

28 September 2022

Cizzle Biotechnology Holdings Plc

("Cizzle", the "Company" or the "Group")

Interim results for the six months ended 30 June 2022

Cizzle Biotechnology Holdings PLC (LSE: CIZ), the UK based diagnostics developer, is pleased to announce its interim results for the six months ended 30 June 2022.

Highlights

- On 14 February 2022 the Group announced a royalty acquisition agreement with Conduit Pharmaceuticals Ltd ("Conduit") and St George Street Capital ("SGSC") to acquire a 5% economic interest in the commercialisation of the AZD1656 asset or such other assets being developed by Conduit or SGSC to treat inflammatory pulmonary and cardiovascular diseases, for a total consideration of £1.88m. The initial consideration of £1m was settled through the issue of 25,000,000 new ordinary shares at a price of 4.0p per share, with the remaining consideration of £880,000 payable in new ordinary shares in the Company issued at 4.0 pence per share, on the sooner of receiving shareholder approval to issue the shares or 14 February 2023.
- Spread the global reach of the Group's technology to both China and the USA, where there is much need for the use of the early detection of lung cancer tests:
 - China: On 8 February 2022 a full commercial agreement was executed to develop and market early lung cancer diagnostic tests in China. This agreement will generate future revenues for the Group via a 10% royalty on the sales of all products and services using its proprietary CIZ1B technology and from payment for monoclonal antibodies and reagents.
 - USA:
 - On 6 May 2022 the Group announced that it had signed a heads of terms to partner with CorePath Laboratories (CorePath), a full service cancer reference laboratory, to develop and offer its proprietary early-stage lung cancer test throughout the USA. The proposal is that the Group would receive a 15% royalty and royalty sharing arrangements on the direct offering of products and services using CIZ1B via CorePath in the USA.
 - On 16 June 2022 a marketing agreement was signed with Behnke Group, USA, to promote, identify and facilitate partnerships for Cizzle with healthcare providers and businesses in the USA.
- On 11 April 2022 a new 12 month research agreement was signed with the University of York, a member of the Russell Group of research-intensive universities and one of the world's premier institutions for inspirational and life-changing research, for the development of potential applications in cancer diagnosis and therapy.

Post Period Highlights

- In July 2022 the Company provided an update on the Company's progress to develop antibodies for use in its proprietary early lung cancer tests, and to announce a new project that may extend the range of early-stage cancers that its technology can detect. The Company reported that it was developing a range of monoclonal antibodies to detect CIZ1B, that additional suppliers have been engaged, and that it has a mouse monoclonal antibody that specifically detects CIZ1B. Assay conditions for its use are now being optimised, and further work is being done to isolate rabbit monoclonals arising from the Company's initial proof of concept studies.

- In August 2022 LanceteClinical Medicine reported the results of SGSC’s Phase 2 clinical trial, ARCADIA. Cizzle has royalty sharing rights for the commercialisation of AZD1656 for COVID-19 and other indications, including inflammatory pulmonary and cardiovascular disease. SGSC is progressing commercial discussions with potential pharmaceutical partners to fund the additional clinical studies required and to bring AZD1656 to the market.
- In September 2022 the Company raised gross proceeds of £500,000 by way of an equity subscription and secured a £500,000 facility to draw down on further funds for a term of 18 months.

Commenting Allan Syms, Chairman of Cizzle Biotechnology, said:

“The Group made significant progress during the first half of 2022 towards meeting its goal to bring to market a simple blood test capable of detecting lung cancer early when clinical intervention can improve patient survival rates. As reported previously, every two minutes someone is diagnosed with cancer in the UK alone and for lung cancer this is compounded by the fact that in its early stage, it can be asymptomatic and remain undetected until the disease has advanced. Our focus is therefore, to develop simple, inexpensive, blood tests for early cancer detection that can help save lives. A number of key milestones were met during the period including development of the key antibodies and reagents for our early-stage cancer test and securing important royalty bearing development and marketing collaborations in the USA and China. We have also extended our research agreement with the University of York to investigate the use of our biomarker in detecting other cancers.*

“Looking forward we have ambitions to expand our target customer base in the pharmaceutical industry through building a portfolio of early cancer detection tests, companion diagnostics and royalty bearing stakes in significant drug assets. In the longer term our technology may have application for screening in doctor’s office testing and In addition, for developing diagnostic products which can be used to identify which patients may prove most likely to respond to new drugs with the least side effect burden to patients. Our partnership with SGSC is important in this regard since our first companion diagnostic will be the delivery of a contracted test for autoimmune disease.

