RNS Number : 9423L
Hemogenyx Pharmaceuticals PLC
25 April 2024

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25 April 2024

Hemogenyx Pharmaceuticals plc
("Hemogenyx Pharmaceuticals" or the "Company")

Final Results

Hemogenyx Pharmaceuticals plc (LSE: HEMO), the biopharmaceutical group developing new therapies and treatments for blood diseases, announces its final audited results for the year ended 31 December 2023. The Annual Report is available to view on the Company's web site at https://hemogenyx.com.

Key Highlights

- Investigational New Drug ("IND") application submitted in May 2023 seeking authorisation from the U.S. Food and Drug Administration ("FDA") to begin a Phase I clinical trial of HEMO-CAR-T for treating acute myeloid leukaemia (AML)
- After a clinical hold period, to address manufacturing issues, HEMO-CAR-T was granted authority from the FDA in February 2024 to commence Phase I clinical trials
- Continuing development of Chimeric Bait Receptor ("CBR") antiviral/biodefence platform and filed a patent application entitled *Chimeric Bait Receptors and Uses Thereof*
- Successfully raised £5.25 million (before expenses) in total through the allotment and issue of new ordinary shares during the year ended 31 December 2023, and a further £3.25 million in early 2024
- Entered into agreement with Prevail InfoWorks Inc. 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 Chairman's Statement below.

Chairman's Statement

I am pleased to report the Company's results for the year ended 31 December 2023. The period was a vital one in the progression of the Company. Development work on our lead HEMO-CAR-T product candidate was completed and we were able to submit an Investigational New Drug ("IND") application to the Food and Drug Administration ("FDA") to enable us to move into clinical trials for HEMO-CAR-T. Unfortunately, the FDA decided that certain aspects of the data initially provided did not meet its rigorous safety standards, so it imposed a clinical hold pending further development of the product. We worked hard in the final months of the year to meet the FDA's additional requirements and, as a result, the clinical hold was lifted in January 2024. Hemogenyx Pharmaceuticals is thereby established as a "clinical stage" company and we are now proceeding to the next step in the development of HEMO-CAR-T, the commencement of Phase I clinical trials.

At the same time, we continued to move forward, insofar as funding would allow, with our other main pipeline assets, our Chimeric Bait Receptor ("CBR") platform and our CDX bi-specific CD3-FLT3 antibody ("CDX"). Significant progress was made on the former, as will be described more fully below.

Fundraising

We raised capital on a number of occasions in the period under review.

In January 2023, we were successful in raising £4,056,250 in new equity capital at 2.5p per share which was intended to take us through the IND process and to the stage of clinical trials for HEMO-CAR-T. The clinical hold delayed matters for some months and of course diminished our cash resources. In December 2023, we therefore raised a further £534,375 at 2.375p per share to take us to the next key stage.

In September, Prevail Partners LLC ("Prevail Partners") made a strategic investment of $830,000 (£680,000) through a subscription for 11,066,067 new ordinary shares in the Company at a price of $0.075 (about 6p), at a premium of approximately 240% to the then share price. Prevail Partners is the investment partner of Prevail Infoworks Inc. ("Infoworks"), a contract research organisation that we have engaged to provide a variety of services necessary for the implementation and management of the clinical trials of HEMO-CAR-T. The price at which Prevail Partners made its investment in Hemogenyx Pharmaceuticals demonstrated its confidence in our HEMO-CAR-T product candidate. Further information on our association with Prevail Partners and Infoworks is described in the section headed "HEMO-CAR-T" below.

Since the period end, and following the lifting of the clinical hold, we raised a further £3.325 million at 2p per share to enable us to move into clinical trials.

While we accept that recent market conditions have been very difficult, we have been disappointed by the successively lower price at which we have had to carry out our fundraisings in the UK market, in the light of the progress we have made and the views taken by Prevail Partners concerning our status. The capital recently raised will undoubtedly take us materially further

view taken by Prevail Partners concerning our status. The capital recently raised will undoubtedly take us materially further forward and we are now looking at a number of strategies for the future development of all three of our current product candidates.

