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Cizzle Bio - Advancing Simple, Accurate, and Cost-Effective Biomarker Blood Tests for Lung and Gastric Cancers

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CEOCFO: ***Mr. Behnke, according to the Cizzle Bio website, you are "Transforming lung cancer detection through pioneering science." What is the general idea behind your approach?***
Mr. Behnke: We are transforming lung cancer detection by bringing a novel biomarker blood test to clinical practice—one that detects cancer at its earliest and most treatable stage. Many people may not realize that lung cancer is the leading cause of cancer deaths in the United States and globally, so there is an unmet clinical need for an early detection tool that helps to diagnose lung cancer in its earliest stage, when it is most treatable. The foundation of our approach is a protein variant of the CIZ1 gene, called CIZ1B, that is highly associated with early lung cancer. Unlike traditional imaging or invasive procedures, our test requires less than a tablespoon of blood and fits easily into routine care.

What sets our science apart is its ability to identify disease at an early stage, when survival rates are much higher. The five-year survival rate for Stage 1 lung cancer is 63%, but it is only 8% when diagnosed in later stages. In clinical studies, our CIZ1B test showed exceptionally high sensitivity for Stage 1 lung cancer. We are further validating these findings in leading U.S. cancer and academic medical centers and preparing for a broader clinical launch. Our mission is simple but powerful—give physicians and patients a better tool for earlier, more accurate detection of lung cancer and save lives.

CEOCFO: *What is the science and how does it compare to what is available today?*
Mr. Behnke: Our CIZ1B test is not one that detects circulating DNA fragments from tumors (ctDNA). These tests are not effective for early detection because fragment levels are too low in the earliest stages of disease. Instead, our test detects a blood biomarker—a variant protein called CIZ1B that binds with fibrinogen in the blood and is highly associated with early lung cancer. Low-dose CT (LDCT) is the current recommended screening tool for lung cancer, but it has high false positives that lead to unnecessary follow-up procedures—and only 5.8% of the 14.2 million Americans eligible for screening undergo LDCT due to access barriers and concerns about radiation. It turns out radiation concerns are valid because a recent study in *JAMA* found that CT scans in 2023 caused more than 100,000 cancers, with lung cancer being the most common.

The science behind CIZ1B is a better question for the scientists who developed the test. Cell biologist and oncology researcher Dawn Coverley, Ph.D., and her team at the University of York in the UK invested $30 million over 20 years in developing the CIZ1B biomarker blood test. This innovative research focused on nuclear matrix proteins and DNA replication, leading to the discovery of the CIZ1B protein variant and its strong association with early-stage lung cancer. Cizzle Bio holds exclusive licensing rights to the proprietary test, including the IP (Intellectual Property), in North America and the Caribbean. Our CIZ1B test has been granted six international patents, with several other patents pending on our testing process.

"Cizzle Bio is a company to watch because we are addressing one of the most urgent challenges in healthcare—detecting cancer early, when it is most treatable. Our focus is on advancing simple, accurate, and minimally invasive blood tests starting with two of the world's deadliest cancers, lung and gastric cancers. Unlike broad, multi-cancer tests, we are taking a focused, clinically driven approach with validated biomarkers. Our goal is to make early detection more accessible and encourage those at risk to get tested because when cancer is found early, lives can be saved."
Bill Behnke

CEOCFO: *Where are you in the process? Is it available today or if not, when might we see it on the market?*
Mr. Behnke: It is not available today but is coming soon to U.S. clinical settings. Healthcare providers will be able to order the test through a portal on our website, and test samples will be processed and analyzed by one of our CLIA-certified and CAP-accredited laboratory partners. We hope those at known risk of lung cancer will be tested, either during their annual physical or a separate visit. They may have a family history of lung cancer, be a previous smoker, or may be concerned about environmental exposures that increase the risk of lung cancer, such as asbestos, radon, or chronic wildfire smoke.

We hope that wide availability and cost effectiveness will encourage people to get tested so that we can significantly move the dial to reduce lung cancer mortality. Five thousand people a day are dying of lung cancer globally. Our mission is to get that number to zero.