“We were also delighted to announce on 21 September 2022 that we have secured additional funding of up to £1m (before expenses) to continue implementing our strategy. This funding brings in new important shareholders to support our ambitions and I would like to thank our new funders and existing shareholders for their support. I look forward to reporting further progress in due course.”

* <https://www.cancerresearchuk.org/health-professional/cancer-statistics-for-the-uk#heading-Zero>

Executive Chairman’s statement

Operational and strategic overview

Since the completion of the acquisition of Cizzle Biotechnology Ltd (“CBL”) on 14 May 2021 and admission to trading on the London Stock Exchange the Group has focussed on realising and commercialising, through systematic development, CBL’s technology for the early detection of cancer.

Research and Development Progress

Cizzle is developing a blood test for the early detection of lung cancer. Its technology is based on the ability to detect a stable plasma biomarker, a variant of CIZ1 known as CIZ1B. CIZ1 is a naturally occurring cell nuclear protein involved in DNA replication, and the targeted CIZ1B variant is highly correlated with early-stage lung cancer.

During 2021 the Company announced a collaboration with FairJourney Biologics (“FJB”) for the development and supply of proprietary key monoclonal antibodies and other detector proteins that are required for developing an enzyme-linked immunosorbent assay (sandwich “ELISA”). Since that time the Company has significantly increased its knowledge on reagent performance and assay formats and is pleased to report that monoclonal reporter antibodies have been successfully produced by FJB.

On 11 April 2022 a new 12 month research agreement was signed with the University of York, a member of the Russell Group of research-intensive universities and one of the world's premier institutions for inspirational and life-changing research, for the development of potential applications in cancer diagnosis and therapy. This new agreement, commencing for a period of 12 months from 25 June 2022, follows the successful programme announced on 17 September 2021 for the development and validation of molecular tools with potential application in cancer diagnosis or therapy, and their configuration into assays for Cizzle's proprietary cancer biomarker variants. Cizzle will own all intellectual property rights arising from the work which strengthens the Company's position in creating new solutions for early cancer diagnostics and therapeutic tools.

In July 2022 the Company provided an update on the Company's progress to develop antibodies for use in its proprietary early lung cancer tests, and to announce a new project that may extend the range of early-stage cancers that its technology can detect. The Company reported that it was developing a range of monoclonal antibodies to detect CIZ1B, that additional suppliers have been engaged, and that it has a mouse monoclonal antibody that specifically detects CIZ1B. Assay conditions for its use are now being optimised, and further work is being done to isolate rabbit monoclonals arising from the Company's initial proof of concept studies.

Development of new future revenue stream

On 14 February 2022 the Group announced a royalty acquisition agreement with Conduit and SGSC to acquire a 5% economic interest in the commercialisation of the AZD1656 asset or such other assets being developed by Conduit or SGSC to treat inflammatory pulmonary and cardiovascular disease, for total consideration of £1.88m. The initial consideration of £1m was settled through the issue of 25,000,000 new ordinary shares at a price of 4.0p per share, with the remaining consideration of £0.88m payable in new ordinary shares at 4.0p per share, on the sooner of receiving shareholder approval to issue the shares or 14 February 2022.

Prior to this in September 2021 the Group entered into a royalty sharing agreement with SGSC to grant the Group potential royalty payments from the commercialisation of SGSC's therapeutic asset AZD1656 of up to £5m, plus potentially further payments from the use of a companion diagnostic. During 2021 the Group paid a total of £0.2m for this investment.

Reaching Global Markets

During the six months to 30 June 2022 the Company extended its global reach of the Group's technology to both China and the USA, where there is much need for the use of the early detection of lung cancer tests:

- China: On 8 February 2022 a full commercial agreement was executed to develop and market early lung cancer diagnostic tests in China. This agreement will generate future revenues for the Group via a 10% royalty on the sales of all products and services using its proprietary CIZ1B technology and from payment for monoclonal antibodies and reagents.
- USA:
 - On 6 May 2022 the Group announced that it had signed a heads of terms to partner with CorePath Laboratories (CorePath), a full service cancer reference laboratory, to develop and offer its proprietary early-stage lung cancer test throughout the USA. The proposal is that the Group would receive a 15% royalty and royalty sharing arrangements on the direct offering of products and services using CIZ1B via CorePath in the USA.
 - On 16 June 2022 a marketing agreement was signed with Behnke Group, USA, to promote , identify and facilitate partnerships for Cizzle with healthcare providers and businesses in the USA.

Funding

Post period end, in September 2022 the Company completed a fund raising providing gross proceeds of £500,000 by way of a subscription for its shares and secured a £500,000 facility to draw down on further funds for a term of 18

months, if required. The funds will be used to provide working capital for the Company and to continue development of a laboratory-developed test (“LDT”) accredited service for the early detection of lung cancer and taking the Company’s proprietary CIZ1B biomarker blood test through to UKCA, CE marking and/or FDA 510(k) clearance.