Results for the Period

The Group incurred a loss for the year to 31 December 2023 of £6,696,493 (31 December 2022: £3,986,982 loss).

In the year to 31 December 2023 the loss mainly arose from operational expenses pursuing the Group's objectives listed in the Strategic Report on page 10, as well as salaries, consulting and professional fees, and general administration expenses. These expenses have been met from the proceeds of equity placings that were undertaken during the period, as further detailed in the Fundraising section above.

HEMO-CAR-T

The principal objective of HEMO-CAR-T is, as shareholders will know, to provide a new and more effective treatment and potential cure for relapsed and/or refractory acute myeloid leukaemia ("R/R AML").

AML is the most common type of acute leukaemia in adults and has poor survival rates; it is currently treated using chemotherapy, rather than the potentially more benign and effective form of cell therapy being developed by Hemogenyx Pharmaceuticals. The successful development of a new therapy for AML would have a major impact on treatment and survival rates for the disease.

Development work on HEMO-CAR-T was largely completed during 2022 and work in 2023 was mainly devoted to preparing the IND application to the FDA, an essential step before being able to commence clinical trials. The FDA's concern, as shareholders will be aware, is primarily with the safety of a treatment, and it rightly works to a very high standard. The work in preparing the IND application was extremely detailed and resulted in an application document running to over 3,000 pages. It was finally submitted in May 2023. As mentioned above, the FDA was not satisfied with a particular aspect of the detail provided and therefore imposed a clinical hold on the HEMO-CAR-T programme in June. Our scientific team worked on resolving the matter through the latter part of the year and on remanufacturing of the CAR-T components. This resulted in the clinical hold being lifted in January 2024. Although this was a setback, it is important to say that the FDA's concerns were limited to one issue, and we were able to satisfy them much more quickly than many other companies whose prospective treatments were put on clinical hold.

The removal of the clinical hold has enabled us to proceed with taking HEMO-CAR-T into clinical trials with the objective of getting an initial patient injected in the coming months. The Company has been actively putting the necessary pieces in place for some time, including discussions with the Hospital of the University of Pennsylvania, one of the leading cancer treatment hospitals in the US, in order to initiate the clinical trials process.

Also, crucially, in September 2023, Hemogenyx Pharmaceuticals contracted with Infoworks, a well-established and experienced contract research organisation ("CRO"), through a Master Services and Contract Agreement for Infoworks to provide clinical services and technologies for the forthcoming Phase I clinical trials over an initial term of 40 months. An initial work plan was agreed, including clinical site coordination, project management, data management, clinical monitoring, and pharmacovigilance (safety management) services, with the use of InfoWorks' integrated real-time data analytics platform for clinical support and real-time analysis. This vital link brings us Infoworks' operational expertise and will ensure smooth execution of the clinical trials and fast, reliable data to lower our clinical risk and speed up our regulatory timeline.

At the same time, Prevail Partners, the investing affiliate of Infoworks, made the investment at a premium in the Company described more fully in the section headed "Fundraising" above.

Chimeric Bait Receptor

While our Chimeric Bait Receptor ("CBR") was initially envisaged as a potential cure for a very wide range of viral diseases, it has recently become clear that it is also potentially a viable approach for the treatment of a range of cancers. The development of CBR as a cure for viral infections continues, and we remain excited about that, but its potential efficacy against cancer may provide a quicker route to successful development, approval and use.