CEOCFO: *What has been the reception from the medical community?*
Mr. Behnke: The response has been incredibly positive! We are engaging with several healthcare systems and academic medical centers, and we are actively launching clinical trials at some of the nation's leading institutions. One trial is already underway at Moffitt Cancer Center in Tampa—one of the 73 NCI-Designated Cancer Centers in the United States—and another is set to begin at Mays Cancer Center/UT Health San Antonio MD Anderson. We also recently signed an agreement with Doctors Hospital in Grand Cayman to offer our tests through their on-site clinical laboratory, expanding our reach into the Caribbean. Across the board, we have been met with enthusiasm and gratitude because people in the medical community recognize the urgent need for a better way to detect lung cancer early.

We have also partnered with Tasso, a company that makes a painless, user-friendly device for collecting blood at home. Patients simply apply it to their upper arm, and it collects a small blood sample—just enough for our test. Then they mail it to the lab for analysis. I have used it several times, and it is remarkably easy. Tasso has already provided their device for more than a million at-home collections, and we see this as a key tool in making early detection more accessible.

CEOCFO: *What happens in the next 60 days?*

Mr. Behnke: We are completing CLIA validation with two additional laboratory partners, and the test will be available to the public soon through healthcare providers. Because a physician's order is required, providers will be able to request the test either through our website or directly through their office EMR system. Results will be delivered back to clinicians through a secure online portal.

CEOCFO: ***What are some of the challenges in getting on the radar screen for the basic family physician that is doing most of the annual check-ups?***
Mr. Behnke: Accessing busy physicians is always a challenge, especially in today's reimbursement environment that limits the time they can spend with each patient. Having built large primary care groups in the past, I know firsthand how difficult it can be to engage this audience. That said, gaining access is easier for our company than most because we can leverage an extensive network of healthcare contacts cultivated by our experienced leadership team. As you will see on our website, our leadership team includes seasoned biotech veterans and healthcare executives from companies like Eli Lilly, Genentech, and Cogent Health. We also have renowned oncologists and pulmonologists on our team from world-class institutions such as the City of Hope Comprehensive Cancer Center and Moffitt Cancer Center. Those relationships and credibility help us open doors that are usually hard to reach.

We are seeing a surge of companies enter the cancer diagnostics space because there is a growing recognition that early detection tools are needed. What sets Cizzle Bio apart is the strength of our science and the proven accuracy of our test. Our strategy is to leverage our established relationships with healthcare systems and maintain a strong presence at major medical conferences to share the clinical evidence behind CIZ1B. One of our key challenges is cutting through the noise and helping providers and stakeholders recognize that we offer a scientifically validated, high-performing test—not just another entry in the field. We are confident that as awareness grows, the impact of CIZ1B will speak for itself.

CEOCFO: ***What is the strategy to reach these people?***
Mr. Behnke: We are taking a multi-pronged approach. First, we are leveraging our established relationships with healthcare systems and physician groups to share the science behind CIZ1B. We are also presenting at key medical conferences to ensure clinical leaders understand how our test stands apart in both accuracy and real-world application. At the same time, we are reaching providers through targeted outreach such as social media, email, direct mail, and in-person efforts. In select markets, we will have teams on the ground, similar to a pharma company field force, educating physicians on the clinical value of our test. We are also exploring broader awareness strategies, including television advertising, like what Cologuard has done successfully.

Another strength of our model is that we are partnering with multiple CLIA-certified labs across the country instead of operating out of a single lab. This enhances our credibility through broader validation and gives us access to large physician groups. For example, one of our laboratory partners holds more than 300 active contracts with payers, allowing us to integrate quickly into existing reimbursement frameworks.

We are also building the case for the economic value of our test. A recent study by a noted healthcare economist, accepted as an abstract at the 2025 American Society of Clinical Oncology (ASCO) Annual Meeting, showed that using our test to screen patients in the at-risk Medicare population could save the Medicare program $518 million annually. That kind of impact, both clinical and financial, is what we are working to deliver.

CEOCFO: ***Is lung your only target for testing?***
Mr. Behnke: No; we also have a highly effective blood test for stomach cancer, or gastric cancer, that we licensed from the City of Hope Comprehensive Cancer Center for worldwide use, and we will be launching this test in the coming months. At this point, our portfolio includes tests for both lung and gastric cancers, and we are actively exploring additional scientifically validated biomarkers to continue expanding our pipeline.

