

30 September 2024

**Cizzle Biotechnology Holdings Plc**

("Cizzle", the "Company" or together with its subsidiaries the "Group")

**Interim results for the six months ended 30 June 2024**

Cizzle Biotechnology Holdings PLC (LSE: CIZ), the UK based healthcare diagnostics developer, is pleased to announce its unaudited interim results for the six months ended 30 June 2024.

**Highlights**

- **March 2024 Fundraising:** The Company successfully raised approximately £0.62 million through an equity placing. These funds will be used by the Group to finalise its first commercial test for detecting CIZ1B, to strengthen its intellectual property, advance its research with the University of York, and support general corporate activities.
- **North America Partnership:** On 2 April 2024, the Group entered into a Strategic Licencing and Partnership Memorandum of Understanding for North America with Cizzle Bio Inc. ("BIO"). Its proprietary CIZ1B biomarker test has subsequently been selected for a major study at a leading US cancer centre. Cizzle received an up-front payment of US 100,000 as a non-refundable fee to grant BIO an exclusive negotiating period from the signing of a memorandum of understanding on 1 April 2024 ("MoU").
- **Research Agreement Extension:** The Group's research agreement with the University of York was extended until July 2025.
- **Financial results:** Loss for the period of £1,411,000 (H1 2023: Loss £457,000), includes a £1,081,000 (H1 2023: £Nil) fair value loss on a financial asset. This being a non-cash item, the Group's net cash used in operating activities (which excludes proceeds from the issue of ordinary shares) was £238,000 (H1 2023: £327,000).

**Post Period Highlights**

- **Partnership with BBI Solutions** In July 2024 the Group announced a strategic agreement with BBI Solutions, the world's largest independent producer of immunodiagnostic reagents, for the supply of monoclonal antibodies. This partnership is a significant step toward commercialising Cizzle's cost-effective biomarker test for early-stage lung cancer detection.
- **Update on Strategic Licensing Partnership in North America** On 25 July 2024, Cizzle agreed a 60-day extension with BIO for the completion of the binding legal agreement as envisaged under the MoU, to enable BIO to complete on additional strategic investment.
- **Moffitt Cancer Center Collaboration** On 9 September 2024, the Group was selected by Moffitt Cancer Center ("Moffitt"), Florida's leading cancer hospital, to test patients with suspicious lung nodules in a clinical evaluation using the Group's proprietary CIZ1B biomarker assay. This will be the first time that suspected lung cancer patients will be tested for the CIZ1B Biomarker as part of a major clinical evaluation.

**Commenting Allan Syms, Chairman of Cizzle Biotechnology, said:**

*"Throughout 2024, the Group has made significant progress in developing its blood test to help in the early detection of lung cancer through (i) the manufacturing of its core antibodies with BBI Solutions in their ISO 13485-certified facilities; (ii) the industrial collaboration with an industry leading laboratory instrumentation*

ISO 13485 certified facilities; (ii) the industrial collaboration with an industry leading laboratory instrumentation partner; and (iii) being selected by the number one cancer centre in Florida to conduct a clinical evaluation of our biomarker for their patients presenting with suspicious lung nodules. Furthermore, the establishment of a partnership with BIO has now moved the business into the commercial phase of bringing our non-invasive, cost effective CIZ1B biomarker lung cancer blood test to market. Not only does this mark the achievement of our planned major milestones targeting full product launch in April 2025, but also makes our goal of helping detect lung cancer early and thereby proving a valuable new means for early intervention and ultimately helping save lives. The partnership with BIO is expected to be completed shortly giving us the potential for a significant guaranteed royalty deal in North America."

## **Executive Chairman's Statement**

### *Operational and strategic overview*

Cizzle has focussed on the systematic development and commercialisation of novel and proprietary clinical diagnostic tests for the early detection of cancer particularly where there is an unmet clinical need. It is widely considered that to beat cancer, early detection and diagnosis is arguably the single most important and impactful objective we can have. Patients diagnosed early have the best chance of curative treatment and long-term survival reducing patient stress and improving healthcare economic performance.

The Group's platform 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. Since the Group's admission to the London Stock Exchange in 2021, it has invested in the development of its technology to now enable its full commercialisation through a global licensing and partnership strategy.

With the commercial manufacture of CIZ1B monoclonal antibodies underway, optimisation of the laboratory platform for the test, collaboration with a major US cancer hospital and entering shortly into a guaranteed royalty bearing partnership in the USA, the Group anticipates its proprietary technology will be available for sale in April 2025.

