UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM C

UNDER THE SECURITIES ACT OF 1933

(Mark one.)

☑ Form C: Offering Statement
☐ Form C-U: Progress Update
☐ Form C/A: Amendment to Offering Statement
  ☐ Check box if Amendment is material and investors must reconfirm within five business days.
☐ Form C-AR: Annual Report
☐ Form C-AR/A: Amendment to Annual Report
☐ Form C-TR: Termination of Reporting

Name of issuer
Breath Diagnostics, Inc. (the "Company" or "we," "us," or "our")

Legal status of issuer

Form
Corporation

Jurisdiction of Incorporation/Organization
Delaware

Date of organization
July 30, 2015

Physical address of issuer
201 East Jefferson Street, Suite 111C, Louisville, Kentucky 40202

Website of issuerhttps://www.breathdiagnostics.com

Address of counsel to the issuer for copies of notices
BEVILACQUA PLLC
1050 Connecticut Avenue, NW
Suite 500
Washington, DC 20036
Attention: Louis A. Bevilacqua, Esq.

Name of intermediary through which the Offering will be conducted
EquiFund Crowd Funding Portal Inc. ("EquiFund" or, the "Intermediary")

CIK number of intermediary
0001705665

SEC file number of intermediary
7-115

CRD number, if applicable, of intermediary
288900

Amount of compensation to be paid to the intermediary, whether as a dollar amount or a percentage of the Offering amount, or a good faith estimate if the exact amount is not available at the time of the filing, for conducting the Offering, including the amount of referral and any other fees associated with the Offering

The Intermediary will receive a cash commission equal to seven percent (7%) of the amount raised in the offering.

Any other direct or indirect interest in the issuer held by the intermediary, or any arrangement for the intermediary to acquire such an interest

The Intermediary will receive a number of shares of common stock of the issuer that is equal to seven percent (7%) of the total number of shares of common stock sold by the issuer in the offering.

Type of security offered
Common Stock

Target number of Securities to be offered
6,667 shares of Common Stock

Price (or method for determining price)
$3.00 per share

Target offering amount
$20,001

Oversubscriptions accepted:

☑ Yes

☐ No

Oversubscriptions will be allocated:
☐ Pro-rata basis
☑ First-come, first-served basis
Other; At the Company's discretion

Maximum offering amount (if different from target offering amount)

$3,000,000

Deadline to reach the target offering amount
March 31, 2026

NOTE: If the sum of the investment commitments does not equal or exceed the target offering amount at the offering deadline, no Securities will be sold in the offering, investment commitments will be cancelled and committed funds will be returned. Affiliates of our Company, including officers, directors and existing stockholders of our Company, may invest in this offering and their funds will be counted toward us achieving the target amount.

Current number of employees

8

Summary financial information is provided below for the fiscal year ended December 31, 2024 and 2023.

	December 31, 2024	December 31, 2023
Total Assets	$ 704,847	$ 490,374
Cash & Cash Equivalents	$ 377,864	$ 80,316
Accounts Receivable	$0	$0
Short-term Debt	$1,287,208	$ 630,211
Long-term Debt	$1,197,700	$ 1,651,626
Revenues/Sales	$0	$0
Cost of Goods Sold	$0	$0
Taxes Paid	$16,517	$1,692
Net Income (Loss)	$ (941,466)	$ (1,077,002)

The jurisdictions in which the issuer intends to offer the Securities:
Alabama, Alaska, Arizona, Arkansas, California, Colorado, Connecticut, Delaware, District Of Columbia, Florida, Georgia, Guam, Hawaii, Idaho, Illinois, Indiana, Iowa, Kansas, Kentucky, Louisiana, Maine, Maryland, Massachusetts, Michigan, Minnesota, Mississippi, Missouri, Montana, Nebraska, Nevada, New Hampshire, New Jersey, New Mexico, New York, North Carolina, North Dakota, Ohio, Oklahoma, Oregon, Pennsylvania, Puerto Rico, Rhode Island, South Carolina, South Dakota, Tennessee, Texas, Utah, Vermont, Virgin Islands, U.S., Virginia, Washington, West Virginia, Wisconsin, Wyoming, American Samoa, and Northern Mariana Islands

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OFFERING STATEMENT

BREATH DIAGNOSTICS, INC.

BREATH DIAGNOSTICS

Offering of a
Minimum of 6,667 Shares of Common Stock ($20,001)
up to a
Maximum of 1,000,000 Shares of Common Stock ($3,000,000)

	Offering Price	Crowdfunding Platform Commissions (1)	Proceeds to Company (2)
Per Share of Common Stock	**$3.00**	**$0.21**	**$2.79**
Minimum Shares of Common Stock Sold	**$20,001**	**$1,400**	**$18,600**
Maximum Shares of Common Stock Sold	**$3,000,000**	**$210,000**	**$2,790,000**

We are offering shares of our common stock at a price per share of $3.00. We are offering a minimum of 6,667 shares for $20,001 and up to a maximum of 1,000,000 shares for $3,000,000. The minimum investment that you may make is $501. We are offering the shares of our common stock to prospective investors through the crowdfunding platform available at https://equifund.com/ and each subdomain thereof, which we refer to as the Platform. The Intermediary, who operates the Platform, is registered with the Securities and Exchange Commission, which we refer to as the SEC, as a funding portal and is a funding portal member of the Financial Industry Regulatory Authority, which we refer to as FINRA. We are required to pay a commission to the Intermediary equal to 7% of gross monies raised in the offering and to issue to the Intermediary a number of shares of our Common Stock equal to 7% of the total shares of Common Stock sold in the offering.

(1) In addition to the commission payable to the Intermediary, we will incur offering costs. The offering costs primarily consist of legal and accounting expenses payable to our counsel and accounting firm. We expect that the offering costs will total approximately $100,000 not including marketing costs. We are also required to issue to the Intermediary as additional consideration a number of shares of our common stock equal to 7% of the shares sold in the offering.

(2) No assurance can be given that all or any portion of the securities offered hereby will be sold. Your funds will be held in an escrow account established by the Intermediary with Enterprise Bank & Trust, who we refer to as the escrow agent, in compliance with applicable securities laws until the minimum offering amount is reached. The subscription amount for the shares may be paid to the escrow account by wire transfer or other electronic funds transfer in accordance with the instructions provided on the Platform and held in escrow until satisfaction of all the conditions to the closing. The closing of this offering is subject to, among other things, subscriptions for the $20,001 minimum amount being received in the escrow

account from qualified investors, which qualified investors may include executive officers and directors of our Company and their affiliates. This offering may be closed at any time after the minimum number of shares of common stock is sold, in one or more closings, and on or before the offering deadline set forth on the cover page of this offering statement. If we do not raise the minimum amount offered by the offering deadline, then we will return all funds received in the escrow account to investors without interest.

The date of this offering statement is May 2, 2025

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LIST OF EXHIBITS

GENERAL OFFERING INFORMATION

This offering statement is furnished solely to prospective investors through the crowdfunding platform available at https://equifund.com/ and each subdomain thereof. EquiFund Crowd Funding Portal Inc., which, collectively with its subsidiaries and affiliates, we refer to as EquiFund or the Intermediary, operates the Platform and is registered with the SEC and is a member of FINRA.

Our corporate name is Breath Diagnostics, Inc. We were incorporated in the State of Delaware on July 30, 2015. Our Company develops noninvasive diagnostics aimed at detecting early-stage lung cancer. Our technology platform is designed to detect cancer with enhanced accuracy over most other currently available means by capturing and quantifying specific biomarkers in a patient's breath in a portable, affordable, and easy to use system, which we believe offers a much-needed alternative to current lung cancer screening and diagnostic methods. We are offering shares of our common stock at a price per share of $3.00 with a minimum investment of $501 required. We are offering a minimum of $20,001 of our common stock and a maximum of $3,000,000 of our common stock.

We are offering shares of our common stock in reliance on the exemption from registration requirements of the Securities Act of 1933, as amended, which we refer to as the Securities Act, pursuant to Section 4(a)(6) thereof and the regulations promulgated with respect to such section.

A crowdfunding investment involves risk. You should not invest any funds in this offering unless you can afford to lose your entire investment.

In making an investment decision, investors must rely on their own examination of the issuer and the terms of the offering, including the merits and risks involved. These securities have not been recommended or approved by any federal or state securities commission or regulatory authority. Furthermore, these authorities have not passed upon the accuracy or adequacy of this document.

The U.S. Securities and Exchange Commission does not pass upon the merits of any securities offered or the terms of the offering, nor does it pass upon the accuracy or completeness of any offering document or literature.

These securities are offered under an exemption from registration; however, the U.S. Securities and Exchange Commission has not made an independent determination that these securities are exempt from registration.

The Company will file a report with the SEC annually and post the report on its website, no later than 120 days after the end of each fiscal year covered by the report. We may terminate our reporting obligations in the future in accordance with Rule 202(b) of Regulation CF (§227.202(b)) by (1) being required to file reports under Section 13(a) or Section 15(d) of the Securities Exchange Act of 1934, as amended, (2) filing at least one annual report pursuant to Regulation CF and having fewer than 300 holders of record, (3) filing annual reports for three years pursuant to Regulation CF and having assets equal to or less than $10,000,000, (4) the repurchase of all the Securities sold in this offering by the Company or another party, or (5) the liquidation or dissolution of the Company.

The shares being offered may not be transferred by any investor during the one year period beginning when the shares are issued, unless the shares are transferred: (i) to our Company; (ii) to an "accredited investor" as defined in Rule 501(a) of Regulation D; (iii) as part of an offering registered with the SEC; or (iv) to a member of the family of the investor or the equivalent, to a trust controlled by the investor, to a trust created for the benefit of a member of the family of the investor or the equivalent, or in connection with the death or divorce of the investor or other similar circumstance. In addition, there is no ready market for the sale of the shares and it may be difficult or impossible for an investor to sell or otherwise dispose of the shares.