Financial overview

During the six months ended 30 June 2022, the Company continued its focus on being a healthcare diagnostics developer. The Group consists of Cizzle Biotechnology Holdings PLC as the parent company with wholly owned subsidiaries, Cizzle Biotechnology Ltd (“CBL”) and Cizzle Biotech Ltd (formerly Enfis Ltd). The current Group structure was formed when the Company completed the acquisition of CBL on 14 May 2021 and was admitted to trading on the standard list of the London Stock Exchange.

The financial results for the six months to 30 June 2022 are summarised as follows:

- Corporate expenses, before exceptional items: £345,000 (H1 2021: £119,000).
- Exceptional corporate expenses relating to a share option charge: £70,000 (H1 2021: £Nil)
- Taxation credit: £25,000 (H1 2021: £Nil)
- Total comprehensive loss in H1 2021: £390,000 (H1 2021, Loss £3,238,000).
- Loss per share in H1 2021: (1.43)p, (H1 2021, Loss of (3.79)p).
- Cash balances as at 30 June 2022: £444,000 (30 June 2021 CBL: £1,425,000).

Responsibility Statement

We confirm that to the best of our knowledge:

- the interim financial statements have been prepared in accordance with International Accounting Standards 34, Interim Financial Reporting;
- give a true and fair view of the assets, liabilities, financial position and loss of the Company;
- the Interim 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 Interim 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 interim report was approved by the Board of Directors and the above responsibility statement was signed on its behalf by Allan Syms on 27 September 2022.

Enquiries:

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About Cizzle Biotechnology

Cizzle Biotechnology is developing a blood test for the early detection of lung cancer. Cizzle Biotechnology is a spin-out from the University of York, founded in 2006 around the work of Professor Coverley and colleagues. Its proof-of-concept prototype test is based on the ability to detect a stable plasma biomarker, a variant of CIZ1 known as CIZ1B. CIZ1 is a naturally occurring cell nuclear protein involved in DNA replication, and the targeted CIZ1B variant is highly correlated with early-stage lung cancer.

For more information please see <https://cizzlebiotechnology.com>

You can also follow the Company through its twitter account @CizzlePlc and on LinkedIn.

Consolidated Statement of Comprehensive Income

For the six months ended 30 June 2022

	Notes	Group Six months ended 30 June 2022 Unaudited £'000	Group Six months ended 2021 Unaudited £'000	Group Year ended 31 December 2021 Audited £'000
Revenue		-	-	-
Cost of Sales		-	-	-
Gross Profit		-	-	-
Administrative Expenses				
-on going administrative expenses		(345)	(119)	(552)
-share option charge		(70)	-	(299)
- IPO transaction costs		-	(304)	(303)
-reverse acquisition expenses		-	(2,815)	(2,804)
Total administrative expenses including exceptional items		(415)	(3,238)	(3,958)
Operating (Loss) and (loss) before income tax		(415)	(3,238)	(3,958)
Income tax	3	25	-	37
(Loss) and total comprehensive income for the period attributable to the equity shareholders of the parent		(390)	(3,238)	(3,921)
Earnings per share (Loss)- basic and diluted - pence	4	(1.43)p	(3.79)p	(2.4)p

**Consolidated Statement of Financial Position
as at 30 June 2022**

	Group 30 June 2022 Unaudited £'000	Group 30 June 2021 Unaudited £'000	Group 31 December 2021 Audited £'000
Non-Current Assets			
Intangible asset	2,080	-	200
Total Non-Current Assets	2,080	-	200
Current Assets			
Trade and other receivables	87	99	80
Cash and cash equivalents	444	1,425	875
Total Current Assets	531	1,524	955
Total Assets	2,611	1,524	1,155
Equity			
Ordinary shares	3,495	3,493	3,493
Share premium	33,564	31,521	32,566
Share capital reduction reserve	10,081	10,081	10,081
Share option reserve	405	13	335
Shares to be issued – deferred consideration	880	-	-
Reverse acquisition reserve	(40,021)	(38,953)	(40,021)
Retained losses	(5,907)	(4,833)	(5,517)
Total equity	2,497	1,322	937
Liabilities			
Current liabilities			
Trade and other payables	114	202	218
Total current liabilities	114	202	218
Total equity and liabilities	2,611	1,524	1,155