While we have had limited resources to apply to the development of our proprietary CBR technology platform, there have been a number of key developments and discoveries during the period under review and in the early part of 2024. We have been able to achieve as much as we have done because development of novel CBR constructs is facilitated and accelerated by *in silico* simulations using Artificial Intelligence ("AI") tools and pipelines. In the wake of the COVID-19 pandemic, and in the face of global threats of emerging as well as engineered biological threats, the need for a nimble and proactive solution against future infectious agents became clear. We developed CBR as a novel, highly innovative, and patented immunotherapy initially for COVID-19. However, CBR has been designed to prevent and defeat infection by any known or emerging virus, potentially subverting the next global pandemic, and rendering virally-engineered bioweapons ineffective. To achieve proof of concept, we successfully designed a CBR construct ("CBR-COVID19") to programme macrophages to neutralise the SARS-CoV-2 virus. We have also demonstrated that CBR-COVID19 is insensitive to several known variants of SARS-CoV-2 that make the original SARS-CoV-2 virus more infectious and challenge existing vaccine approaches. We are testing the efficacy of CBR-COVID19 against live infectious replicating SARS-CoV-2 virus in a major Biosafety Level 3 facility.

One of the ultimate threats from emerging viruses, whether natural or man-made, is their uncertainty and unpredictability. Current therapeutic responses require extensive knowledge of the agent(s) as well as time-consuming and duplicative research efforts to develop effective treatments after an outbreak has begun. In this light, our first-in-class CBR platform allows for minimal lead time between first infection or pre-emptive intelligence and first response, providing protection for those on the front line of such a threat at a scale that has thus far not been achieved.

As we announced in February 2024, CBR in relation to viruses is innovative in three ways: it will be an off-the-shelf therapeutic against airborne viral infections, it will be effective against emerging mutations of the targeted viruses, and it will be able to be stored, deployed and administered in the field using a standard atomiser/inhaler. These innovative features have been tested in the laboratory, and the ability of CBR to be delivered intranasally in spray form has been tested by our scientists *in vivo* in small animals. This recent work on the intranasal delivery of CBR is a breakthrough, enabling its development as an off-the-shelf prevention and/or treatment that will be cost-effective and simple to administer, making it ideal for the protection both of the civilian population and in biodefence.

Moving onto cancer-related CBR innovations, we have found that a number of difficult conditions can potentially be treated using CBR. We have established that macrophages programmed with CBR have several potential advantages compared to other existing anti-cancer therapies. Our studies suggest that they can, *inter alia*, penetrate solid tumours, provide a better safety profile for treatment, and potentially cross the blood-brain barrier to target brain cancers and/or certain neurodegenerative diseases.

As announced last November, we have now demonstrated that CBR could be used effectively in the treatment of a number of cancer conditions, in particular that CBR-programmed macrophages show promise for treatment of Non-Hodgkin Lymphoma ("NHL"). Our scientists have demonstrated that human macrophages, a type of immune cells, programmed with a purpose designed CBR, are able to eliminate NHL-derived cells with high efficiency *in vitro*. This result suggests that the Company may be able to develop an efficient treatment for people suffering from relapsed and/or refractory stage III/IV metastasized NHL. Our work also suggests that such CBRs can also be adapted to target several solid tumours such as epithelial ovarian cancer. NHL is the eleventh most common cancer in humans, with a poor rate of recovery and cure from present treatments. There are currently an estimated 540,000 new cases diagnosed globally with an estimated 260,000 deaths per year. The successful

development of a new CBR-related therapy for NHL could have a major impact on treatment and survival rates for the disease.

Our work further suggests that such CBRs can be adapted to target several solid tumours such as epithelial ovarian cancer. We have also begun to see evidence that a CBR-based approach may also potentially be effective against certain neurodegenerative diseases, some of which are currently very difficult or impossible to treat, including possibly Alzheimer's disease. In this regard, in February 2024 we announced a further significant development for CBR, this time in relation to brain cancers and potentially to neurodegenerative diseases. We have established that CBR can be delivered into the brain via programmed microglial cells. Delivery of therapeutics across the blood-brain barrier is one of the most difficult problems in the treatment of brain diseases. Our scientists have developed a means of transplanting human blood stem cells ("HSC") that allows their engraftment and differentiation into immune cells that reside in the brain, carrying out their work *in vivo* in the brains of immune-compromised mice. We believe that HSCs genetically modified to make CBR and transplanted back into a patient would give rise to microglial cells which could potentially find and destroy brain cancer cells.