### *Research and Development Progress*

Based on the original published research by Professor Coverley and her team at the University of York, it has been shown that CIZ1B can be measured with high sensitivity that should allow for non-intrusive, cost effective testing in a high-throughput, hospital-friendly format and in the future a rapid point of care test for use in doctors' offices and pharmacies. During the period, Cizzle continued to support its research agreement and collaboration with the University of York which has been extended to July 2025, and to work with external expert partners and suppliers to develop and supply of proprietary key monoclonal antibodies and other detector proteins for its assay platform.

Following the successful generation of new proprietary monoclonal antibodies which are the central component of the tests to detect the presence of the CIZ1B biomarker, the Company announced on 18 July 2024 that it had ordered its first batch of antibodies from BBI Solutions ("BBI"), the world's largest independent producer of immunodiagnostic reagents. The initial order is being manufactured at BBI's ISO 13485-certified facilities and are expected to support up to 5,000 assays, including the Moffat Cancer Centre programme, marking a significant inflection point for the Company as it moves from research and development into commercial manufacture and commencement of the use of Cizzle's technology for testing patients in cancer clinics.

### *Licensing Strategy and Commercial Progress*

The Company operates a global licensing and partnership strategy because the directors believe this is the fastest and most cost-effective means to bring its technology to market. For product solutions, this aims to leverage partners expertise and pre-existing high throughput platforms to accelerate deployment and installation of laboratory testing. Expansion into different geographies aims to maximise speed and scale of market entry through specialist licensing partners that provide expert clinical and commercial teams based in territory that fund all clinical and commercial activities thereby preserving shareholder funds to focus on next generation products such as point of care tests and the detection of a wider range of cancers. Wherever possible we seek up-front fees, guaranteed royalty income and other benefits where appropriate.

On 19 Sep 2023 the Company announced it had successfully completed an evaluation programme aimed at

assessing the feasibility of using the Simple Western platform from ProteinSimple for high throughput detection of the CIZ1B cancer biomarker. ProteinSimple is part of Bio-Techne Corporation, a NASDAQ Tech listed company. The Company has continued to optimise that platform to make it suitable for use in laboratories accredited by the College of American Pathology Pathologists (CAP) with Clinical Laboratory Improvement Amendments (CLIA) certification.

With commercial antibodies in production and continuing the programme with BioTechne, the Company was pleased to announce on 2 April 2024 that it had signed a Memorandum of Understanding ("MoU") with a new business, funded by high-net worth individuals as an exclusive licensing partner for the USA and Canada. To align the interests of the two businesses, the US entity was named Cizzle Bio. The Company received a non-refundable upfront fee of US 100,000 and following the completion of the binding legal agreement, an initial up front royalty of US 300,000 is payable to Cizzle. Thereafter a royalty of 10% will be paid on revenues using the Company's technology, guaranteed by sequential minimum US 1 million payments on the 15<sup>th</sup> and 30<sup>th</sup> month anniversaries. The Company will also benefit in a 10% equity stake for no cash consideration.

BIO expects to register its first US CLIA accredited lab with the FDA (US Food and Drug Administration) for the CIZ1B Laboratory Developed Test (LDT) shortly after completing the licensing agreement and then plans to achieve CLIA Certification for the LDT test in November 2024, with insurer reimbursement code achievement and full product launch April 2025.

Since signing the MOU, BIO has been making significant progress in promoting the CIZ1B biomarker test and building relationships with clinicians and hospitals across the USA. The extensive network being generated by BIO and following scientific review, the Group announced on 9 September 2024 that it had been selected by Moffitt, to test patients with suspicious lung nodules in a clinical evaluation using the Group's proprietary CIZ1B biomarker assay. This is a significant development given the project will be carried out in the real-world setting of a busy comprehensive cancer centre with a large lung cancer practice and a high volume, well-organized clinical thoracic research program.

As part of Moffitt's Phase 2 programme, "Using Biomarkers for Diagnosis, Risk Stratification of Post-treatment Recurrence and Long Term Survival of Lung Cancer" ("the programme"), the Company will for the first time be analysing patient blood samples to determine biomarker accuracy in predicting whether or not a nodule is likely to be cancer. The programme is a large observational prospective study in patients with suspicious indeterminate (undiagnosed) lung nodules seen in the Lung Cancer Early Detection (LEAD) Center Lung Nodule Clinic, led by its Director Dr. Lary Robinson. The study follows US recommended guidelines and will be using the first batch of the Company's new commercial monoclonal antibody, to provide new sensitivity and specificity data of the CIZ1B biomarker blood test in the diagnosis of early-stage lung cancer in people with indeterminate lung nodules. The blood sample tests for CIZ1B will be conducted in Professor Dawn Coverley's laboratory at the University of York.