Consolidated Statement of Cash Flows
For the six months ended 30 June 2022

	Group 6 Months ended 30 June 2022 Unaudited £'000	Group 6 Months ended 30 June 2021 Unaudited £'000	Group Year ended 31 December 2021 Audited £'000
Cash flow from operating activities			
Operating (loss) before tax	(415)	(3,238)	(3,958)
Adjustment for:			
Reverse acquisition share based expense	-	2,815	2,804
Share option charge	70	-	299
Transaction costs settled through share issue	-	-	32
Share based payment to former director	-	-	11
Operating cash flow before working capital movements	(345)	(423)	(812)
Decrease / increase in trade and other receivable	18	(49)	7
(Decrease) / increase in trade and other payables	(104)	(116)	(204)
Net cash used in operating activities	(431)	(588)	(1,009)
Cash flow from investing activities			
Cash acquired in acquisition of subsidiary	-	46	46
Purchase of investment in intangible assets	-	-	(200)
Net cash inflow / (outflow) from investing activities	-	46	(154)
Cash flow from financing activities			
Proceeds from the issue of ordinary shares (net of issue costs)		1,970	2,041
Borrowings repaid	-	(10)	(10)
Net cash (outflow) / inflow from financing activities	-	1,960	2,031
Net increase/ (decrease) in cash and cash equivalents	(431)	1,418	868
Cash and cash equivalents at the start of the period	875	7	7
Cash and cash equivalents at the end of the period	444	1,425	875

At 1 January 2021	3	1,585	-	-	-	(1,596)	(8)
Issue of shares	-	11	-	-	-	-	11
Transfer to reverse acquisition reserve	(3)	(1,596)	-	-	1,599	-	-
Recognition of plc equity at acquisition date	3,470	8,852	10,081	-	(22,621)	-	(218)
Issue of shares for acquisition of subsidiary	21	21,679	-	-	(21,803)	-	(103)
Reverse acquisition expense	-	-	-	-	2,804	-	2,804
Issue of shares for cash	2	2,198	-	-	-	-	2,200
Issue of shares in settlement of fees	-	32	-	-	-	-	32
Issue of warrants	-	(36)	-	36	-	-	-
Cost of share issue	-	(159)	-	-	-	-	(159)
Share option charge	-	-	-	299	-	-	299
	3,493	32,566	10,081	335	(40,021)	(1,596)	4,858
Comprehensive Loss for the year	-	-	-	-	-	(3,921)	(3,921)
At 31 December 2021	3,493	32,566	10,081	335	(40,021)	(5,517)	937

Notes to the financial statements

For the six months ended 30 June 2022 (unaudited)

1. Basis of preparation

These condensed interim financial statements have been prepared in accordance with IAS 34 – Interim Financial Reporting using the recognition and measurement principles of UK-adopted International Accounting Standards and should be read in conjunction with the audited consolidated financial statements of the Group for the year ended 31 December 2021.

The principal accounting policies used in preparing these condensed interim financial statements are those expected to apply to the Group's Consolidated Financial Statements for the year ending 31 December 2022.

The results for the six-months ended 30 June 2022 are the Group results.

The financial information for the six months ended 30 June 2022 is unaudited and does not constitute statutory financial statements for those periods. The financial information for the year ended 31 December 2021 has been extracted from the audited financial statements for this period. The financial information has been prepared in accordance with accounting policies consistent with those set out in the Group financial statements for the year ended 31 December 2021.

2. Continuing and discontinued operations

The Group is considered to have one class of business which is focused on the early detection of lung cancer via the development of an immunoassay test for the CIZ1B biomarker.

3. Income Tax

The Income tax credit of £25,000 for the six months ended 30 June 2022 relates to an accrual for the recovery of tax on research and development expenditure. There was no income tax for the Group for the six months ended 30 June 2021 and an income tax credit of £37,000 for the year ended 31 December 2021.

4. Earnings per share

	Group 6 months ended 30 June 2022	Group 6 months ended 30 June 2021	Group Year ended 31 December 2021
Basic loss per share:			
Total comprehensive (loss) - £'000	£(390)	£(3,238)	£(3,921)
Weighted number of Ordinary Shares – '000	271,956	85,448	160,516
(Loss) per share - operations - pence	(1.43p)	(3.79p)	(2.4p)

As the Group result for the six months ended 30 June 2022, 30 June 2021 and year ended 31 December 2021 is a loss, any exercise of share options or warrants would have an anti-dilutive effect on earnings per share. Consequently earnings per share and diluted earnings per share are the same, as potentially dilutive share options have been excluded from the calculation.

5. Copies of Interim Report

Copies of this interim report are available upon request to members of the public from the Company Secretary, SGH Company Secretaries Limited, 6th Floor, 60 Gracechurch Street, London, EC3V 0HR. This interim report can also be viewed on the Group's website: <https://cizzlebiotechnology.com>.