No person other than our Company has been authorized to provide prospective investors with any information concerning our Company or the offering or to make any representation not contained in this offering statement. To invest in the shares being offered, each prospective investor will be required to (i) register for an investor account with the Platform, (ii) make representations regarding the investor's investment eligibility and complete a questionnaire to demonstrate his or her understanding of the risks involved in investing in the shares and (iii)

execute the subscription documents. We reserve the right to modify any of the terms of the offering and the subscription documents at any time before the offering closes.

Certain information contained in this offering statement constitutes "forward looking statements" that can be identified by the use of forward looking terminology such as "may," "will," "should," "expect," "anticipate," "estimate," "intend," "continue," or "believe" or the negatives or variations thereof. Furthermore, any forecasts or other estimates in this offering statement, including estimates of returns or performance, are "forward looking statements" and are based upon certain assumptions that may change. Due to various risks and uncertainties, including the risk factors described in this offering statement, actual events or results or the actual performance of the securities may differ materially from those contemplated in such forward looking statements. Moreover, actual events are difficult to project and often depend upon factors that are beyond the control of our Company or the Intermediary. Neither the delivery of this offering statement at any time nor any sale of securities under this offering statement shall under any circumstances create an implication that the information contained herein is correct as of any time after the earlier of the relevant date specified herein or the date of this offering statement.

TERM SHEET

Company	Breath Diagnostics, Inc., is a Delaware corporation that was formed on July 30, 2015. Our Company develops noninvasive diagnostics aimed at detecting early-stage lung cancer. Our technology platform is designed to detect cancer with enhanced accuracy over most other currently available means by capturing and quantifying specific biomarkers in a patient's breath in a portable, affordable, and easy to use system, which we believe offers a much-needed alternative to current lung cancer screening and diagnostic methods.
Use of Proceeds	We are seeking financing through the sale of the shares of our common stock (as described below under Securities Offered) in order to provide funding for research and development and general corporate and working capital purposes. See "Question 10" below.
Securities Offered	Shares of common stock of our Company for $3.00 per share in a minimum amount per investor of $501.
Targeted Offering Amount; Oversubscriptions Accepted; Maximum Offering Amount	The targeted offering amount is 6,667 shares of common stock or $20,001. We will accept subscriptions in excess of the targeted amount at our discretion. The maximum offering amount is 1,000,000 shares of our common stock or $3,000,000.
Low Target Amount; No other funds may be Raised	The initial purchasers of our common stock in this offering risk that we will not raise sufficient funds to sustain the growth of our Company. The minimum amount of securities that must be sold for our Company to accept subscriptions is 6,667 shares of securities. Once we raise the $20,001 minimum in this offering, we intend to accept subscriptions as they are received. Thus, investors who purchase securities prior to the offering being subscribed in full will bear the risk of whether there will be additional investors to complete the offering or that our Company would be able to raise funds in another manner. Even if we raise the maximum amount, we will need to raise additional capital in the future. Our officers, other employees and directors may invest in this offering and any funds that they invest would be counted toward our achievement of the minimum offering amount.
Capital Stock	
Authorized Capitalization	On August 11, 2022, we amended and restated our articles of incorporation. Prior to the filing of the amended and restated articles of incorporation, which we refer to as the Restated Articles, we were authorized to issue 50,000,000 shares of common stock, $0.0001 par value per share, and 15,000,000 shares of preferred stock, $0.0001 par value per share, of which 7,000,000 were designated as Series Seed Preferred Stock, $0.0001 par value per share. Upon the filing of the Restated Articles, our authorized capital stock was increased to (i) 200,000,000 shares of common stock, $0.0001 par value per share, and all outstanding Series Seed Preferred Stock was converted to common stock, at a ratio of 1.6334 shares of common stock for the conversion of every one (1) share of Series Seed Preferred Stock and (ii) 20,000,000 shares of preferred stock, $0.0001 par value per share.

	! On October 9, 2023, we filed the First Amendment to the Restated Articles, and immediately thereafter and on such date, each one (1) share of our common stock that was issued and outstanding at such time, was split into five (5) fully paid, nonassessable shares of common stock, which we refer to as the First Reverse Split. On November 20, 2023, we filed the Second Amendment to the Restated Articles, and immediately thereafter and on such date, each (1) share of our common stock that was issued and outstanding at such time, was split into two (2) fully paid, nonassessable shares of common stock, which we refer to as the Second Reverse Split. Immediately after the filing of the Second Amendment to the Restated Articles, and on the date hereof, a total of 10,714,454 shares of common stock are outstanding and no shares of preferred stock are outstanding. The Company has 6,812,764 warrants outstanding and 2,280,800 (non-vested employee options 157,500, vested options 898,300 and performance based options of 1,225,000) shares of common stock underlying stock options issuable under its 2016 Equity Incentive Plan. The Company also has convertible debt of $1,990,128.
Dividends	Dividends will be declared if and when determined by the board of directors of our Company in its sole discretion. We do not expect to declare any dividends for the foreseeable future.
Voting and Control	Holders of common stock are entitled to one vote per share of common stock. The subscription agreement for this offering which you will sign if you participate also includes a proxy provision that grants our Chief Executive Officer the authority to vote on your behalf as a shareholder. Under this provision, our Chief Executive Officer, or the successor thereto or assignee thereof to any Chief Financial Officer, if any, as the case may be, will have the power to vote all of your shares and the shares held by each other participant in this offering, execute consents, and take any action necessary as deemed appropriate in their sole discretion, which may include voting against a proposal which would result in an acquisition of our Company by a third party. Moreover, the proxy is irrevocable and coupled with an interest, meaning it survives the death or incapacitation of the shareholder or the reorganization of an entity holding our shares. The proxy terminates upon the earliest of a public offering, registration of our shares under the Exchange Act, or five years from the execution of the subscription agreement. Additionally, our Chief Executive Officer is indemnified against any losses arising from actions taken in good faith under the proxy, with limited exceptions for gross negligence or willful misconduct. See "*Risk Factors – Certain provisions of our certificate of incorporation and bylaws, the Delaware General Corporate Law, and the subscription agreement you will sign as a condition to your participation in this offering may have the effect of discouraging or delaying a change in control of our company*" for more information.
Anti-Dilution Rights	The shares of common stock do not have anti-dilution rights, which means that future equity financings will dilute your ownership percentage of our Company.
Board of Directors; Management Team; Board of Advisors	The business and affairs of our Company are managed, and all corporate powers are exercised by or under the direction of our board of directors. The current board members are Ivan Lo, Phillip Douglas, Michael Bousamra, Victor van Berkel, Dean Johnson, and Jeffrey Rich. The senior executives of the Company oversee the day-to-day operations of our Company, subject to the board's oversight. Ivan Lo serves as the Chief Executive Officer of our Company and oversees all of our operations. Victor van Berkel serves as the Chief Medical Officer and Secretary of our Company and oversees our communications with hospitals and clinic contractors .

Shares Being Sold under 4(a)(6) Crowdfunding Exemption	We are offering the securities in reliance on the exemption from registration requirements of the Securities Act, pursuant to Section 4(a)(6) thereof and the regulations promulgated with respect to such section. The following limitations apply to investment amounts by individual investors in this offering: • Individual investors, over the course of a 12-month period, are permitted to invest in the aggregate across all crowdfunding offerings up to: • If either their annual income or net worth is less than $107,000, then the greater of: ◦ $2,200 or ◦ 5 percent of the lesser of their annual income or net worth. • If both their annual income and net worth are equal to or more than $107,000, then 10 percent of the lesser of their annual income or net worth; and • During the 12-month period, the aggregate amount of securities sold to an investor through all crowdfunding offerings may not exceed $107,000, regardless of the investor's annual income or net worth.
Transfer Restrictions	The securities will be issued without registration under the Securities Act pursuant to the crowdfunding exemption under Section 4(a)(6) of the Securities Act. The securities may not be transferred by any purchaser of such securities during the one- year period from when the securities were first issued unless such securities are transferred: (1) to the issuer of the securities; (2) to an accredited investor; (3) as part of an offering registered with the SEC; or (4) to a member of the family of the purchaser or the equivalent, to a trust controlled by the purchaser, to a trust created for the benefit of a member of the family of the purchaser or the equivalent, or in connection with the death or divorce of the purchaser or other similar circumstance. We will be under no obligation to register the resale of the securities under the Securities Act.
High-Risk Investment	An investment in the securities involves a high degree of risk and is suitable only for investors who can afford to lose their entire investment. See "Risk Factors" for a description of the material risks of investing in our Company.

THE COMPANY

1. **Name of Issuer.**

The name of the issuer is Breath Diagnostics, Inc. The issuer is a Delaware corporation.

ELIGIBILITY

2. **[X] Check this box to certify that all of the following statements are true for the issuer:**

- Organized under, and subject to, the laws of a State or territory of the United States or the District of Columbia.

- Not subject to the requirement to file reports pursuant to Section 13 or Section 15(d) of the Securities Exchange Act of 1934.
- Not an investment company registered or required to be registered under the Investment Company Act of 1940.
- Not ineligible to rely on this exemption under Section 4(a)(6) of the Securities Act as a result of a dis-qualification specified in Rule 503(a) of Regulation Crowdfunding.
- Has filed with the Commission and provided to investors, to the extent required, the ongoing annual reports required by Regulation Crowdfunding during the two years immediately preceding the filing of this offering statement (or for such shorter period that the issuer was required to file such reports).
- Not a development stage company that (a) has no specific business plan or (b) has indicated that its business plan is to engage in a merger or acquisition with an unidentified company or companies.

3. **Has the issuer or any of its predecessors previously failed to comply with the ongoing reporting requirements of Rule 202 of Regulation Crowdfunding? [ ] Yes [X] No**

Explain: Not applicable.

