



Hemogenyx Pharma Plc - Half-year Report

9/30/2019

RNS Number : 04090

Hemogenyx Pharmaceuticals PLC

30 September 2019

Hemogenyx Pharmaceuticals plc

("Hemogenyx" or "the Company")

Half-year Report

Interim Results for the period ended 30

June 2019

Hemogenyx Pharmaceuticals plc (LSE: HEMO), the Standard Listed biopharmaceutical group developing therapies designed to transform blood disease treatment, announces unaudited interim results for the six months ended 30 June 2019.

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

Key highlights

CDX bi-specific antibodies

- First data results show CDX antibodies can attack and eliminate Acute Myelogenous Leukaemia ("AML") both *in vitro* and *in vivo*

- Continued progress towards the goal of submitting an Investigational New Drug ("IND") application to the US Food and Drug Administration ("FDA") for CDX antibodies
- Preliminary discussions regarding a potential licensing deal are continuing with the global biopharmaceutical company following a Development Agreement announced in May 2018

Humanised mice

- Hemogenyx's wholly owned subsidiary Immugenyx, LLC ("Immugenyx") has developed an Advanced peripheral blood Hematopoietic Chimera ("ApbHC"), a novel type of humanised mouse that presents several advantages over other mouse models
- Collaboration agreement with Janssen Research & Development, LLC ("Janssen"), one of the Janssen Pharmaceutical Companies of Johnson & Johnson, on the development of a model of systemic lupus erythematosus (SLE) is progressing
- Immugenyx is in discussions with potential industry partners to further develop and commercialise the humanised mice platform

Human Postnatal Hemogenic Endothelial Cell ("Hu-PHEC") cell therapy

- Hemogenyx established a wholly owned subsidiary, Hemogenyx-Cell SPRL ("Hemogenyx-Cell") which was incorporated in Belgium on 9 April 2019
- Hemogenyx-Cell is focused on developing Hu-PHEC, a cell replacement product candidate that aims to generate cancer-free, patient-matched blood stem cells after transplantation into the patient
- Hemogenyx-Cell continues to consider non-dilutive funding opportunities in relation to the Hu-PHEC suite of products

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

Commenting on the Outlook for Hemogenyx, Sir Marc Feldmann, Executive Chairman, said:

"The Board is very pleased with the progress being made with the unlocking of additional opportunities for the CDX antibodies, as well as the potential value that can be created through the Company's updated humanised mouse model. The Company is confident that these novel humanised mice will continue to attract the interest of large biopharmaceutical companies and are proving to be the basis of significant collaborations. The Board believes that the Company is well advanced on the planned development steps for its CDX antibodies that were announced at Admission, and we hope to provide further updates to shareholders as we progress. The Company looks forward to the future with confidence."

Interim Management Report

Hemogenyx Pharmaceuticals plc is the holding company for Hemogenyx LLC ("Hemogenyx"), a US based biotechnology company developing therapies to transform bone marrow and blood stem cell transplant procedures. The Company is developing products for the multi-billion dollar bone marrow/haematopoietic stem cell transplant market which could replace chemotherapy and radiation as a means of pre-transplant conditioning and treat several types of leukaemia, as well as addressing the problem of stem cell donor availability and issues around relapse or cell rejection after transplantation.

These products are:

Conditioning product ("CDX antibodies") - CDX bi-specific antibodies which redirect a patient's own immune cells to eliminate unwanted blood stem cells preparing a patient for bone marrow transplantation;

Cell therapy product ("Hu-PHEC") - a cell replacement product using Human Postnatal Hemogenic Endothelial Cells to generate cancer-free, patient-matched blood stem cells after transplant into the patient.

The Company has also developed a platform technology for disease modelling and drug discovery:

Advanced Hematopoietic Chimeras ("AHC") - Hemogenyx has developed a new type of humanised mice to advance the development of its CDX antibodies. The unique properties of the AHC give them a functional human immune system that converts them into a platform technology that is opening up exciting opportunities for the Company. These include disease modelling (blood cancers and severe autoimmune diseases) and pre-clinical testing of novel drugs and treatments. AHC are a source of revenue for the Company via paid collaborations with biopharmaceutical companies and research institutions. In addition, Hemogenyx's wholly owned subsidiary Immugenyx, LLC has developed ApbHC, a novel type of humanised mouse that presents several advantages over other mouse models, as described in further detail in the progress update below. Immugenyx was established by the Company to develop and commercialise the Company's AHC or humanised mice, and the new ApbHC represents a significant further development in that direction.