Moffitt note that of the low number of lung cancer patients surviving long term, most are early-stage patients who had surgical resection. Unfortunately, with current screening using low dose chest CT scans ("LDCT"), only 17% are found with localized, potentially curable disease. And although LDCT is an effective tool in high-risk populations, only 3.9% of eligible people obtain a scan. Developing a high sensitivity (>90%) and high specificity (>90%) blood-based biomarker would greatly facilitate the evaluation of the 1.6 million new lung nodules found yearly on CT scans in the U.S., differentiating malignant from benign nodules. The study also recognises that a highly sensitive and specific biomarker potentially could be employed for initial lung cancer screening with just a blood test at the primary care physicians' office .

BIO expect to announce further clinical evaluations with additional major US cancer centres and clinics this year, to be conducted in their growing network of CAP and CLIA laboratories.

The Group already has a further licensing deal in China which is being progressed as the supply of the Company's commercial antibodies increases. The programme will commence after the first laboratory in the US has achieved CLIA accreditation.

### *Funding*

In April 2024 the Company successfully raised approximately £0.62 million through an equity placing, as announced on 26 March 2024. The funds will be utilised towards completing the Company's first proposed

commercial test to detect CIZ1B which will be used in the US through our partnership with BIO and planned for full release in April 2025, to further protect the Company's Intellectual Property, progress the Company's research with the University of York and for general corporate purposes. The Company also terminated the £500,000 loan facility agreement with E3 Fund SP that was entered into in 2022 and had not been drawn down. In May 2024 the Company received £78,000 in respect of a non-refundable fee to grant Cizzle Bio an exclusivity period to negotiate a licensing deal to Cizzle Bio throughout the USA and Canada.

#### *Financial overview*

During the six months ended 30 June 2024, the Company continued its focus on being a healthcare diagnostics developer.

The financial results for the six months to 30 June 2024 are summarised as follows:

- Other income and interest receivable: £79,000 (H1: £Nil)
- Corporate expenses, before exceptional items: £299,000 (H1 2023: £342,000).
- Non-cash administrative expenses relating to:
  - Share option charge: £120,000 (H1 2023: £115,000)
  - Net fair value loss on financial asset: £1,081,000 (H1 2023: £Nil)
- Taxation credit: £10,000 (H1 2023: £26,000)
- Total comprehensive loss of £1,411,000 (H1 2023, Loss £431,000).
- Loss per share 0.37p, (H1 2023, Loss of 0.12p).
- Cash balances as at 30 June 2024: £484,000 (30 June 2023: £451,000).

#### *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 29 September 2024.

\*<https://www.cancerresearchuk.org/funding-for-researchers/research-opportunities-in-early-detection-and-diagnosis/early-detection-and-diagnosis-roadmap>

#### **Enquiries:**

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#### **About Cizzle Biotechnology**

Cizzle is developing a blood test to help in the early detection of lung cancer. Based on the pioneering work of Professor Coverley and colleagues, at the University of York, on a naturally occurring cell nuclear protein

involved in DNA replication called CIZ1, they discovered that a variant called CIZ1B is highly associated with the presence of early-stage cancer. The Company has now entered into commercial royalty bearing licensing agreements and collaborations with leading centres of excellence in cancer for the use of its proprietary technology as part of its strategy to bring its non-intrusive, cost effective blood test to market. Cizzle was admitted to the Standard List of the main market of the London Stock Exchange in May 2021.

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

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

## Condensed Consolidated Statement of Comprehensive Income

For the six months ended 30 June 2024

		Group Six months ended 30 June 2024 Unaudited £'000	Group Six months ended 30 June 2023 Unaudited £'000	Group Year ended 31 December 2023 Audited £'000
Notes				
<b>Revenue</b>		-	-	-
Cost of Sales		-	-	-
<b>Gross Profit</b>		-	-	-
Other income		78	-	-
Interest receivable		1	-	-
Administrative Expenses				
-on-going administrative expenses		(299)	(342)	(669)
-cost associated with put option		-	-	(120)
-share option charge		(120)	(115)	(307)
-gain on transfer of intangible asset		-	-	44
-net fair value loss on financial asset measured at fair value through profit or loss		(1,081)	-	(711)
Total administrative expenses including exceptional items		(1,500)	(457)	(1,763)
<b>Operating Loss and loss before income tax</b>		(1,421)	(457)	(1,763)
<b>Income tax</b>	3	10	26	46
<b>Loss and total comprehensive income for the period attributable to the equity shareholders of the parent</b>		(1,411)	(431)	(1,717)
<b>Earnings per share Loss- basic and diluted - pence</b>	4	(0.37)p	(0.12)p	(0.5)p

