

29 September 2025

Cizzle Biotechnology Holdings plc

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

Update on Clinical Laboratory Partnerships in USA

Cizzle Biotechnology, the UK based diagnostics developer of early cancer tests, is pleased to announce further progress on the commercial roll out of the Company's CIZ1B biomarker test in North America by its exclusive licencing partner Cizzle Bio Inc ("BIO"). BIO is now completing validation of the test with its new clinical diagnostics laboratory group, Omni Health Diagnostics ("Omni"), as part of a national expansion strategy based on Omni's active laboratory acquisitions and partnerships programme to provide testing capability in Texas, New York, California, South Carolina, Tennessee and Florida which will provide nationwide testing coverage. It is expected that BIO will add further clinical laboratory partners as required to be able to meet anticipated market demand across North America when the test completes Clinical Laboratory Improvement Amendments ("CLIA") accreditation as a Laboratory Developed Test ("LDT").

BIO continues to make regular payments as part of the revised advance royalty payment schedule of US 2.4m to be paid in full by the end of 2026, as announced on 18 August 2025.

Highlights

- BIO, as part of a US wide roll out strategy, has partnered with Omni to complete its validation programme for the Company's CIZ1B biomarker test to help in the early detection of lung cancer. Omni intends to enable a multiple site testing capability from COLA or CAP and CLIA accredited laboratories to meet anticipated demand following the planned launch of the test in the near term.
- The Company has received further advance payments from BIO as part of the revised royalty payment schedule.

BIO's strategy to launch the Company's CIZ1B biomarker test at multiple sites throughout the USA

The Company has been working closely with its exclusive licensing partner BIO to market its proprietary CIZ1B biomarker test to help detect early-stage lung cancer, throughout the USA, Canada and the Caribbean as a LDT in CLIA accredited laboratories.

As announced on 18 August 2025, BIO has initiated a US national strategy for accreditation and market launch across multiple sites as part of a wider co-ordinated and comprehensive campaign to roll out the CIZ1B biomarker test in North America to help detect early-stage lung cancer. The Company can now announce that BIO has teamed with Omnia CLIA-certified diagnostic laboratory headquartered in Richardson, Texas. It specialises in a comprehensive range of testing services, including pharmacogenomics, molecular diagnostics, clinical testing, genetic testing, and diagnostics for medical fields such as cardiology, oncology, neurology, and infectious diseases. Omni focuses on delivering precise, accurate, and reliable results to support healthcare providers and patients and has an active expansion programme to acquire or partner with other accredited laboratories throughout the USA including New York, California, South Carolina, Tennessee and Florida to enable a nationwide testing capability. While initially to be offered as a private pay for test, they intend to secure CPT (Current Procedural Terminology) codes to allow payment by Medicare and Medicaid. BIO and Omni will engage in a progressive marketing campaign, working closely with patient advocacy groups to enable easy patient engagement and so reduce premature cancer deaths and improve survival rates and quality of life for cancer patients.

Advance Royalty Agreement with BIO

On 18 August 2025, the Company announced that it had received initial payments totalling US 525,000 from its exclusive licensing agreement with BIO as part of a guaranteed payment schedule due to the Company totalling US 2.4 million to be paid in full before the end of 2026. These payments are advance payments from royalties of 10% on sales revenue in North America and the Caribbean. BIO has since made further payments as part of a revised regular payment that continues to support the Company's cash flow requirements.

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

"I am delighted to announce further details on the progress being made by our partner BIO, especially as they implement their strategy to reach as many people as possible who are at risk of lung cancer across multi-site accredited clinical laboratories. The team at Omni have been working hard, and with support from both BIO and the Company are striving to validate and get our CIZ1B test launched in the near future. With over 14.5 million people identified as being at high risk of getting lung cancer in the USA, it is important to develop a nationwide testing capability and I am sure we will see this develop further as demand increases.

"The important advance royalty payments received from BIO continue and demonstrates the full commitment of BIO to this partnership, providing a significant revenue line to the Company to meet its cash flow requirements.

"I had the pleasure of joining Bill Behnke, Chairman and CEO of BIO, and his team as their guest at the Prevent Cancer Foundation® 40th Anniversary and Gala on September 18th, which they sponsored at the National Building Museum in Washington, D.C. With over 1,000 guests it marked four decades of the Foundation's leadership in making prevention central to the fight against cancer. The 2025 event spotlighted nationwide progress in prevention and early detection while advancing the Foundation's goal of securing congressional representation from all 50 states to honour the institutions, communities, and advocates driving change. With other guests from the Saville Cancer Screening and Prevention Center at Inova Schar Cancer Institute, a leading cancer center offering comprehensive, patient-centered care across the full spectrum of prevention, diagnosis, treatment, and survivorship and the LUNGevity Foundation, the largest national lung cancer nonprofit, which accelerates research and provides vital support for patients, the evening provided a powerful platform to raise our profile and the importance of our CIZ1B biomarker as a breakthrough tool in early lung cancer detection. To see more visit <https://www.prnewswire.com/news-releases/cizzle-bio-champions-cancer-survivors-early-detection-as-sponsor-of-prevent-cancer-foundation-40th-anniversary-and-gala-302564695.html>.

"I look forward to providing further updates on our partnerships as we continue to develop our global licensing strategy to make the CIZ1B biomarker test available globally."

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About Cizzle Biotechnology

Based on the pioneering work of Professor Coverley and colleagues, on a naturally occurring variant of the cell nuclear protein CIZ1, the CIZ1B biomarker is highly associated with the presence of early-stage cancer. The company has developed CIZ1B into a non-invasive, cost-effective blood test to help in the early detection of lung cancer and has now entered commercial royalty-bearing arrangements to license its proprietary technology, and into collaborations with centres of excellence in cancer care. Cizzle was admitted to the Standard segment 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.

About BIO

Cizzle Bio is a Texas-based biotechnology company dedicated to revolutionizing cancer diagnostics by advancing biomarker-based blood tests, starting with early detection of lung and gastric cancers. Our goal is to empower patients, equip clinicians, and improve outcomes through innovation, compassion, and life-saving solutions. We hold exclusive licensing rights for our groundbreaking CIZ1B biomarker test in the United States, Canada, and the Caribbean and a worldwide exclusive license for our DEX-G2 biomarker gastric cancer test. Cizzle Bio is commercializing both tests for U.S. clinical environments.

For more information, please see <https://www.cizzlebio.com>

About Omni Health Diagnostics

Omni Health Diagnostics is a diagnostic laboratory based in Richardson, TX, offering a comprehensive range of testing services, including pharmacogenomics, molecular diagnostics, and clinical testing. The facility is COLA accredited and CLIA-certified, ensuring precise and accurate testing with a focus on providing high-quality care and reliable results. Their services cater to various medical fields such as cardiology, oncology, neurology, and infectious diseases, as well as genetic testing. Omni Health aims to support both patients and healthcare providers with advanced diagnostic solutions.

For more information, please see <https://www.omnihealthdx.com>

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