To date, Hemogenyx has made impressive progress on its products whilst efficiently using the Company's limited financial resources. The main focus is to progress the CDX antibodies to readiness for clinical trials, as well as to continue to develop the Hu-PHEC cell therapy product.

H1 progress update

During the first half of the year, Hemogenyx continued to make progress towards the completion of a development agreement with a global biopharmaceutical company and the goal of submitting an IND (Investigational New Drug) application to the FDA for CDX antibodies.

The Company was able to demonstrate that CDX bi-specific antibodies were capable of attacking and eliminating the blood cancer Acute Myelogenous Leukaemia (AML) *in vivo*, demonstrating that the lead candidate is effective in the treatment of AML. The Company has demonstrated that CDX is capable of conditioning bone marrow transplants in AHC (humanised mice) *in vivo*. The Company hopes to be able to show that CDX bi-specific antibodies are capable of redirecting a patient's own immune cells to eliminate both AML and blood stem cells, preparing a patient with relapsed/refractory AML for bone marrow transplantation. If successful, this product would be able to complement, or possibly replace, traditional methods of chemotherapy and radiation currently used both in AML treatment and conditioning. The Company has also demonstrated that CDX is capable of eliminating a subset of acute lymphoblastic leukaemia (ALL) cells *in vitro*.

The ApbHC was initially developed as a research and development tool for the investigation of mature blood cell populations such as human T-cells, B-cells and antibody-producing plasma cells. The major advantage of the ApbHC compared to other humanised mouse models known to the Directors is the absence of Graft versus Host Disease (GvHD), a disease that complicates and often renders impossible the efficient use of peripheral blood mononuclear cells in transplanted mice. Hemogenyx has demonstrated that the ApbHC can potentially be used for testing multi-specific antibodies, including its own bi-specific CDX antibody for the elimination of acute myeloid leukaemia (AML) and the conditioning of patients for bone marrow transplantation. ApbHC may also be used for the development and testing of new cell therapies involving immune cell reprogramming, such as CAR-T. Immugenyx has further demonstrated that the ApbHC can potentially be used for the modeling of autoimmune diseases, such as Systemic Lupus Erythematosus (aka Lupus), with a goal of developing fundamentally new treatments for those diseases. The Directors also believe that the ApbHC could potentially be used as a tool for the rapid development and/or isolation of human antibodies against unknown human-specific pathogens (biodefence applications).

As with AHC, the Company believes that the ApbHC will be of considerable interest to other drug developers and the initial interest shown is promising.

Hemogenyx has primarily focused attention on the CDX antibody product candidate and humanised mouse model but has also taken clear steps to bring forward its Human Postnatal Hemogenic Endothelial Cell ("Hu-PHEC") based suite of product candidates, including the incorporation of Hemogenyx-Cell in April 2019. Hemogenyx-Cell continues to consider non-dilutive funding opportunities for the development of this promising therapy.

Financial Results

During the six months ended 30 June 2019 the Company recorded a loss of £706,670 (H1 2018: £647,423 loss). The increase in loss from the comparable period in 2018 reflects a continued increase in operational development, and in particular diversification of activities, made possible by the reverse acquisition and fundraising completed in October 2017.

The Company recorded consultancy income of £82,763 during the period ended 30 June 2019 (H1 2018: £91,358) which relates to funds received from a third party under a research collaboration programme associated with humanised mice.

Outlook

Overall the Board is very pleased with the progress being made, in particular the unlocking of opportunities for CDX antibodies, as well as the potential value that can be created through the Company's new type of humanised mice. Hemogenyx is confident that its ApbHC will be of further interest to large biopharmaceutical companies and has the potential to form the basis of significant future collaborations. The Company hopes to update shareholders on progress in this area.

The Board believes that the Company is well-advanced on the planned development steps that were described in the 2018 annual report and it hopes to provide further updates to shareholders as the Company progresses. The Company looks forward to the future with confidence.

Responsibility Statement

We confirm that to the best of our knowledge:

- the Half Year Report has been prepared in accordance with International Accounting Standards 34, Interim Financial Reporting, as adopted by the EU; 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.