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

		Group 30 June 2024 Unaudited £'000	Group 30 June 2023 Unaudited £'000	Group 31 Dec 2023 Audited £'000
Notes				
<b>Non-Current Assets</b>				

Intangible asset	-	2,080	-	
<b>Total Non-Current Assets</b>	-	2,080	-	
<b>Current Assets</b>				
Investment held at fair value through profit or loss	5	332	-	1,413
Trade and other receivables		107	223	136
Cash and cash equivalents		484	451	144
<b>Total Current Assets</b>		923	674	1,693
<b>Total Assets</b>		923	2,754	1,693
<b>Equity</b>				
Ordinary shares		3,507	3,504	3,504
Share premium		35,910	35,330	35,335
Share capital reduction reserve		10,081	10,081	10,081
Share option reserve		598	314	478
Reverse acquisition reserve		(40,021)	(40,021)	(40,021)
Retained losses		(9,281)	(6,584)	(7,870)
<b>Total equity</b>		794	2,624	1,507
<b>Liabilities</b>				
<b>Current liabilities</b>				
Trade and other payables		129	130	186
<b>Total current liabilities</b>		129	130	186
<b>Total equity and liabilities</b>		923	2,754	1,693

**Condensed Consolidated Statement of Cash Flows**  
**For the six months ended 30 June 2024**

	Group 6 Months ended 30 June 2024 Unaudited £'000	Group 6 Months ended 30 June 2023 Unaudited £'000	Group 12 Months ended 31 Dec 2023 Unaudited £'000
<b>Cash flow from operating activities</b>			
Operating loss before tax	(1,421)	(457)	(1,763)
Adjustment for:			
Movement on put option	-	-	120
Gain on transfer of intangible asset	-	-	(44)
Net fair value loss on financial assets measured at fair value through profit or loss	1,081	-	711
Share option charge	120	115	307
Operating cash flow before working capital movements	(220)	(342)	(669)
(Increase) / Decrease in trade and other receivable	(9)	30	(24)
Increase / (Decrease) in trade and other payables	(55)	(15)	13
<b>Cash used in operations</b>	<b>(284)</b>	<b>(327)</b>	<b>(680)</b>
<b>Tax received</b>	<b>46</b>	<b>-</b>	<b>41</b>
<b>Net cash used in operating activities</b>	<b>(238)</b>	<b>(327)</b>	<b>(639)</b>
<b>Cash flow from financing activities</b>			
Proceeds from the issue of ordinary shares (net of issue costs)	578	300	305
<b>Net cash inflow from financing activities</b>	<b>578</b>	<b>300</b>	<b>305</b>
<b>Net increase / (decrease) in cash and cash equivalents</b>	<b>340</b>	<b>(27)</b>	<b>(334)</b>

Cash and cash equivalents at the start of the period	144	4/8	4/8
Cash and cash equivalents at the end of the period	484	451	144

**Condensed Consolidated Statement of Changes in Equity**  
**For the six months ended 30 June 2024 (unaudited)**

Group	Ordinary Share Capital £'000	Share Premium £'000	Capital Redemption Reserve £'000	Share Option Reserve £'000	Reverse Acquisition Reserve £'000	Retained Losses £'000	Total £'000
At 1 January 2024	3,504	35,335	10,081	478	(40,021)	(7,870)	1,507
Issue of shares for cash	3	648	-	-	-	-	651
Share issue costs	-	(73)	-	-	-	-	(73)
Share option charge	-	-	-	120	-	-	120
Total transactions with owners	3	575	-	120	-	-	698
Comprehensive Loss for the Period	-	-	-	-	-	(1,411)	(1,411)
At 30 June 2024	3,507	35,910	10,081	598	(40,021)	(9,281)	794