DIRECTORS OF THE COMPANY

4. **Provide the following information about each director (and any persons occupying a similar status or performing a similar function) of the issuer:**

Phillip B. Douglas, Chairman and Director **Dates of Board Service: June 2018 - Present**

Phillip B. Douglas has served as the chairman of the board of directors since June 2018, and Mr. Douglas has 40 years of experience as a seasoned and innovative leader with management and board experience spanning diverse organizational settings and industries. Mr. Douglas has served as a member of our board of directors since 2018 and as the Chairman of our board of directors since October 2022. From December 2016 to April 2024, Mr. Douglas served as a board member and an audit committee member of Oceans Healthcare, a behavioral health hospital. Since November 2018, Mr. Douglas has also served as a board chairman, audit and compensation committee member at Ernest Healthcare, a rehabilitation hospital. Since October 2020, he has also served as a board member of PartnerCare, a pain management company. Mr. Douglas also serves as a board member of VoltaTechnology, a position he has held since November 2021. Since February 2022 Mr. Douglas has also maintained a board member position at Palmetto Technology, an information technology company. Mr. Douglas graduated from the University of Kentucky in 1980 with a Bachelor of Science in Accounting.

Philip B. Douglas' Business Experience for the Last Three Years

Employer: Oceans Healthcare
Employer's Principal Business: Behavioral Health Hospitals
Dates of Service: December 2016 – April 2024
Responsibilities: Board Member and Audit Committee Member

Employer: Ernest Healthcare
Employer's Principal Business: Rehab Hospitals
Dates of Service: November 2018 – Present
Responsibilities: Board Chairman, Audit and Compensation Committee Member

Employer: PartnerCare
Employer's Principal Business: Pain Management
Dates of Service: October 2020 – Present
Responsibilities: Board Member

Employer: Palmetto Technology
Employer's Principal Business: IT Outsourcing
Dates of Service: Feb 2022 – Present
Responsibilities: Board Member

Employer: VoltaTechnology
Employer's Principal Business: IT Outsourcing
Dates of Service: November 2021 – Present
Responsibilities: Board Member

Education: B.S. Accounting University of Kentucky, 1980

Ivan Lo, Chief Executive Officer and Director **Dates of Board Service: Aug. 2022 - Present**

Ivan Lo has been our Chief Executive Officer since August 1, 2023 and a member of our board of directors since August 2022. Mr. Lo is also the founder of Wealth Stream Capital Corp., or WSCC, a private company that invests in private and public companies across various sectors. WSCC was formed as a result of the seed and early-stage investments Mr. Lo made. Mr. Lo has led multiple strategic financing initiatives and has been instrumental in the success of numerous private and public companies, playing a key role in the structure and financing of companies across various sectors. He has funded over 100 private and public companies who collectively have raised over $1 billion.

Ivan Lo studied Urban Land Economics at the University of British Columbia.

Ivan Lo's Business Experience for the Last Three Years

Employer: Breath Diagnostics, Inc.
Employer's Principal Business: Development and commercialization of lung cancer diagnostic tests.
Title: Chief Executive Officer and Director
Dates of Service: August 2022 - Present
Responsibilities: Responsible for all aspects of the Company, including strategy and development of business plan, investor relations, product development, strategic partnerships, and day-to-day operations.

Employer: Wealth Stream Capital Corp.
Employer's Principal Business: Capital markets advisory service assisting private and public corporations, acting as capital markets consultants and leading strategic financing and capital market initiatives
Title: Founder
Dates of Service: January 2009 – Present
Responsibilities: Responsible for all aspects of the company, including strategy and development of business plan, investment decisions, and day-to-day operations.

Education: University of British Columbia, Urban Land Economics 2003-2006.

Jeff Rich, Director **Dates of Board Service: November 2019 - Present**

Jeff Rich has served as a member of our board of directors since November 2019. Dr. Rich is currently the President and CEO of Value Based Healthcare Solutions LLC, a position he has held since April 2020. Prior to that he served as the Cleveland Clinic's Chairman of Strategic Operations and Strategy for the Sydell and Arnold Miller Family Heart and Vascular Institute from July 2017 until March 2020. He previously served as the Surgical Director of the Sentara Cardiac Research Institute and as past President of the Society of Thoracic Surgeons and held leadership positions within the National Quality Forum (NQF) to include Chair of the Council on Research and Quality Improvement and Member of the Board of Directors. Very importantly, Dr. Rich served as the Director of the Center for Medicare at the Centers for Medicare and Medicaid Services (CMS) where he oversaw all regulatory issues for

the Traditional Medicare Fee for Service Program with oversight of a $445B budget. He testified four times before Congress and served on Federal Advisory Committees for CMS as well as the FDA Circulatory System Devices Panel of the Medical Devices Advisory Committee.

Jeff Rich's Business Experience for the Last Three Years

Employer: Value Based Healthcare Solutions, LLC
Employer's Principal Business: Healthcare Improvement and restructuring processes of care to enhance efficiency and lower costs in major healthcare systems.
Title: President and CEO
Dates of Service: 2020 – Present
Responsibilities: In depth analysis of hospitals and healthcare systems to include administration, physician leadership, nursing leadership, pre-op evaluation, cardiac catheterization lab workflow and results, EP lab, intra-op anesthesia care, OR staff and workflow, surgeons, post-op ICU care, intensivist care, step-down care, and system engineering analysis of efficiency with suggestions in each of these areas.

Education:

Undergraduate Northwestern University Evanston, IL	1971-1973
University of Illinois BS in Biomedical Engineering Chicago, IL	1975-1977
Graduate University of Chicago Doctor of Medicine Chicago, IL	1977-1981
Post-Graduate Harvard Medical School General Surgery Boston, MA	1981-1987
Stanford University Cardiothoracic Surgery Stanford, CA	1987-1990

Michael Bousamra, Founder and Director **Dates of Board Service: Aug. 2015 - Present**

Michael Bousamra is one of our founders and has served as a member of our board of directors since our inception in 2015. Dr. Bousamra is a thoracic (chest) surgeon with Ascension Michigan in Detroit, Warren, and Southfield Michigan, specializing in the care of patients with lung cancer, esophageal cancer, and in the full spectrum of malignant and benign non-cardiac diseases of the chest, a position he has held since January 2021. Since January 2021, Dr. Bousamra has been the chief of thoracic surgery in for Ascension Health in southeast Michigan and is responsible for the development and implementation of a comprehensive lung cancer program focusing on early detection. Dr. Bousamra is graduate of University of Michigan Medical School and a member of the American Association for Thoracic Surgery.

Michael Bousamra's Business Experience for the Last Three Years

Employer: Ascension Health Michigan
Employer's Principal Business: Hospital and clinical practice of thoracic surgery.
Title: Head of Thoracic Surgery, Ascension SE Michigan
Dates of Service: January 2021 - Present

Responsibilities: Lead clinical, educational and administrative tracks for thoracic surgery within the Department of Cardiothoracic Surgery Ascension SE Michigan.

Education:
University of Michigan-Dearborn BS '81
University of Michigan Medical School, MD '85
Medical College of Virginia Surgery Residency '91
Washington University School of Medicine
Cardiothoracic Surgery Residency '93

Victor van Berkel, Chief Medical Officer, Secretary, Director Dates of Board Service: Aug. 2015 - Present

Victor van Berkel is one of our founders and has served as a member of our board of directors since our inception in 2015. Dr. Victor van Berkel, MD, PhD, has been a Professor of Surgery in the Department of Cardiovascular and Thoracic Surgery at the University of Louisville since 2010, he has also served as the Chief of the Division of Thoracic Surgery, and he is currently the vice-chair of the Department. He is a co-investigator for several oncologic clinical trials through the Brown Cancer Center and sits on two FDA panels that deal with the approval of medical devices. In addition to his clinical practice, he has an active research lab. His research on the use of breath analysis to identify lung cancer led to him being a cofounder of our Company.

Victor Van Berkel's Business Experience for the Last Three Years

Employer: University of Louisville School of Medicine
Employer's Principal Business: Providing healthcare, training physicians
Title: Professor of Surgery
Dates of Service: 2010 – Present
Responsibilities: Providing surgical care for thoracic oncology patients and end stage lung disease. Educating general surgery residents and medical students
Education:

Doctor of Medicine, Washington University School of Medicine, St. Louis 2003
Ph.D., Washington University School of Medicine, Missouri,
Fellowship, Barnes-Jewish Hospital, Cardiothoracic Vascular Surgery, St. Louis 2010
Residency, Massachusetts General Hospital, General Surgery, Boston, 2008

Dean Johnson, Senior Project Manager, Director Dates of Board Service: November 2023 - Present

Dean Johnson has served as a member of our board of directors since November 2023, and has served as our senior project manager since July 1, 2023. Mr. Johnson holds a CPA designation as well as project management certification. From July 2019 to November 2021, Mr. Johnson was involved in a cannabidiol company called AB, LLC. He also worked with PureTech Services in Calgary, Alberta, a company specializing in Project Services as a senior project manager from 2013 to 2019. Mr. Johnson holds an Advanced Bachelor of Arts degree in Economics and a Bachelor of Administration in Finance and Marketing, both from the University of Regina in Regina, Saskatchewan, Canada. He achieved his Certified Public Accountant designation in 1994.

Dean Johnson's Business Experience for the Last Three Years

Employer: Robert Half
Employer's Principal Business: HR Services
Title: Senior Project Manager
Dates of Service: June 1, 2022 – April 28, 2023
Responsibilities: Project management, risk management, develop new programs that involve detailed project plans, budgets, cost & progress tracking and reporting to executives of project status.

Employer: AB, LLC

Employer's Principal Business: CBD Development and manufacturing
Title: President, Chief Executive Officer, Chief Financial Officer
Dates of Service: July 2019 – November 2021
Responsibilities: The creation and scaling of a CBD company, managing all aspects of operations, including strategic direction, fiscal management, human resources, government relations, marketing and advertising, and intellectual property matters, such as patents and formulations.

