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Cizzle Biotechnology Holdings PLC
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Cizzle Biotechnology Holdings plc

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

Strategic Licensing and Partnership Memorandum of Understanding for North America

Cizzle Biotechnology, the UK based diagnostics developer, is pleased to announce that it has signed a non-binding Memorandum of Understanding ("MoU") for a strategic and exclusive licensing agreement to develop and offer its proprietary test for the CIZ1B biomarker which is highly associated with early-stage lung cancer, throughout the USA and Canada ("North America").

The new partnership is intended to incorporate the Company's existing relationship with Corepath Laboratories, a full-service cancer reference laboratory, as announced on 6 May 2022, through a dedicated, recently incorporated, US based company Cizzle Bio Inc ("BIO"). As set out below, and subject to binding documentation, the proposed royalty arrangements with CorePath will be restructured to enable the Company to gain significant cash flows from new royalty payments and significant cost savings. All planned expenditure related to clinical trials and the commercialization of diagnostic tests for the CIZ1B biomarker in the USA are expected to be funded directly by BIO. In addition, the Company will benefit from the free issue of shares in BIO. BIO is paying a non-refundable upfront fee of US$100,000 within 30 days of signing the MoU for a 120-day exclusivity period to complete the formal legally binding agreement.

Key Highlights

- The MoU envisages Cizzle providing an exclusive licence to BIO to develop and market clinical diagnostic assays based on the CIZ1B biomarker to facilitate the early detection of lung cancer in North America
- Cizzle will receive an up-front payment of US$100,000 within 30 days as a non-refundable fee to grant BIO an exclusive negotiating period of 120 days
- Subject to entering binding documentation, Cizzle will receive minimum advance royalty payments of US$2.3 million over a period of 30 months, payable as to US$0.3 million on signing the binding agreement and a further US$1.0 million on each of the fifteenth and thirtieth month anniversaries of signing as part of annual royalty fees of 10% of net sales
- BIO intends to fully fund all expenditure on development, clinical trials, accreditation and marketing of diagnostic tests for the CIZ1B Biomarker in North America which would represent a significant saving on current planned expenditure by the Company
- Cizzle will participate in the ownership of BIO through a grant of a 10% equity stake in BIO for no cash consideration
- Cizzle will benefit from inventions and improvements to CIZ1B technology for sale in the rest of the world

Further Information

Cizzle's vision is to meet the challenges of early lung cancer detection, reduce premature cancer deaths, improve survival rates and increase quality of life for cancer patients by helping detect cancer as early as possible through a simple blood test.

On 26 March 2024, the Company completed a placing raising gross proceeds of £620,000,which will be utilised towards completing Cizzle's first proposed commercial test to detect CIZ1B, further protect its Intellectual Property (IP), progress the Company's research with the University of York and for general corporate purposes. Key expected future milestones are the manufacturing and scale up of key antibodies and reagents, that following performance testing in clinical trials are intended to become the core components of the Company's commercial test for the CIZ1B biomarker.

It is intended that the clinical trials and first commercial tests will be launched in the USA, in part because lung cancer is by far the leading cause of cancer death there and the US Preventive Services Task Force guidelines now recommends screening for 14.2 million at-risk adults*. With current take up of lung cancer screening tests at less than 10% of the at-risk population, the unmet need is for a simple blood test such as that being developed by Cizzle for the CIZ1B Biomarker.

The Company believes that as we enter this pivotal phase to accelerate the development, regulatory approval and launch of its biomarker diagnostic tests in North America the establishment of an independently financed and locally managed business is the appropriate route to take. BIO will be able to focus on bringing the Company's technology to market through building close relationships with key hospitals and clinical cancer centres and bringing together key opinion leaders and clinicians to drive adoption in this important market.

BIO will be led by Bill Behnke, who was appointed by the Company on 16 June 2022 to identify and facilitate growth within the USA through his network in the clinical and healthcare industry. He was responsible for putting in place Cizzle's co-operation with CorePath Laboratories. Through BIO, the Company will benefit from working closely with CorePath's College of American Pathologists (CAP) and Clinical Laboratory Improvement Amendments (CLIA) accredited specialist oncology reference laboratory in San Antonio, Texas, which brings together leading clinicians, scientists, academic affiliates and state of the art facilities.