CEOCFO: ***Would you tell us about the stomach test?***
Mr. Behnke: Our early detection gastric cancer test, called DEX-G2, was developed from decades of research by renowned scientist A.J. Goel, Ph.D., AGAF, at the City of Hope Comprehensive Cancer Center in Duarte, California. Gastric cancer is the third leading cause of cancer-related deaths worldwide mainly because it is often diagnosed at an advanced stage when there are few treatment options. DEX-G2 is a blood test that combines cell-free and exosomal miRNA biomarkers to detect gastric cancer with high accuracy. A multicenter clinical trial showed the test has a sensitivity of 95% for early-stage detection—and this is when treatment is most effective. Traditional screening methods like

endoscopy are invasive, expensive, and not widely used for screening. Our DEX-G2 is easy to administer, accessible, and better suited for use in clinical settings.

CEOCFO: *Should you be working with organizations like the American Heart Association?*
Mr. Behnke: We are actively engaging with cancer advocacy groups and nonprofit organizations across the country, and there is real enthusiasm about our mission to advance early detection and save lives. Several members of our leadership team will be attending the Prevent Cancer Foundation's 40th Anniversary Gala in Washington, D.C., this September, and we are having promising conversations with groups nationwide. At the same time, we understand that some organizations are cautious. They have seen many new technologies come and go, so they tend to wait and see what gains traction in the medical community and becomes part of standard care. As we begin testing patients, we expect to see momentum and adoption grow.

CEOCFO: *What have you learned from previous experience about bringing medical products to market?*
Mr. Behnke: It is certainly a challenge but also a tremendous opportunity. The medical community is constantly evaluating new innovations, and understandably, there is a high bar for what is considered clinically valid, impactful, and likely to be adopted by both providers and patients. The goal is clear—improved quality, a better clinical experience, and better outcomes. My guiding philosophy throughout 30 years of working with healthcare startups is to focus on solutions that improve outcomes, enhance safety and quality, and reduce costs for the system. What we are doing at Cizzle Bio aligns perfectly with those values.

When you look at the numbers—124,000 lives lost every year in our country to lung cancer and more than 10,000 each year to gastric cancer—we are talking about two of the top three deadliest cancers worldwide. Our tests are designed to detect these cancers earlier, when they are most treatable. Consider the impact if we could intervene before they reach an advanced stage. That is the potential we see—not just innovation for its own sake, but a real chance to save lives every single day.

CEOCFO: *Are you seeking funding, investment or additional partnerships?*
Mr. Behnke: Yes, we are currently accepting investments and actively building relationships with strategic partners. To date, our funding has come from private individuals and angel investors who are aligned with our mission and see the strong potential in our approach to early cancer detection. We have not pursued venture capital or private equity at this point, as we have been focused on building a strong clinical and business foundation. Our board of directors includes two highly accomplished healthcare leaders—Joe Kelley is a seasoned executive who was vice president of Eli Lilly's Global Government Affairs organization, and Dr. Ron Greeno, a board-certified physician in internal medicine, pulmonary medicine, and critical care, founded Cogent Healthcare and has more than 30 years' experience in the physician services management field. We are also in active discussions with several other respected leaders in healthcare and business to join the board and help guide our growth. As we scale, we are continuing to raise capital, primarily from high-net-worth individuals who believe in our mission and want to be a part of something that can genuinely change lives. For anyone interested in investing, we have a current Reg CF offering at: https://invest.cizzlebio.com. Also, we encourage people to visit our company website at www.cizzlebio.com. It is a great place to explore our vision, meet our team, and discover how to get involved.

CEOCFO: *Why is Cizzle Bio the company to watch; why is it so important in the health arena?*
Mr. Behnke: Cizzle Bio is a company to watch because we are addressing one of the most urgent challenges in healthcare—detecting cancer early, when it is most treatable. Our focus is on advancing simple, accurate, and minimally invasive blood tests starting with two of the world's deadliest cancers, lung and gastric cancers. Unlike broad, multi-cancer tests, we are taking a focused, clinically driven approach with validated biomarkers. Our goal is to make early detection more accessible and encourage those at risk to get tested because when cancer is found early, lives can be saved.