**For the six months ended 30 June 2023 (unaudited)**

Group	Ordinary Share Capital £'000	Share Premium £'000	Capital Redemption Reserve £'000	Share Option Reserve £'000	Shares to be issued £'000	Reverse Acquisition Reserve £'000	Retained Losses £'000	Total £'000
At 1 January 2023	3,502	34,917	10,081	199	115	(40,021)	(6,153)	2,640
Issue of shares for cash	2	465	-	-	(115)	-	-	352
Share issue costs	-	(52)	-	-	-	-	-	(52)
Share option charge	-	-	-	115	-	-	-	115
Total transactions with owners	2	413	-	115	(115)	-	-	415
Comprehensive Loss for the Period	-	-	-	-	-	-	(431)	(431)
At 30 June 2023	3,504	35,330	10,081	314	-	(40,021)	(6,584)	2,624

**Condensed Consolidated Statement of Changes in Equity (continued)**

**For the year ended 31 December 2023 (Audited)**

Group	Ordinary Share Capital £'000	Share Premium £'000	Shares to be issued £'000	Capital Redemption Reserve £'000	Share Option Reserve £'000	Reverse Acquisition Reserve £'000	Retained Losses £'000	Total £'000
At 1 January 2023	3,502	34,917	115	10,081	199	(40,021)	(6,153)	2,640

Registration of shares to be issued	-	115	(115)	-	-	-	-	-
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Issue of shares for cash	2	348	-	-	-	-	-	350
Costs of share issue	-	(45)	-	-	-	-	-	(45)
Share option charge	-	-	-	-	279	-	-	279
Total transactions with owners	2	418	(115)	-	279	-	-	584
Comprehensive Loss for the year	-	-	-	-	-	-	(1,717)	(1,717)
At 31 December 2023	3,504	35,335	-	10,081	478	(40,021)	(7,870)	1,507

## Notes to the financial statements

### For the six months ended 30 June 2024 (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 2023. The interim report does not include all of the notes of the type normally included in an annual financial report. Accordingly, this report is to be read in conjunction with the annual report for the year ended 31 December 2023, which has been prepared in accordance with UK-adopted international accounting standards and the requirements of the Companies Act 2006, and any public announcements made by the Company during the interim reporting period.

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 2024. The results for the six-months ended 30 June 2024 are the Group results. The financial information for the six months ended 30 June 2024 is unaudited and does not constitute statutory financial statements for those periods. The financial information for the year ended 31 December 2023 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 2023.

##### 1.1. Going concern

The interims financial statements have been prepared on a going concern basis which the directors consider to be appropriate as the directors are confident that the Group and Company will have sufficient funds to continue to meet its liabilities as they fall due for at least 12 months from the date of approval of these financial statements.

#### 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 £10,000 for the six months ended 30 June 2024 relates to accrued income for the recovery of tax on qualifying research and development expenditure. For the six months ended 30 June 2023 there was income tax credit of £26,000 and a credit of £46,000 for the year ended 31 December 2023.

#### 4. Earnings per share

	Group 6 months ended 30 June 2024	Group 6 months ended 30 June 2023	Group Year ended 31 December 2023
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Basic loss per share:

	2024	2023	2023
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Total comprehensive loss - £'000	(1,411)	(431)	(1,717)
Weighted number of Ordinary Shares - '000	378,328	347,765	355,861
Loss per share - operations - pence	(0.37p)	(0.12p)	(0.5p)

As the Group result for the six months ended 30 June 2024, 30 June 2023 and year ended 31 December 2023 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. Current assets

Included within current assets is an investment held at value through profit or loss that had a market value at 30 June 2024 of £332,000 (30 June 2023: £nil). At 31 December 2023 the market value of this investment was £1,413,000 and during the 6 months to 30 June 2024 there has been a decrease in the value of £1,081,000 which has been accounted for within the Consolidated Statement of Comprehensive Income. As noted in the group accounts to 31 December 2023 the Company exercised, in September 2023, a Put Option to acquire £3,250,000 payable in shares in Conduit Pharmaceuticals Inc, a company that was subsequently listed on NASDAQ during December 2023.

The Put Option arose in December 2022 when the Company agreed to sell its:

- i) 5% economic interest in the commercialisation of the AZD 1656 asset to treat inflammatory pulmonary and cardiovascular disease; and
- ii) Its royalty sharing agreement with St George Street Capital, a UK-based biomedical charity

to Conduit Pharmaceuticals Limited.

## 6. 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, 8<sup>th</sup> Floor, 60 Gracechurch Street, London, EC3V 0HR. This interim report can also be viewed on the Group's website: <https://cizzlebiotechnology.com>.

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