Mr Behnke will be joined on the Board of BIO by Dr Ron Greeno, a veteran physician executive with 30 years of experience in the hospitalist practice management field. He was the founder of Cogent Healthcare and served as its EVP for strategy and Chief Medical Officer until its merger with Sound Physicians. He has also served in physician executive positions at IPC and TeamHealth. He was board certified in internal medicine, pulmonary medicine and critical care. He has been a senior advisor for government relations with the Center for Medicare and Medicaid Innovation ("CMMI"), also known as the 'Innovation Center', which was authorised under the Affordable Care Act and tasked with designing, implementing, and testing new health care payment models to address growing concerns about rising costs, quality of care, and inefficient spending. CMMI is managed by the Centers for Medicare and Medicaid Services (CMS).

BIO's ability to meet its financial obligations is dependant on a group of sophisticated high net worth investors in the USA. BIO intends to fully fund all expenditure on development, clinical trials, accreditation and marketing of diagnostic tests for the CIZ1B Biomarker, resulting in a free carry for the Company through to commercialization in North America. The Company will retain rights to improvements and inventions resulting from this commercialization process in the rest of the world.

The Company is now focused on finalising binding legal documentation with BIO and will make further announcements in due course, as appropriate.

Allan Syms, Executive Chairman of Cizzle Biotechnology, said:

"*We are delighted to have entered into this Memorandum of Understanding to create an independently financed and locally managed company that can build a business to serve the North American market. Apart from securing important guaranteed minimum and ongoing licensing revenue and free equity participation for the Company, there will be a significant reduction on planned costs associated with clinical trials and product accreditation. This represents a substantial opportunity to expand the Company's presence in North America through securing non-dilutive major investment and in building a high value dedicated US based leadership team to establish operations and drive adoption in this important market.*"

Bill Behnke, CEO of BIO, commented:

"*Lung cancer is the leading cause of cancer deaths in the USA because of the unmet need for a simple blood test to aid physicians in the early detection of cancer. Through a strong appreciation of the potential value of the CIZ1B biomarker in improving patient survival rates we are very excited by the opportunity to secure an exclusive license from Cizzle for the North American market. Our investor group sees this as an important opportunity to make a major difference to lung cancer survival rates and we have already made progress in developing further relationships with major cancer hospitals as we seek endorsement from clinicians and key opinion leaders.*"

*The 2021 USPSTF lung cancer screening guidelines: a new frontier - The Lancet Respiratory Medicine

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About Cizzle Biotechnology

Cizzle is developing a blood test for the early detection of lung cancer. The Company 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.

About Cizzle Bio Inc

Cizzle Bio Inc, a company registered in Texas USA, has been created by a group of high-net-worth individuals with a passion to improve cancer patient survival. Recognising that one of the main causes of poor survival rates for certain cancers and in particular, lung cancer, is because diagnosis is often when the disease is at an advanced state, there is an unmet need for a simple blood test that can be used to detect cancer early. BIO is led by Bill Behnke, who has been pioneering Cizzle Biotechnology's marketing activities in the USA and is an accomplished entrepreneur and performance-driven senior executive with an extensive background of success in funding and building healthcare businesses through direct sales, marketing, sales management, and business development. He is heavily engaged in charitable work for cancer, and served a nine-year tenure on the national board of the Leukemia and Lymphoma Society. He currently serves on the boards of the ASCO Foundation's Conquer Cancer; the AYA Cancer Foundation; The Wheeler Group; Children's Shelter of San Antonio; South Texas Blood and Tissue Center; and the Leukemia and Lymphoma Society.

About CorePath laboratories

Founded and headquartered in San Antonio, Texas as one of the few international laboratories with the ability to offer immunohistochemistry, cancer cytogenetics, molecular genetics and multicolour flow cytometry services at one location. CorePath brings academic expertise, compassion and state of the art technology to help physicians help their patients and achieve the most accurate time-sensitive results for early treatment.

Together, they are a highly specialised team with a shared passion: "Caring for Lives."

CorePath provides an extensive range of haematopathology services to healthcare providers across the USA and internationally. They work closely with the biopharma industry through a seasoned project management team with relevant scientific and therapeutic expertise in cancer drug study needs. Their team of board-certified pathologists are subspecialised in different areas of oncology to precisely diagnose cancers using cutting edge technology. Customers include ICON, Alexion, Covance, Ventana (Roche) and Becton Dickenson

For more information, please see https://www.corepath.us/

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