Meanwhile, we continue to look to our patent position and, in September 2023, our patent application for CBR with the World Intellectual Property Organization was published, though it remains to be approved.

In summary, we should say that the considerable potential breadth and versatility of CBR has become increasingly evident over the past fifteen months, and evidence of its practical viability has been considerably established. It is not too much to say that CBR, which we always considered to have great potential, can now be seen as possibly revolutionary, now that its widespread probable applicability to difficult or presently untreatable conditions is being established in multiple preclinical studies.

CDX bi-specific antibody

CDX remains an important part of the Company's product candidate portfolio, although it remains to a certain extent in abeyance while we push on with HEMO-CAR-T. However, some steps have been taken with CDX, including approval of the patent application in the USA entitled "Method of Eliminating Hematopoietic Stem Cells/Hematopoietic Progenitors (HSC/HP) in a Patient Using Bi-specific Antibodies" as patent No. 11,945,866. This is a significant addition to the patent protection for CDX, which remains one of our key product candidates for the future. It also solidifies the Company's position as a leader in the area of conditioning of patients for bone marrow transplants.

Conclusion

It remains for me to thank the Board and our strong, highly committed group of scientists for their hard and effective work, and to look forward to another successful year in the future development of Hemogenyx Pharmaceuticals in this new phase as a clinical-stage company.

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

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Consolidated Statement of Comprehensive Income

Group - Continuing Operations	**Year Ended 31 December 2023**	Year Ended 31 December 2022
	£	£
Revenue	-	-
Administrative Expenses	**(5,820,165)**	(3,433,476)
Depreciation Expense	**(645,681)**	(564,072)
Operating Loss	**(6,465,846)**	(3,997,548)
Finance Income	**85,344**	10,599
Finance Costs	**(315,991)**	(33)
Loss before Taxation	**(6,696,493)**	(3,986,982)

Income tax	**-**	-
Loss for the year	**(6,696,493)**	(3,986,982)
Loss attributable to:		
- Owners of Hemogenyx Pharmaceuticals plc	**(6,690,678)**	(3,979,314)
- Non-controlling interests	**(5,815)**	(7,668)
	(6,696,493)	(3,986,982)
Items that may be reclassified subsequently to profit or loss:		
Translation of foreign operations	**903,067**	(954,642)
Other comprehensive income for the year	**903,067**	(954,642)
Total comprehensive loss for the year	**(5,793,426)**	(4,941,624)
Attributable to:		
Owners of Hemogenyx Pharmaceuticals plc	**(5,787,611)**	(4,933,956)
Non-controlling interests	**(5,815)**	(7,668)
Total comprehensive loss for the year	**(5,793,426)**	(4,941,624)
Basic and diluted earnings loss per share attributable to the equity owners of the Company	**(0.006)**	(0.005)

Consolidated Statement of Financial Position

Group

	31 December 2023	31 December 2022
Assets	**£**	£
Non-current assets		
Property, plant and equipment	**966,423**	1,023,252
Right of use asset	**2,346,015**	2,892,261
Security deposit	**153,668**	140,821
Intangible asset	**470,173**	441,493
Total non-current assets	**3,936,279**	4,497,827
Current assets		
Trade and other receivables	**922,013**	62,024
Cash and cash equivalents	**1,247,601**	2,532,758
Total current assets	**2,169,614**	2,594,782
Total assets	**6,105,893**	7,092,609
Equity and Liabilities		
Equity attributable to shareholders		
Paid-in Capital		
Called up share capital	**11,755,660**	9,797,493
Share premium	**19,938,556**	16,808,647
Other reserves	**1,164,637**	921,801
Reverse asset acquisition reserve	**(6,157,894)**	(6,157,894)
Foreign currency translation reserve	**(77,496)**	(980,563)
Retained Earnings	**(23,804,734)**	(17,114,056)
Equity attributable to owners of the Company	**2,818,729**	3,275,428
Non-controlling interests	**(37,723)**	(31,908)
Total equity	**2,781,006**	3,243,520
Liabilities		
Non-current liabilities		
Lease liabilities	**2,672,802**	3,100,678
Total non-current liabilities	**2,672,802**	3,100,678
Current liabilities		
Trade and other payables	**379,001**	426,254
Lease liabilities	**273,084**	322,157
Total current liabilities	**652,085**	748,411
Total liabilities	**3,324,887**	3,849,089