Education: CPA/CMA – Professional Accounting Designation 1994
Bachelor of Arts Advanced (Economics), University of Regina 1993
Bachelor of Administration (Finance and Marketing), University of Regina 1988
Project Management Certificate, SAIT (PMP Program) 2011

OFFICERS OF THE COMPANY

5. **Provide the following information about each officer (and any persons occupying similar status or performing a similar function) of the issuer:**

Ivan Lo, Chief Executive Officer and Director
See "Directors of the Company" section above.

Victor van Berkel, Chief Medical Officer and Director
See "Directors of the Company" section above.

Aaron Roebuck, President

Aaron Roebuck's Business Experience for the Last Three Years

Employer: Vero Biotech
Employer's Principal Business: Medical device sales and solutions for hospitals
Title: National Director of Customer Engagement, Director of Application Engineering and Clinical Education, Senior Director of Clinical Sciences
Dates of Service: January 2020 – October 2024
Responsibilities: Lead the clinical and sales teams to increase revenue and add new customers while maintaining current business in a highly competitive market. Responsible for device improvements, successful human factors testing, and FDA approval of next generation devices and new clinical use cases. In charge of clinical research efforts, journal publications, and presentations at scientific meetings.

Education: MS – Organizational Leadership with a concentration in Clinical Trial Design and Regulatory Affairs 2015
BS –Respiratory Therapy 1996

PRINCIPAL SECURITY HOLDERS

6. **Provide the name and ownership level of each person, as of the most recent practicable date, who is the beneficial owner of 20 percent or more of the issuer's outstanding voting equity securities, calculated on the basis of voting power.**

Name of Holder*	No. and Class of Securities Now Held	% of Voting Power Prior to Offering
Wealth Stream Capital Corp.*	2,591,428 Shares of Common Stock	24.18%

FCML Trust (2019)**	2,705,563 Shares of Common Stock	25.25%

*Wealth Stream Capital Corp. is owned and controlled by Ivan Lo

** Ivan Lo is the trustee of FCML Trust (2019).

BUSINESS AND ANTICIPATED BUSINESS PLAN

7. **Describe in detail the business of the issuer and the anticipated business plan of the issuer.**

Our Company

Our Company develops noninvasive diagnostics aimed at detecting early-stage lung cancer and other diseases such as pneumonia. Our technology platform is currently designed to detect lung cancer with enhanced accuracy over most other currently available means by capturing and quantifying specific biomarkers in a patient's breath in a portable, affordable, and easy to use system, which we believe offers a much-needed alternative to current lung cancer screening and diagnostic methods. We are also working on predicting and diagnosing pneumonia in patients undergoing surgery.

The Company' s breath analysis technology is based on three US patents for development of the breath process device and breath analysis for detection of lung cancer. The breath analysis technology was initially supported by the Gates Foundation for detection of Tuberculosis by breath analysis in 2011, development of a chemoselective device for analysis of trace carbonyl compounds in exhaled breath in 2012. The development of breath analysis for detection of lung cancer was funded by Kentucky Lung Cancer Research Program, Coulter Foundation Program and then NIH National Cancer Institute.

Our Corporate History and Structure

We were formed as a Delaware corporation on July 30, 2015. Research and optimization of our platform technologies are conducted by us in our laboratories at The University of Louisville in Kentucky, located at 201 E Jefferson Street, Suite 303, Louisville, Kentucky, USA 40202.

We do not have any subsidiaries.

Our Industry

Lung cancer is by far the leading cause of cancer death in the United States, accounting for about 1 in 5 of all cancer deaths. Each year, more people die of lung cancer than of colon, breast, and prostate cancers combined.

Lung cancer (“LC”) has the highest mortality rate of all cancers worldwide when adjusted for age differences. In 2023, the American Cancer Society estimated that about 238,340 new cases of LC will be diagnosed, and 127,070 deaths are expected. The 5-year survival rate for LC patients is much lower (18.1%) than that for other common cancers (colon, 64.9%; breast, 89.7%; prostate, 98.6%). The relatively late stage at which lung cancer is diagnosed contributes to this low survival rate: only approximately 15.9% of cases of LC are diagnosed at Stage 1 (localized). However, the 5-year survival rate drastically improves when LC is diagnosed when the disease is still localized (55.2% vs. the current 18.1%). Thus, we believe that regular surveillance of the at-risk population can potentially mitigate the current high mortality rate for lung cancer.

On November 16, 2023, after nearly 10 years, the American Cancer Society released an update to its lung cancer screening guidelines in an attempt to help reduce the number of people dying from the disease due to smoking history. The new guideline recommends yearly screening for people between the ages of 50 and 80 years old who smoke or formerly smoked and who have a 20-year or greater pack-year history (a pack-year being equal to smoking a pack

of cigarettes per day for a year; for example, a person could have a 20 pack-year history by smoking 1 pack a day for 20 years, or by smoking 2 packs a day for 10 years).

The advent of computed tomography, or "CT" scanning has allowed for large scale screening for LC. The National Lung Screening Trial, or "NLST", published in 2011, detected a high proportion of early cancers (49% stage IA) using low dose CT scans, which enabled early intervention with curable intent, resulting in a 20% reduction in LC mortality ("Reduced Lung-Cancer Mortality with Low-Dose Computed Tomographic Screening," The National Lunch Screening Trial Research Team , the New England Journal of Medicine, Volume 365 No. 5, 395-409, August 4, 2011). Among the 18,146 patients who tested positive for LC in the NLST, only 649 (3.6%) had cancer. The remaining 17,497 (96.4%) false positive results were primarily patients with pulmonary nodules that would have passed through their benign processes without causing any harm to the patient. These false positive patients required further investigation, including serial CT scanning, positron emission tomography, or "PET", bronchoscopy or percutaneous biopsy, or even surgical intervention. It has been noted that it takes up to 50 scans to find one cancer. That's because CT scans find small nodules frequently, and more than 95% of those nodules are not cancerous. Rather, lung nodules can be the result of infections or remnants of previous smoking or other conditions and are usually harmless. The excessive costs involved with repeated radiographic scans and the morbidity due to unnecessary invasive procedures for benign nodules weigh against the benefit provided by CT screening for lung cancer.

As a result of these shortcomings, our goal was to develop a diagnostic tool that could discern harmless pulmonary nodules from those that cause cancer, without the excessive follow up of multiple CT scans or PET scans. Our target market, the global LC diagnostics market, is estimated to reach a value of $107.45 billion in 2023, with a projected compound annual growth rate of 6.16% from 2024 to 2030 ("Cancer Diagnostics Market Size, Share & Trends Analysis Report," 2024-2040, Grand View Research).

Pneumonia is one of the most common and serious post-operative complications in patients undergoing elective cardiac surgery, including coronary artery bypass grafting (CABG) and valve replacement procedures. This form of hospital-acquired pneumonia (HAP), often classified as post-operative pneumonia (POP), is associated with a substantial increase in morbidity, mortality, length of ICU and hospital stays, and overall healthcare costs.

The ability to accurately predict and diagnose pneumonia pre- or peri-operatively is a critical unmet need, as it enables clinicians to intervene earlier and tailor care pathways to mitigate risk. The market for pneumonia detection tools in this surgical subset is therefore uniquely positioned at the intersection of AI-driven diagnostics, predictive analytics, perioperative risk management, and critical care medicine.

According to publicly available data, over 900,000 cardiac surgeries are performed annually in the US. It is estimated that pneumonia affects 2%–20% of these cases depending on patient risk factors and clinical settings. The economic impact of post-operative pneumonia is profound, with studies estimating additional costs of $20,000–$50,000 per case, presenting a compelling value proposition for prevention-oriented diagnostic platforms.

Our Products and Services

Our Company has developed what we believe is a more accurate and less invasive and costly technique to detect lung cancer and other diseases– the OneBreath test. Originally designed to diagnose lung cancer by analyzing volatile organic compounds ("VOCs") in exhaled breath, our technology is also being applied to additional critical clinical areas — most notably, the prediction and diagnosis of pneumonia in patients undergoing elective cardiac surgery.

Our lung cancer test works to diagnose a patient with LC based on the increased production by a patient's body of specific volatile organic compounds, or "VOCs", during cancer metabolism. The oxidative stress produced by the

variable redox environment within cancer increases the production of these VOCs, which are then exhaled. However, breath analysis methods have not been clinically adopted for cancer detection due to a host of challenges: the large number of distinct VOCs in the breath, low VOC concentrations, variations in breath samples, the lack of identification of cancer-specific VOC biomarkers, and a failure to accurately quantify suspect VOCs. Though, in our extensive preliminary research involving over 800 patients, we believe that we have effectively overcome these difficulties.

Our method is simple for the patient, who delivers one tidal (around 500-1000 mL) volume breath into a non-reactive sample bag. The breath sample then is evacuated through a chemical-coated microchip that captures, stabilizes, and ionizes the carbonyl VOCs that are subsequently eluted and analyzed by mass spectrometry, or "MS".

Our studies revealed that the concentration of specific carbonyl compounds are elevated in lung cancer patients when compared to healthy smokers, with our test identifying cancer with a sensitivity of 94% and a specificity of 85% ("High sensitivity for lung cancer detection using analysis of exhaled carbonyl compounds," Schumer, Erin M., et. al., The Journal of Thoracic and Cardiovascular Surgery, Volume 150, Issue 6, 1517-1524, August 31, 2015). In a separate population of patients with indeterminate nodules, our test was able to distinguish between patients with lung cancer and with benign disease with a sensitivity of 83% and specificity of 74%. ("Quantitative analysis of exhaled carbonyl compounds distinguishes benign from malignant pulmonary disease," Bousamra, Michael et al., The Journal of Thoracic and Cardiovascular Surgery, Volume 148, Issue 3, 1074 – 1081, September 2014).

Building on this platform, we are now leveraging machine learning to enhance our diagnostic capabilities for postoperative pneumonia, a significant and potentially life-threatening complication in cardiac surgery patients. The pathogenesis of pneumonia is also associated with metabolic and inflammatory responses that alter the composition of VOCs in breath.

