terms of the MSTA, Prevail InfoWorks is to provide clinical services and technologies for the Company's upcoming Phase I study of its CAR-T cells in subjects with relapsed/refractory AML over an initial term of 40 months.

The subscription funds will in large part defray the payment made by the Company for the first stage of the work being undertaken by InfoWorks under the MSTA.