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

27 SEPTEMBER 2019

Market Abuse Regulation (MAR) Disclosure

Certain information contained in this announcement would have been deemed inside information for the purposes of Article 7 of Regulation (EU) No 596/2014 until the release of this announcement.

Contacts

Hemogenyx Pharmaceuticals plc

Dr Vladislav Sandler, Chief Executive Officer & Co-Founder

www.hemogenyx.com

headquarters@hemogenyx.com

Sir Marc Feldmann, Chairman

SP Angel Corporate Finance LLP

Matthew Johnson, Vadim Alexandre, Soltan Tagiev

Tel: +44 (0)20 3470 0470

Peterhouse Corporate Finance Limited

Lucy Williams, Duncan Vasey

Tel: +44 (0)20 7469 0930

US Media enquiries

Lowell Goodman

Tel: +1 (323) 646-3249

lowell@corbomitecomms.com

Condensed Consolidated Interim Statement of Comprehensive Loss

For the six months ended 30 June 2019

Continuing Operations	Note	6 months to 30 June 2019 Unaudited £	6 months to 30 June 2018 Unaudited £
Revenue		-	-
Administrative Expenses		759,598	715,474
Depreciation Expense		27,554	24,747
Operating Loss		(787,152)	(740,221)
Other Income	5	82,763	91,358
Interest income		9,220	1,440
Finance Costs		(11,501)	-
Loss before Taxation		(706,670)	(647,423)
Tax credit		-	-
Loss for the period attributable to equity owners		(706,670)	(647,423)
Items that will be reclassified subsequently to profit or loss:			
Translation of foreign operations		(3,137)	20,783
Other Comprehensive income for the year		(709,807)	(626,639)

Total comprehensive income to the year attributable to the equity owners		<u>(709,807)</u>	(626,639)
Basic and diluted earnings (per share)	6	<u>(0.00)</u>	(0.00)

Condensed Consolidated Interim Statement of Financial Position

As at 30 June 2019

	Note	30 June 2019 Unaudited £	Year Ended 31 December 2018 Audited £
<u>Assets</u>			
Non-current assets			
Property, plant and equipment	7	153,712	173,943
Intangible asset		273,759	272,753
Total non-current assets		<u>427,471</u>	446,696
Current assets			
Trade and other receivables		30,844	90,475
Cash and cash equivalents		1,092,702	1,762,428

Total current assets		1,852,903
	1,123,546	
Total assets		2,299,599
	1,551,017	

Equity and Liabilities

Equity attributable to shareholders

Paid-in Capital

Called up share capital	8	3,601,762	3,601,762
Share premium		7,377,925	7,340,267
Other reserves		616,197	620,059
Reverse asset acquisition reserve		(6,157,894)	(6,157,894)
Foreign currency translation reserve		33,910	37,047
Retained Earnings		(5,188,745)	(4,482,075)
		283,155	959,166

Total Equity

Liabilities

Non-current liabilities

Borrowings		1,176,973	1,172,826
Total non-current liabilities		1,176,973	1,172,826

Current liabilities

Trade and other payables		90,889	167,607
Total Current Liabilities		90,889	167,607
Total Liabilities		1,267,862	1,340,433

Total equity and liabilities

2,299,599
1,551,017

The 2018 comparatives are the audited consolidated group for the year ended 31 December, 2018 as published on 29 April 2019.

Condensed Consolidated Interim Statement of Changes in Equity**For the six months ended 30 June 2019**

	Called up Share Capital	Share Premium	Other reserves	Reverse acquisition reserve	Foreign currency translation reserve	Retained losses	Total Equity
	£	£	£	£	£	£	£
As at 1 January 2018	3,600,514	7,341,056	369,147	(6,157,894)	(13,984)	(3,006,982)	2,131,857
Loss in period	-	-	-	-	-	(647,423)	(647,423)
Other Comprehensive Income	-	-	-	-	20,783	-	20,783
Total comprehensive income for the period	-	-	-	-	20,783	(647,423)	(626,640)
Issue of share	-	-	-	-	-	-	-