Our technology captures these changes using the same non-invasive breath collection method as our lung cancer test, but looking at different biomarkers. By applying advanced machine learning algorithms, we can analyze the complex VOC data to predict pneumonia risk and detect early onset.We have a unique technology platform to quantitatively analyze organic compounds from a single breath. The expansion of OneBreath™ into pneumonia diagnosis exemplifies the broader clinical utility of our VOC analysis platform. We believe our system provides a much-needed alternative to current diagnostic methods not only for lung cancer, but also for infectious and inflammatory diseases where metabolic stress is reflected in the breath metabolome.

This unique platform holds promise for broad clinical integration, offering a portable, affordable, and easy-to-use solution for disease screening and monitoring.

Potential Detection of Other Diseases with Our Product

In April 2023, a 23-subject feasibility study was reported to assess how UV absorbance measurements on exhaled breath samples collected from our silicon microreactors can be used to detect COVID-19. The data indicated statistically significant differences that may allow us to detect COVID-19 positive subjects using our test.

In October 2023, another study was published using our microreactor technology, identifying a marker of infection in the breath using a porcine pneumonia model. Generally, the diagnosis of pneumonia can be masked by other disease processes and is often diagnosed after the patient is already experiencing the disease. A noninvasive, sensitive test for pneumonia could decrease hospitalizations and length of stay for patients. Using our technology, our founders, along with other scientists and doctors, were able to show the potential for this test to be further used to detect pneumonia in pigs. A clinical study has been initiated among patients in a hospital setting to determine whether our technology can identify biomarkers associated with pneumonia. We anticipate receiving final results from this study in the summer of 2025. If the results are favorable, we plan to proceed with a validation trial in support of our commercialization strategy.

Our Market Opportunity and Customers

Our Company plans to embark on clinical trials using the OneBreath test for two major lung cancer indications: 1) characterization of pulmonary nodules and differentiation of benign disease from malignancy, and 2) screening to detect early-stage LC. As discussed above, current radiographic technologies like the CT and PET lack the capability to provide definitive diagnostic value in these indications. Using OneBreath as an adjuvant test to CT scanning can reduce ambiguity for physicians and thus reduce invasive biopsy procedures or excessive radiation exposure from unnecessary screening for the patient. Furthermore, the early detection of LC will allow patients to seek early curative intervention, which would be expected to increase life expectancy. In summary, by completing the development of OneBreath technology, we feel that we would satisfy an acute diagnostic need by providing a more specific, non-invasive, accessible, and low-cost tool for LC detection.

In terms of market segmentation, the total attainable market for our product encompasses the entire LC diagnostic market space, with North America being a dominant player due to its high adoption rates of advanced diagnostic technologies and the presence of key market players. The serviceable available market focuses on the North American market, as it targets the most lucrative and accessible opportunities in this region.

There are various types of LC diagnostic tests available, including biopsy, imaging, and liquid biopsy tests. Each of these tests has its unique advantages and disadvantages, and they are often used in combination to provide a comprehensive diagnosis. We believe breath analysis will become a diagnostic medium combined with other tests.

The growing demand for early detection and personalized treatment options is driving the market for these diagnostic tests.

The LC diagnostics market is a rapidly growing industry driven by the increasing prevalence of lung cancer, by technological advancements, and by initiatives aimed at improving early detection and treatment ("Lung Cancer Diagnostics Market, Size, Global Forecast 2024-2030, Industry Trends, Share, Growth, Insight, Impact of Inflation, Companies Analysis," ResearchAndMarkets.com, March 2024).

Because of advantages unique to the OneBreath technology, we feel there is an opportunity for Breath Diagnostics to become the leading company in the surveillance of LC.

Beyond its utility in lung cancer detection, OneBreath technology presents a substantial adjacent opportunity in the early prediction and diagnosis of post-operative pneumonia in patients undergoing cardiac surgery. Pneumonia is one of the most common and severe complications following procedures such as coronary artery bypass grafting (CABG) and valve replacement surgeries, leading to increased ICU utilization, extended hospital stays, heightened morbidity, and significant healthcare costs. In the U.S. alone, approximately 900,000 cardiac surgeries are performed annually, with post-operative pneumonia affecting up to 10% of these patients—representing a potential impact on 90,000 individuals per year. Each pneumonia case can add $20,000 to $40,000 in healthcare expenses, underscoring the critical need for predictive tools that can enable earlier intervention and better perioperative management. By integrating the OneBreath test into surgical care pathways, clinicians may be able to non-invasively assess pneumonia risk in real time, complementing traditional imaging and clinical assessments.

This indication represents a new addressable U.S. market of up to $675 million annually, based on widespread procedural volume and feasible per-patient pricing for risk prediction and early detection. Even with early adoption in 10%–50% of eligible patients, the serviceable obtainable market (SOM) would range from approximately $70 million to $337 million. Importantly, success in the cardiac surgery domain would establish a strong clinical foundation and regulatory precedent, positioning the company to expand into broader high-risk surgical populations

such as thoracic, abdominal, and orthopedic procedures, where post-operative pneumonia is also a major concern. Such an expansion would, of course, require targeted clinical trials to validate OneBreath's predictive utility across diverse surgical settings. However, the potential upside is considerable—enabling Breath Diagnostics to play a central role in reducing pulmonary complications across a wide spectrum of inpatient surgeries. This strategic extension of the OneBreath platform would significantly amplify its value proposition as a versatile, non-invasive diagnostic tool in respiratory care.

Competitive Strengths

To our knowledge, only the OneBreath technology has quantitatively measured, using only one breath, specific carbonyl biomarkers (ng/L) in breath to detect LC. This patented technology has been clinically tested in around 800 patients and reported in 10 peer-reviewed journal articles.

The analysis of VOCs in breath is a potentially information-rich means for assessing a person's health; however, establishing clinical diagnostic technology using exhaled breath has proven challenging. The major obstacles to clinical applications using breath analyses include variations in sampling methods, the low concentration of biomarkers, the presence of exogenous artifacts, and the absence of standardized techniques. We believe that OneBreath overcomes these challenges.

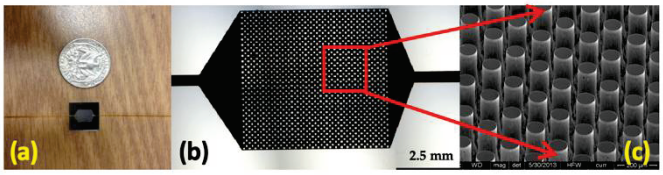

Figure 1. (a) A microfabricated microchip with fused silica tubes attached to inlet and outlet ports; (b) close-up photo of the silicon microchip; (c) SEM micrograph of the micropillar array within the microreactor.

The key innovation is the OneBreath microreactor (Fig. 1), which consists of an array of thousands of silicon micropillars that are coated with a chemoselective aminooxy reagent, or "ATM". The optimized microfluidic design of the chips ensures that the breath sample passing through these micro-channels will be uniformly distributed, affording maximum VOC interactions with ATM. The breath carbonyl compounds undergo instantaneous and irreversible oximation reactions with the ATM coating (Fig. 2), thereby concentrating the carbonyls on the pillar surface while allowing the non-carbonyl VOCs to pass through. The ATM-ECC adducts are conveniently and completely eluted using a cold solvent rinse and analyzed using mass spectrometry.

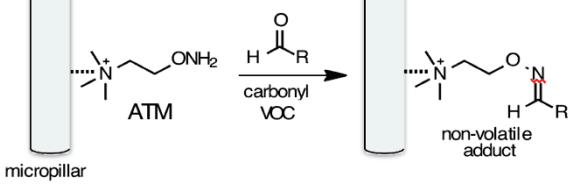

Figure 2. Illustration of coating ATM and chemical reactions with carbonyl compounds.

We have performed preliminary clinical testing of the OneBreath test for 3 cancer indications: 1) Early detection of LC, 2) Differentiation of benign nodules from malignancy, and 3) Normalization of exhaled carbonyl compounds, or "ECCs," post resection of LC tumor.

Early Detection

We have identified the ECCs affected by LC, quantified them, and compared the ECC concentrations between LC patients and healthy controls. The results indicate that OneBreath may be a superior technology for early detection of LC compared to CT scanning.

Differentiation of Nodules

Pulmonary nodule discrimination was proven by quantifying 4 ECC biomarkers: 2-butanone, 3-hydroxy-2-butanone, hydroxyacetaldehyde and 4-hydroxy-2- hexenal. Our results revealed that the OneBreath test demonstrated superior specificity in differentiating benign pulmonary nodules from malignant tumors when compared to PET scan, while maintaining similar sensitivity.

Normalization of ECC Post Resection of Tumors

To study ECC concentration trends following resection of LC tumors, we monitored pathologically confirmed LC patients who underwent surgical resection with curative intent and compared results to healthy controls. Our results indicated that the elevated ECC levels in LC patients dropped to "normal" levels (the ECC levels observed in healthy controls) post tumor resection.

Expansion into Post-Operative Pneumonia Prediction: A Unique Competitive Advantage

The extension of the OneBreath technology platform into the prediction of post-operative pneumonia (POP) represents a significant and differentiated competitive strength for Breath Diagnostics. Pneumonia remains one of the most prevalent and costly complications following major surgeries, particularly in patients undergoing cardiothoracic procedures such as coronary artery bypass grafting (CABG), valve replacement, and aortic repair. This serious condition not only increases patient morbidity and mortality but also imposes substantial burdens on intensive care units (ICUs), lengthens hospital stays, and adds tens of thousands of dollars in cost per patient episode.