Total equity and liabilities	**6,105,893**	7,092,609

Company Statement of Financial Position

Company

	31 December 2023	31 December 2022
	£	£
Assets		
Non-current assets		
Loan to subsidiaries	**18,097,857**	14,451,733
Investment in subsidiary	**8,000,000**	8,000,000
Total non-current assets	**26,097,857**	22,451,733
Current assets		
Trade and other receivables	**14,820**	20,405
Cash and cash equivalents	**219,236**	88,909
Total current assets	**234,056**	109,314
Total assets	**26,331,913**	22,561,047
Equity and Liabilities		
Equity attributable to shareholders		
Foreign currency translation reserve		
Paid-in Capital		
Called up share capital	**11,755,660**	9,797,493
Share premium	**19,938,556**	16,808,647
Other reserves	**1,163,533**	920,697
Retained Earnings	**(6,721,085)**	(5,100,447)
Total Equity	**26,136,664**	22,246,390
Liabilities		
Current liabilities		
Trade and other payables	**195,249**	134,657
Total current liabilities	**195,249**	134,657
Total liabilities	**195,249**	134,657
Total equity and liabilities	**26,331,913**	22,561,047

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 2023 was £1,620,638 (2022: profit of £1,202,014).

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 2022	9,797,493	16,808,647	904,226	(6,157,894)	(25,921)	(13,134,742)	(24,240)	8,167,569
Loss in year	-	-	-	-	-	(3,979,314)	(7,668)	(3,986,982)
Other Comprehensive Income	-	-	-	-	(954,642)	-	-	(954,642)
Total comprehensive income for the year	-	-	-	-	(954,642)	(3,979,314)	(7,668)	(4,941,624)
Extension of options	-	-	17,575	-	-	-	-	17,575
As at 31 December 2022	**9,797,493**	**16,808,647**	**921,801**	**(6,157,894)**	**(980,563)**	**(17,114,056)**	**(31,908)**	**3,243,520**

Loss in year	-	-	-	-	-	**(6,690,678)**	**(5,815)**	**(6,696,493)**
Other Comprehensive Income	-	-	-	-	**903,067**	-	-	**903,067**
Total comprehensive income for the year	-	-	-	-	**903,067**	**(6,690,678)**	**(5,815)**	**(5,793,426)**
Issue of shares	**1,958,167**	**3,296,458**	-	-	-	-	-	**5,254,625**
Cost of capital	-	**(166,549)**	-	-	-	-	-	**(166,549)**
Issue of options	-	-	**242,836**	-	-	-	-	**242,836**
As at 31 December 2023	**11,755,660**	**19,938,556**	**1,164,637**	**(6,157,894)**	**(77,496)**	**(23,804,734)**	**(37,723)**	**2,781,006**