capital	1,248	3,745	-				4,993
Issue of options (Note 8)	-	-	77,507	-	-	-	77,507
Market value of warrants	-	(4,170)	4,170	-	-	-	-
	3,601,762	7,340,631					
			450,824	(6,157,894)	6,799	(3,654,405)	1,587,717
As at 30 June 2018 (unaudited)							
As at 1 January 2019	3,601,762	7,340,267	620,059	(6,157,894)	37,047	(4,482,075)	959,166
Loss in period	-	-	-	-	-	(706,670)	(706,670)
Other Comprehensive Income	-	-	-	-	(3,137)	-	(3,137)
Total comprehensive income for the period	-	-	-	-	(3,137)	(706,670)	(709,807)
Embedded derivative - Convertible loans	-	-	6,280	-	-	-	6,280
Issue of options (Note 8)	-	-	27,516	-	-	-	27,516
Market value of warrants	-	37,658	(37,658)	-	-	-	-
As at 30 June 2019 (unaudited)	3,601,762	7,377,925	616,197	(6,157,894)	33,910	(5,188,745)	283,155

Condensed Consolidated Interim Statement of Cash Flows

For the six months ended 30 June 2019

Group	Note	6 months to 30 June 2019 Unaudited £	6 months to 30 June 2018 Unaudited £
<u>Cash flows generated from operating activities</u>			
Loss for the period		(706,670)	(647,423)
Depreciation		27,554	24,747
Other non-cash items interest/professional fees (shares issued)		-	-
Foreign exchange gain		(6,920)	-
Interest income		(9,220)	(1,440)
Interest expense		11,501	-
Share based payments	9	27,516	77,507
(Decrease)/increase in trade and other payables		(75,039)	32,276

Decrease/(increase) in trade and other receivables	58,477	(113,430)
Net cash outflow used in operating activities	(672,801)	(627,763)
<u>Cash flows generated from financing activities</u>		
Proceeds from issuance of equity securities	-	4,993
Net cash flow generated from financing activities	-	4,993
<u>Cash flows generated from investing activities</u>		
Interest income	9,220	1,440
Purchase of property, plant & equipment	(7,098)	(24,351)
Net cash flow generated from investing activities	2,122	(22,911)
Net decrease in cash and cash equivalent	(670,679)	(645,681)
Effect of exchange rates on cash	953	11,952
Cash and cash equivalents at the beginning of the period	1,762,428	1,876,655
Cash and cash equivalents at the end of the period	1,092,702	1,242,926

Major non-cash transactions

There were no major non-cash transactions during the period.

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. The products under development are designed to address a range of problems that occur with current standard of care treatments.

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

2. INTERIM FINANCIAL INFORMATION

The condensed consolidated interim financial statements are for the six months period ended 30 June 2019. 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 2018, which were prepared under International Financial Reporting Standards (IFRS) as adopted by the European Union (EU).

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 2018 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 2018 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 financial statements requires an assessment on the validity of the going concern assumption.

The Consolidated Financial Statements have been prepared on a going concern basis. As a pharmaceutical development company, Hemogenyx has a continuing need for funds to take forward its product candidates and to explore any additional projects that may be identified. The Company has a number of discussions in hand which may bring in revenues or non-dilutive funding. However, the Company may in due course need to raise additional capital.

Segmental Reporting

The Group's operations are located in New York, USA and Liège, Belgium, with the head office located in the United Kingdom.

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.

Accounting Policies

The accounting policies applied by the Group in these half-yearly results are the same as those applied by the Group in its consolidated financial information in its 2018 Annual Report and Accounts, with the exception of the new standards the Group adopted as of 1 January 2019, included below.

The same accounting policies, presentation and methods of computation have been followed in these condensed interim financial statements as were applied in the preparation of the Group's annual financial statements for the year ended 31 December 2018 except for the impact of the adoption of the Standards and interpretations described below.

Changes in accounting policy and disclosures

(a) Accounting developments during 2019

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 2019 but did not result in any material changes to the financial statements of the Group.

The following standards were adopted by the Group during the year:

- IFRS 16 - Leases (effective 1 January 2019)
- IFRS 9 (Amendments) - Prepayment features with negative compensation (effective 1 January 2019)
- Annual Improvements 2015-2017 Cycle
- IAS 19 - Plan amendment, curtailment or settlements (effective 1 January 2019)
- IAS 28 - Long term interests in associates and joint ventures (effective 1 January 2019)
- IFRIC 23 - Uncertainty over income tax treatments (effective 1 January 2019)

IFRS 16 became effective for the Group as of 1 January 2019 and was adopted from this date. IFRS 16, which replaces IAS 17, leases, requires the Group to recognise lease liabilities in relation to leases which had previously been classified as 'operating leases' under the principles of the old

standards.