Despite the high clinical and economic burden of post-operative pneumonia, no currently available diagnostic or predictive tool provides a non-invasive, quantitative, and pre-symptomatic assessment of pneumonia risk. This creates a significant unmet need in perioperative care, where early identification of at-risk patients could allow for tailored prophylactic strategies, closer monitoring, and targeted respiratory therapy interventions. Most existing approaches rely on clinical scoring systems or reactive diagnostics, such as chest X-rays or inflammatory markers, which detect pneumonia only after clinical deterioration begins—often too late to avoid complications.

OneBreath is uniquely positioned to address this gap through its patented carbonyl biomarker detection technology. By using a single exhaled breath sample, OneBreath captures and quantifies exhaled carbonyl compounds (ECCs). The platform's microreactor chip, which features silicon micropillars coated with a chemoselective aminooxy reagent (ATM), allows for ultra-sensitive, selective, and reproducible detection of volatile organic compounds (VOCs) that correlate with systemic and respiratory pathophysiology. This provides a novel mechanism to stratify risk before clinical symptoms emerge—a powerful proposition in pre- and post-surgical workflows.

Importantly, Breath Diagnostics may hold the first-mover advantage in this emerging field. While other companies are focused on pneumonia treatment or imaging-based diagnostics, no other technology to date offers a point-of-care, non-invasive breath-based tool to predict pneumonia risk in post-operative patients.

Growth Strategies

Because of what we believe are the unique advantages of our OneBreath technology, we see an opportunity for our Company to become a leading force in detecting and monitoring respiratory conditions, including pneumonia and lung cancer. A clinical study in patients using our core technology is underway to determine whether our technology can identify biomarkers associated with pneumonia.

Under the FDA's risk-based classification system, in vitro diagnostic (IVD) devices are categorized by the potential risk they pose to patients. Because pneumonia detection involves identifying an existing clinical condition—one that can be confirmed by complementary clinical assessments (e.g., sputum culture, chest X-ray)—it may be considered a moderate-risk indication. Consequently, a successful pneumonia detection trial could qualify our technology as a Class II device, for which clearance can often be obtained via the 510(k) or de novo pathway, depending on the novelty of the device and its similarity to an existing legally marketed predicate. This classification typically involves shorter, less costly clinical trials and a more streamlined regulatory process, which could allow us to bring a pneumonia detection device to market on a faster and less costly basis than for a lung cancer device.

By contrast, a device intended to detect or screen for lung cancer often poses a higher risk, because the diagnostic outcome may lead to invasive follow-up procedures, significant patient anxiety, and major treatment decisions. As such, an IVD for lung cancer screening is more likely to be regulated as a Class III device requiring Premarket Approval (PMA). This distinction underscores our strategy to prioritize pneumonia detection and prediction if trial data continues to support positive outcomes, as success in this indication could provide a more rapid and cost-effective initial path to commercialization.

Accordingly, we plan to engage the FDA's Office of In Vitro Diagnostics to seek guidance on pre-clinical trials and the optimal regulatory strategy. We anticipate submitting OneBreath for FDA approval covering two major lung cancer indications: (1) characterization of pulmonary nodules and differentiation of benign disease from malignancy, and (2) screening to detect early-stage lung cancer. Such approval would enable us to market OneBreath directly to U.S. physicians and patients and facilitate reimbursement discussions with payors. In parallel, we also intend to pursue Breakthrough Device Designation from the FDA for the pneumonia indication, given the urgent clinical need, lack of predictive tools, and the potential of OneBreath to significantly improve outcomes in post-operative care. If granted, this designation would provide several regulatory advantages, including prioritized review, access to expedited development pathways, more frequent interactions with the FDA, and enhanced visibility with payors—all of which could accelerate time to market and facilitate broader adoption.

We believe the existing marketplace infrastructure can readily support implementation of OneBreath technology, much like blood or urine tests, by partnering with diagnostic laboratories equipped with mass spectrometry capabilities. In addition, given the rapidly evolving field of breath diagnostics, we expect to explore partnerships with, or potential acquisitions of, complementary breath analysis technologies.

Competition

Due to the immense global demand for improved medical solutions, numerous companies and academic institutions are working to create and market tests that can detect cancer in its early stages, when treatment is most effective. These efforts encompass various techniques, such as in-vivo radiographic imaging and in-vitro tests utilizing diverse bodily samples like blood (serum or whole), urine, saliva, stool, sputum, and exhaled breath.

Breathe Biomedical

Breathe Biomedical employs a technology that combines VOC detection in breath with infrared, or "IR", spectroscopy and machine learning algorithms. They utilize Infrared Cavity Ring-Down Spectroscopy to assess the effectiveness of infrared CRDS breath profiles in distinguishing non-small cell lung cancer patients from control subjects.

When it comes to breath collection, their sampler exclusively captures alveolar breath. This process requires 10 liters of breath, which takes approximately 30 minutes, and the collected samples are stored at -20°C for further analysis.

The Company is actively engaged in clinical trials related to LC, including collaborations with Dr. Georges L. Dumont University Hospital, West Virginia University, and the University of California, Irvine.

Breathe Biomedical's primary focus is the development of technology for screening biomarkers related to various disease states, with a primary emphasis on cancers such as lung, breast, liver, and colorectal cancers, as well as respiratory conditions like COPD, Tuberculosis, and asthma. Recent developments include developing a noninvasive breath test for detecting breast cancer, particularly in women with dense breast tissue, as of January 9, 2024.

However, they do face challenges, including accuracy and reliability issues, dependency on large breath samples, high costs, and evolving screening methods. Regulatory challenges also exist due to their reliance on machine learning and artificial intelligence, which is a common hurdle for diagnostic methods of this nature.

Owlstone Medical

Owlstone Medical specializes in its Breath Biopsy platform, comprising the ReCIVA Breath Sampler and Breath Biopsy OMNI, with a core focus on non-invasive diagnostics for early disease detection and precision medicine. Their technology finds application in diagnosing conditions related to LC, liver disease, digestive health, and respiratory diseases.

Owlstone Medical has 101 articles published since 2009 and is actively involved in clinical trials. This phase focuses on evaluating the OWL-EVO1 breath test's ability to differentiate between LC patients and contrast groups, with the secondary objective of optimizing the test protocol for accuracy, healthcare worker effort, and patient tolerability.

Owlstone Medical continues to concentrate on the development of non-invasive diagnostics for early disease detection, with a strong focus on LC, liver disease, digestive health, and respiratory diseases.

Breathomix, eNose

Breathomix specializes in breath analysis technology, notably SpiroNose, which combines an electronic nose, or eNose, with spirometry. At the core of their approach is Molecular Pattern Recognition, harnessing VOCs in exhaled breath as non-invasive biomarkers for assessing diseases.

The breath collection process revolves around the SpiroNose, an eNose breath sampling device designed specifically for longitudinal studies. It captures a comprehensive mixture of VOCs over time. This integration extends to the BreathBase cloud platform, facilitating real-time breath analysis powered by AI and cloud computing.

The company actively engages in clinical research, particularly in diseases like cancer, asthma, and COPD. Their focus lies in conducting real-world studies to enhance the generalizability of their findings. A notable project is the BreathCloud study, a collaboration with Amsterdam University Medical Centres.

Illumina/GRAIL

GRAIL is a company specializing in cancer diagnostics and offers the Galleri blood test. This test relies on whole genome methylation analysis, utilizing a targeted assay for circulating tumor DNA, or ctDNA, to detect cancer.

One of the significant claims associated with Galleri is its ability to accurately identify 50 types of cancer through a single blood test. However, recent published data has revealed limitations, with Galleri exhibiting a low Positive Predictive Value, or PPV, of less than 10% for nearly all cancer types. Sensitivities for early cancer detection are also unacceptably low, standing at 17% for stage I, 40% for stage II, and 27.5% for stage I-II. Specifically for lung cancer, the PPV is reported at 13.9%.

GRAIL holds 103 patents, with 19 currently active, 78 pending, and 6 inactive patents. The company has also contributed significantly to the field, publishing 42 articles since 2017.

20/20 GeneSystems Inc.

20/20 GeneSystems Inc. offers OneTest for Lung Cancer, a serum biomarker panel designed to assess the risk of LC. This test employs an algorithm that combines scores from cancer markers and clinical risk factors to calculate an individual's risk score.

OneTest for Lung Cancer utilizes a proprietary AI algorithm based on "Deep Learning Neural Networks," providing risk prediction scores. The biomarkers involved in this panel include CEA (carcinoembryonic antigen), CA-125, CYFRA-21-1 (cytokeratin-19 fragment 21-1), and NY-ESO-1 (Autoantibody = New York esophageal cancer-1).

A breakthrough in computing or algorithmic processing that results in a significantly improved and highly reliable algorithm could potentially reshape the company's competitive position in disease testing and detection.

Bioaffinity Technologies: CyPath Lung

CyPath® Lung is a test for early-stage LC that is designed to meet the need for greater diagnostic certainty. Based on their internal analysis, its use in conjunction with LDCT is predicted to improve the positive predictive value (the probability that patients with a positive LDCT scan truly have the disease) by a factor of five. Their analysis concludes that improving the positive predictive value of LDCT with the use of CyPath® Lung has the potential to subject fewer patients to the stresses of misdiagnosis or unnecessary diagnostic procedures such as biopsies, while also reducing healthcare costs.

Bioaffinity has developed an algorithm as part of a test validation trial that used machine learning to distinguish samples from high-risk patients who had LC from those who are cancer-free. However, Cypath Lung faces several challenges. Its sensitivity and specificity in clinical settings must be rigorously proven to establish it as a reliable and trustworthy diagnostic tool. The competitive landscape in the field of LC detection is fierce, requiring Cypath Lung to outperform existing solutions to gain market acceptance. Moreover, navigating regulatory and reimbursement challenges is a common hurdle for diagnostic tests, particularly those that rely on complex algorithms or AI for their results.

Sourcing and Suppliers

The primary raw materials used in the manufacture of our products are microchips, various chemical compounds, tedlar bags, semiconductors, and a variety of other components. The cost of these raw materials is a key factor in pricing our products.