Company Statement of Changes in Equity

Company

	Called up Share Capital £	Share Premium £	Foreign currency translation reserve £	Other reserves £	Retained earnings £	Total Equity £
As at 31 December 2021	9,797,493	16,808,647	-	903,122	(6,302,461)	21,206,801
Income in year	-	-	-	-	1,202,014	1,202,014
Other Comprehensive Income	-	-	-	-	-	-
Total comprehensive income for the year	-	-	-	-	1,202,014	1,202,014
Issue of options	-	-	-	17,575	-	17,575
As at 31 December 2022	**9,797,493**	**16,808,647**	**-**	**920,697**	**(5,100,447)**	**22,426,390**
Loss in year	**-**	**-**	**-**	**-**	**(1,620,638)**	**(1,620,638)**
Other Comprehensive Income	**-**	**-**	**-**	**-**	**-**	**-**
Total comprehensive income for the year	**-**	**-**	**-**	**-**	**(1,620,638)**	**(1,620,638)**
Issue of shares	**1,958,167**	**3,296,458**	**-**	**-**	**-**	**5,254,625**
Cost of capital	**-**	**(166,549)**	**-**	**-**	**-**	**(166,549)**
Issue of options	**-**	**-**	**-**	**242,836**	**-**	**242,836**
As at 31 December 2023	**11,755,660**	**19,938,556**	**-**	**1,163,533**	**(6,721,085)**	**26,136,664**

Consolidated Statement of Cash Flows

Group	**Year Ended 31 December 2023**	Year Ended 31 December 2022
	£	£
Cash flows generated from operating activities		
Loss before income tax	**(6,696,493)**	(3,986,982)
Depreciation	**645,681**	195,246
Other non-cash items	**81**	81
Interest income	**(85,344)**	(10,599)
Interest expense	**315,991**	33
Share based payments	**242,836**	17,575
Changes in right of use asset and lease liability, net	**306,759**	627,515
Foreign exchange gain (loss)	**(1,485)**	12,937
(Decrease)/Increase in trade and other payables	**28,579**	(27,120)
Decrease/(Increase) in trade and other receivables	**4,469**	(2,109)
Decrease/(Increase) in prepaid and deposits	**(866,644)**	271,819

Net cash outflow used in operating activities	**(6,105,570)**	(2,910,604)
Cash flows generated from financing activities		
Proceeds from issuance equity securities, net of issue costs	**5,088,076**	-
Payment of lease liabilities	**(638,765)**	(110,144)
Net cash flow generated from/(used in) financing activities	**4,449,311**	(110,144)
Cash flows generated from investing activities		
Interest income	**85,344**	10,599
Payment of security deposit for lease	**-**	(1,908)
Purchase of property & equipment	**(117,285)**	(428,945)
Net cash flow used in investing activities	**(31,941)**	(420,254)
Net decrease in cash and cash equivalents	**(1,688,200)**	(3,432,002)
Effect of exchange rates on cash	**403,043**	(876,209)
Cash and cash equivalents at the beginning of the year	**2,532,758**	6,840,969
Cash and cash equivalents at the end of the year	**1,247,601**	2,532,758

Company Statement of Cash Flows

Company	**Year Ended 31 December 2023**	Year Ended 31 December 2022
	£	£
Cash flows generated from operating activities		
(Loss)/gain before income tax	**(1,620,638)**	1,202,014
Foreign exchange gain	**910,832**	(1,539,778)
Share based payments	**242,836**	17,575
Increase/(decrease) in trade and other receivables	**5,585**	(4,927)
Increase in trade and other payables	**60,592**	228
Net cash outflow used in operating activities	**(400,793)**	(324,888)
Cash flows generated from financing activities		
Proceeds from issuance of equity securities, net of issue costs	**5,088,076**	-
Net cash flow generated from financing activities	**5,088,076**	-
Cash flows generated from/(used in) investing activities		
Loan (to)/from related parties	**(4,556,312)**	301,421
Net cash flow (used in)/generated from investing activities	**(4,556,312)**	301,421
Net Increase/(decrease) in cash and cash equivalents	**130,971**	(23,467)
Effect of exchange rates on cash	**(644)**	1,131
Cash and cash equivalents at the beginning of the year	**88,909**	111,245
Cash and cash equivalents at the end of the year	**219,236**	88,909

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