Management has assessed all arrangements which could be considered to contain a lease and assessed the impact of transition to the new standard on the financial statements. There has been no material effect of transition to the Group as there are no material lease arrangements in the Group.

(b) New standards, amendments and interpretations in issue but not yet effective or not yet endorsed and not early adopted

Standard		Effective date
IFRS 3 (Amendments)	Business Combinations	1 January 2020
IAS 1 (Amendments)	Presentation of Financial Statements	1 January 2020
IAS 8 (Amendments)	Accounting policies, Changes in Accounting Estimates	1 January 2020
IFRS 17	Insurance	1 January 2021

* Subject to EU endorsement

The Directors are actively considering the effects upon the financial statements and at the time of approval do not consider that the financial statements will be subject to material changes.

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 2018.

5. OTHER INCOME

Other income of £82,763 during the period ended 30 June 2019 (H1 2018: £91,358) relates to funds received from a third party under a research collaboration programme relating to humanised mice.

6. EARNINGS PER SHARE

The calculation of the Basic and fully diluted earnings per share is calculated by dividing the loss for the six months from continuing operations of £706,670 (six months to 30 June 2018: £647,423) for the Group by the weighted average number of ordinary shares in issue during those periods of 360,176,186 and 360,072,739 respectively.

Dilutive loss per Ordinary Share equals basic loss per Ordinary Share as, due to the losses incurred in the six months to 30 June 2019 and six months to 30 June 2018, there is no dilutive effect from the subsisting share options.

7. PROPERTY, PLANT AND

EQUIPMENT

During the six months ended 30 June 2019, the Group acquired assets with a cost of £7,098 (the six months ended 30 June 2018: £24,351).

8. CALLED UP SHARE CAPITAL

Group	Ordinary shares Number	£
As at 1 January 2018	360,051,358	3,600,514
Issue of shares for exercise of warrants 29 May 2018	124,826	1,248
As at 30 June 2018	360,176,184	3,601,762
As at 1 January 2019	360,176,184	3,601,762
As at 30 June 2019	360,176,184	3,601,762

9. SHARE-BASED PAYMENTS

Options

During the six months to 30 June 2019 no options were issued to directors or employees and no options were cancelled.

A schedule of options granted is below:

	Number options
Employees, including directors	26,725,616
Members of the Scientific Advisory Board	9,346,125
Total	36,071,741

The weighted average fair value of the options granted during the six months ended 30 June 2019 was £Nil (30 June 2018: £0.0086).

There were no options issued for the six months ended 30 June 2019. The following table lists the inputs to the models used for the plan for the six months ended 30 June 2018:

	January 2018 (EMP)	April 2018 (EMP)
Expected volatility %	50.09	45.32
Risk-free interest rate %	0.577	0.918
Expected life of options (years)	2	3
Weighted average exercise price - pence	3.5	3.5
Weighted average share price	2.4	3.2
Expected dividend yield	-	-
Model used	Black Scholes	Black Scholes

For the six months ended 30 June 2019, the Group has recognised £27,516 of share-based payment expense in the statement of profit or loss (30 June 2018: £77,507).

Warrants

The share placement that completed on 4 October 2017 with the issue of 57,142,857 shares at £0.035 carried 1 for 2 warrants for qualifying shareholders over 62,021,429 new ordinary shares at £0.04 per share. In order to qualify for these warrants the shareholder must have retained the shares for a period of 60 days after admission.

A total of 49,361,678 warrants had been issued to eligible IPO participants who had been identified, and of this amount 124,826 warrants had been exercised. The period of time allowed for eligible IPO participants to claim warrants has expired and the 12,659,751 unidentified warrants can no longer be claimed. No value for these unclaimed warrants has been brought to account in the Condensed Consolidated Interim Statement of Financial Position.

10. EVENTS AFTER THE REPORTING PERIOD

There have been no significant events post period end.

This information is provided by RNS, the news service of the London Stock Exchange. RNS is approved by the Financial Conduct Authority to act as a Primary Information Provider in the United Kingdom. Terms and conditions relating to the use and distribution of this information may apply. For further information, please contact rns@lseg.com or visit www.rns.com.

END

IR BXGDCLXDBGCI