We source our raw materials from a singular foreign supplier. Our primary supplier is a contract research, development and manufacturing organization (CDMO) with 29 global offices, and a microelectromechanical systems foundry in Japan. Raw materials from Asian-based suppliers such as our supplier may be subjected to import duties, depending on various foreign policies of the U.S. government. As such, we continue to explore partnership or supplier opportunities to optimize our costs.

We have historically purchased certain key raw materials from a limited number of suppliers. We purchase raw materials based on anticipated volume. Currently, this volume is based on what we believe to be the requirements of our FDA clinical trials. We have contracts in place for the materials required for our anticipated clinical trials. While we believe that there is an ample supply of most of the raw materials that we need, in the absence of firm and long-term contracts, we may not be able to obtain a sufficient supply of these raw materials from our existing suppliers or alternates in a timely fashion or at a reasonable cost. If we fail to secure a sufficient supply of key raw materials in a timely fashion, it would result in a significant delay in delivering our products. Furthermore, failure to obtain a sufficient supply of these raw materials at a reasonable cost could also harm our future revenue and gross profit margins. Please see "*Risk Factors — Risks Related to Our Business and Industry — We have historically depended on a limited number of third parties to supply key raw materials to us and the failure to obtain a sufficient supply of these raw materials in a timely fashion and at reasonable costs could significantly delay our delivery of products*" for a description of the risks related to our supplier relationships.

Intellectual Property

We safeguard our intellectual property rights through a comprehensive approach that includes patents, patent applications, copyrights, trademarks, and various contractual agreements. Additionally, we utilize trade secret laws to safeguard unpatented knowledge and ongoing technological advancements.

Our success depends upon our ability to protect our technologies through patent coverage. As of January 11, 2023, we have an exclusive license agreement with the University of Louisville on key patents that have been issued in the U.S., as well as outside the U.S., including in key European Union countries, India, and other countries, covering our use of a micro-preconcentrating method for the analysis of volatile organic compounds in breath, a noninvasive method for diagnosis of LC and other cancers, and the capture and analysis of exhaled carbonyl compounds to diagnose cancer. This exclusive license comes with a 2.5% royalty on commercial sales, and milestones we have to meet in order to retain exclusive rights to the patents. By December 31, 2028, we, as the licensee, or a sublicensee selected by us will either: (a) submit an application to the FDA to obtain 510(k), pre-market approval, or other approval to market and sell licensed products and/or licensed services in the United States; or (b) submit an application to obtain CE mark approval to market and sell licensed products and/or licensed services in the United Kingdom or the European Union. By obtaining CE mark approval, we will be able to market that our product has been assessed by the manufacturer and deemed to meet EU safety, health and environmental protection requirements. Such CE certification is required for products manufactured anywhere in the world that are then marketed in the European Union. Within 24 months of obtaining appropriate approval or clearance from the FDA and no later than December 31, 2030, whichever occurs first, licensee or a sublicensee will make a First Commercial Sale (as defined by the European Commission standards) in a member country of the European Union or the United Kingdom. Within 24 months of obtaining CE mark approval or other appropriate regulatory or governmental approval and no later than December 31, 2030, whichever occurs first, a licensee or a sublicensee will make a First Commercial Sale in a member country of the European Union or the United Kingdom. We are also obligated to reimburse the University of Louisville Research Foundation for all documented costs for patent filing, prosecution, and maintenance of patents and patent applications for licensed patents.

Country of Filing	Patent/ Application	Patent No./ Application No.	Type	Patent Name	Patent Date/ Application Date	Status
United States	Patent	8,663,581	Non-Provisional		3/14/2014	Issued
Germany	Patent	DE 12714139.8	Foreign		2/27/2019	Validation
France	Patent	FR 12714139.8	Foreign		2/27/2019	Validation
United Kingdom	Patent	UK 12714139.8	Foreign		2/27/2019	Validation
Italy	Patent	IT 12714139.8	Foreign		2/27/2019	Validation
Spain	Patent	ES 12714139.8	Foreign		2/27/2019	Validation
Poland	Patent	PL 12714139.8	Foreign		2/27/2019	Validation
Romania	Patent	RO 12714139.8	Foreign		2/27/2019	Validation
United States	Patent	14/471,793	Non-Provisional		5/2/2017	Issued
Europe	Application	14762191	European Patent Office		3/21/2016	Published

India	Application	201617010108	Foreign		3/23/2016	Issued
Australia	Patent	2014312293	Foreign		8/13/2020	Issued
Canada	Application	2922233	Foreign		3/8/2016	Filed
Japan	Patent	2016-537851	Foreign		5/11/2020	Issued
United States	Patent	15/223,756	Non-Provisional		5/25/2021	Issued
France	Patent	FR 16754031.9	Foreign		2/12/2018	Filed
Germany	Patent	DE 16754031.9	Foreign		11/13/2019	Validation
Italy	Patent	IT 16754031.9	Foreign		11/13/2019	Validation
Poland	Patent	PO 16754031.9	Foreign		11/13/2019	Validation
Spain	Patent	ES 16754031.9	Foreign		11/13/2019	Validation
United Kingdom	Patent	UK 16754031.9	Foreign		11/13/2019	Validation
United States	Application	17/238,082	Nonprovisional - Continuation		4/22/2021	Validation

We are committed to safeguarding our vital proprietary technologies crucial to our business. This includes the pursuit and maintenance of patent protection for our diagnostic tests, pipeline product candidates, and their applications, alongside other essential inventions. In addition to patents, we secure our valuable assets through copyrights, trademarks, trade secrets, and know-how, facilitated by confidentiality agreements, invention assignment agreements, and a trade secret program. These measures protect aspects of our business that may not be suitable for patent protection.

Confidentiality agreements are specifically designed to shield our proprietary information, while invention assignment agreements help us gain control and ownership of technologies developed by our employees, consultants, or third parties on our behalf. We take rigorous steps to maintain the integrity and confidentiality of our data and trade secrets, including physical security measures at our premises, robust information technology systems security, and non-disclosure agreements with individuals who handle our confidential information.

The term of individual patents varies based on the legal requirements of the countries where they are obtained, but they typically last 20 years from the earliest non-provisional patent application filing date.

Beyond patent protection, we rely on know-how and trade secret safeguards for proprietary information not suitable for patent protection, which is essential for maintaining our proprietary position. However, protecting trade secrets can be challenging. Despite our efforts to secure proprietary information, including access restrictions and agreements with employees, consultants, advisors, and potential collaborators, third parties may independently develop similar proprietary information or gain access to ours, potentially hindering our ability to protect our know-how, trade secrets, and other proprietary data.

In June 2023, we filed a new application for the use of the trademark OneBreath under US Serial number 98061619. This was filed to replace a prior pending application in order to give us more time to prove we are using the trademark

on a product in commerce, and the time to prove that we had used the trademark in commerce before the first application had expired.

Furthermore, we plan to leverage regulatory protections like data exclusivities and market exclusivities in addition to patent and trade secret protections.

Human Capital

We prioritize the recruitment, growth, and retention of our team, which comprises accomplished scientists and medical committed to advancing scientific breakthroughs from laboratory research to practical application. Our founders and directors consist of those at the highest level of experience within their respective fields of organic chemistry, chemical engineering, thoracic surgery, healthcare services, and the Center for Medicare and Medicaid Services.

As of December 1, 2024, we had four (4) full time employees and four (4) consultants, all of whom were in the United States. None of our employees are represented by labor unions, and we believe that we have an excellent relationship with our employees.

Legal Proceedings

From time to time, we may become involved in various lawsuits and legal proceedings which arise in the ordinary course of business. However, litigation is subject to inherent uncertainties and an adverse result in these, or other matters may arise from time to time that may harm our business. We are currently not aware of any such legal proceedings or claims that we believe will have a material adverse effect on our business, financial condition or operating results.

Facilities

Our corporate headquarters are located in Louisville, Kentucky, on the grounds of the campus of the University of Kentucky. Our current facilities at our Louisville location consist of approximately 1,000 square feet of space and include a lab and office space. Separately, we also conduct some of our current research and development at the University of Louisville's Department of Chemistry, paid for under a services agreement, for a 1,000 sq. ft lab at the University's One Innovation Centre on a month-to-month lease. We anticipate expanding our space to an additional lab and additional office space, bringing our total area to 2,334 sq. ft.

We believe that our property is adequately maintained, is in generally good condition, and is adequate for our business.

Government and Environmental Regulations

Diagnostic Products (including medical devices and tests)

In the United States, medical devices, including in vitro diagnostic products, or "IVDs", are subject to rigorous regulation by the United States Food and Drug Administration, or "FDA", as stipulated in the Federal Food, Drug, and Cosmetic Act, or "FDCA", and its implementing regulations, along with various federal and state statutes and regulations. These laws and regulations oversee various aspects of medical device management, encompassing design, manufacturing, storage, recordkeeping, approval, labeling, promotion, post-approval monitoring, reporting, distribution, import, and export.

IVDs represent a specific category of medical devices obtainable by clinical laboratories for conducting laboratory tests. They include reagents and instruments designed to detect specific chemicals or biomarkers in human specimens, primarily for diagnosing or detecting diseases or conditions. IVDs are also utilized for predictive, prognostic, and screening testing. Similar to other medical devices, IVDs may necessitate premarket review, clearance, or approval from the FDA.

Non-compliance with these regulatory requirements can result in various administrative and legal penalties. Consequences may include FDA refusal to approve pending “Pre-Market Approval” applications, issuance of warning letters or untitled letters, mandatory product recalls, import detentions, civil monetary penalties, and potential judicial actions, such as product seizures, injunctions, and criminal prosecutions.

Laboratory-Developed Tests

We may offer tests classified as Laboratory Developed Tests, or "LDTs," and we may also plan to introduce certain products currently in development to the market as LDTs.. The U.S. Food and Drug Administration (FDA) defines LDTs as tests that are designed, validated, and performed within a single laboratory.

Historical FDA Approach to LDT Regulation

Historically, the FDA has asserted that it has the authority to regulate LDTs as in vitro diagnostics (IVDs) under the Federal Food, Drug, and Cosmetic Act (FDCA). Despite this stance, the FDA in the past has generally exercised "enforcement discretion," meaning it has not actively enforced regulatory requirements—such as premarket approval, authorization, or clearance—for most LDTs conducted by laboratories certified under the Clinical Laboratory Improvement Amendments (CLIA). This leniency was largely due to the limited number of LDTs, their relative simplicity, and their common use in diagnosing rare diseases or less prevalent conditions.

Recent Developments and Current Status

Since 2006, the FDA has signaled its intent to impose varying levels of oversight on LDTs, including those we may offer. The FDA has previously explored increasing its regulation of LDTs through formal rulemaking. On October 3, 2023, the agency published a proposed rule in the Federal Register, aiming to amend its regulations to explicitly classify IVDs—including those manufactured by laboratories—as devices under the FDCA. This proposal outlined a plan to phase out enforcement discretion for LDTs, aligning their oversight with that of other IVDs to enhance public health protections by ensuring their safety and effectiveness and on May 6, 2024 the FDA issued its final rule extending the regulatory definition of IVDs to include LDTs, thereby explicitly subjecting them to regulation as medical devices. However, on March 31, 2025, a federal court vacated the FDA's final rule. The court determined that the FDA lacked the authority to regulate LDTs as devices under the FDCA, given the existing oversight of clinical laboratories by the Centers for Medicare & Medicaid Services (CMS) through CLIA. Consequently, the FDA's enforcement discretion policy persists, and no specific regulatory requirements have been imposed on LDTs as of this date.

Looking ahead, it is uncertain whether or when the FDA might alter its enforcement discretion approach. The agency could potentially choose to regulate specific LDTs on a case-by-case basis, particularly if significant public health concerns arise. Any shift away from enforcement discretion could have a substantial impact on our ability to develop and market LDTs.

Legislative Proposals

Several legislative efforts have sought to clarify or redefine the FDA’s oversight of LDTs:

VALID Act: Introduced in March 2020, reintroduced in July 2021, and again in March 2023, the Verifying Accurate Leading-edge IVCT Development (VALID) Act proposes a new regulatory framework for IVDs and LDTs. It could require premarket approval for certain tests, including some LDTs not currently subject to FDA review.

VITAL Act: Introduced in March 2020 and reintroduced in May 2021, the Verifying Innovative Life-saving Advances for Test (VITAL) Act aims to transfer LDT regulation from the FDA to CMS.

As of the date of this offering statement neither the VALID Act nor the VITAL Act has been enacted into law. The prospects for congressional passage of these or similar bills remain uncertain, as does their potential effect on the FDA's authority over LDTs. Future legislation could either grant the FDA explicit regulatory power or affirm that such authority lies elsewhere, potentially with CMS.

Dual Oversight by FDA and CMS

While the FDA maintains that it can intervene in LDT regulation when necessary—particularly to address significant public health risks—CMS continues to oversee clinical laboratory operations through the CLIA program. This dual framework adds complexity to the regulatory environment for LDTs.

Implications for the Future

The ongoing uncertainty surrounding FDA enforcement discretion and potential legislative changes poses challenges for our LDT-related plans. A future shift in FDA policy—whether through new rulemaking or legislative action—could mandate clearance or approval for LDTs, significantly affecting our development and marketing efforts. For now, as of April 9, 2025, the status quo of enforcement discretion remains in place, shaped by the recent court decision and the absence of enacted legislative reforms.

Clinical Laboratory Improvement Amendments of 1988

Clinical laboratories conducting disease diagnosis or health assessment tests on specimens collected in the U.S. are subject to CLIA unless they qualify for an exemption. CLIA sets forth stringent quality standards for all clinical laboratory testing to ensure the precision, dependability, and promptness of patient test results, regardless of the testing location.

Specifically, these regulations necessitate that clinical laboratories either obtain certification from the federal government or an accreditation organization with delegated authority from the federal government. Alternatively, they must operate within a state that has received an exemption from CLIA requirements because the state enforces laws equivalent to or more rigorous than CLIA regulations. CLIA also mandates that laboratories adhere to quality assurance, quality control, and personnel standards, partake in proficiency testing, and undergo regular inspections. The standards imposed on clinical laboratories under CLIA vary depending on the complexity of the tests performed, which are categorized as "waived," "moderate complexity," or "high complexity." In cases involving tests conducted with IVDs, the FDA determines the complexity classification of the IVDs.

The College of American Pathologists, or "CAP", is a membership-based organization comprising nearly 20,000 board-certified pathologists. CAP's Laboratory Accreditation Program holds deeming authority from the federal government, enabling CAP accreditation to serve as a means to obtain CLIA certification and meet CLIA inspection criteria.

Medical Devices

Devices that fall under FDA regulation must undergo premarket review before they can be commercially marketed, unless they are exempt from such scrutiny. The regulatory framework governing our OneBreath test may impose significant restrictions on how we can market and sell it, such as requiring it to be available only by prescription.

Moreover, we may be obligated to conduct a post-approval study as a condition of FDA approval. It is important to note that there is no guarantee that the outcomes of our studies will meet the FDA's expectations, and they could lead to modifications or withdrawals of potential OneBreath test approvals.

Furthermore, manufacturers of medical devices are obligated to adhere to various regulatory obligations outlined in the FDCA and its associated regulations, which encompass quality system standards, facility registration, product listings, labeling criteria, and certain post-market monitoring responsibilities, unless specific exemptions apply. Entities that fail to comply with FDA requirements may face criminal or civil penalties, including product recalls, production halts, and limitations on labeling and promotional activities, among other potential repercussions.

Some of our products currently in development, or additional diagnostic products and services we aim to create, may fall under FDA regulation as medical devices. The regulatory evaluation and approval process for medical devices can be expensive, time-consuming, and uncertain. This process may require us to successfully complete further clinical trials and submit a premarket clearance notification or a premarket approval application to the FDA. If FDA premarket review is mandated, there is no assurance that our tests will receive clearance or approval in a timely manner, or even at all. Additionally, there is no guarantee that the labeling claims approved by the FDA will align with our current claims or be sufficient to support the ongoing acceptance and reimbursement of our products. Ongoing compliance with FDA regulations may escalate our business costs, expose us to FDA inspections and other regulatory measures, and potentially result in penalties if we fail to adhere to these requirements.

The FDCA categorizes medical devices into three classes based on their associated risks and the level of control required to ensure safety and effectiveness. Class I devices, characterized by low risk, are subject solely to general regulatory controls. Class II devices, posing moderate risks, are subject to both general controls and, potentially, special controls. Class III devices, representing the highest level of risk, must obtain premarket approval and adhere to postmarket conditions in addition to complying with general regulatory controls.

Typically, establishments engaged in the design and/or manufacturing of devices are obligated to register their facilities with the FDA. They are also required to furnish the FDA with a comprehensive list of the devices designed and/or manufactured within their facilities.

The FDA enforces its regulations through market surveillance and periodic inspections, which may be announced or unannounced. These inspections encompass the examination of records, equipment, facilities, laboratories, and processes to verify compliance with regulatory requirements. These inspections may extend to the facilities of subcontractors as well. Subsequent to an inspection, the FDA may issue a report, referred to as a Form 483 notice of observations, detailing instances where the manufacturer has failed to meet applicable regulations and/or procedures. The FDA may also release a public warning letter. In cases where a manufacturer does not adequately address a Form 483 notice or warning letter, the FDA may take enforcement actions against the manufacturer, imposing sanctions or consequences that could include:

- Issuing cease and desist orders.
- Implementing injunctions or consent decrees.
- Imposing civil monetary penalties.
- Initiating recalls, detentions, or seizures of products.
- Imposing operational restrictions or partially or completely shutting down production facilities.
- Refusing or delaying the granting of requests for 510(k) clearance, de novo classification, or premarket approval for new or modified products.
- Withdrawing previously granted 510(k) clearances, de novo classifications, or premarket approvals.

- Refusing to grant export approval or export certificates for devices.
- Pursuing criminal prosecution as deemed necessary.

Premarket Authorization and Notification

While many Class I devices and some Class II devices can be marketed in the U.S. without prior FDA authorization, most Class II devices and nearly all Class III medical devices can only be legally sold within the U.S. if the FDA has taken one of the following actions:

(i) Granted approval for a Pre-Market Approval, or "PMA" application before marketing, a requirement generally applicable to most Class III devices.

(ii) Issued clearance for the device in response to a premarket notification, commonly referred to as a "510(k) submission," a necessity for some Class I devices and most Class II devices.

(iii) Authorized the device for market entry through the de novo classification process, which is typically applicable for novel devices with low to moderate risks.

It is important to note that the submission of PMA applications, 510(k) premarket notifications, and de novo requests entails the payment of user fees.

510(k) Premarket Notification

In the United States, the marketing of most Class II devices and a limited subset of Class I devices typically follows the 510(k) premarket notification pathway. To secure 510(k) clearance, manufacturers must submit a premarket notification demonstrating that the proposed device is substantially similar to a legally marketed device, known as the "predicate device." The predicate device can be a previously cleared 510(k) device, a Class III device that entered commercial distribution before May 28, 1976 (for which the FDA has not requested a PMA application), or a product that received a Class II or Class I classification through the de novo classification process. Manufacturers must establish that the proposed device shares the same intended use as the predicate device and either possesses identical technological characteristics or, if different, is proven to be equally safe and effective without raising distinct safety or effectiveness concerns compared to the predicate device.

The FDA aims to complete the 510(k)-review process within 90 calendar days, but this timeline may be paused if the FDA issues an Additional Information request, with a maximum response period of 180 days. During the COVID-19 Public Health Emergency, companies were granted an additional 180 days to respond, making the potential total review time up to 270 days, though it may practically take longer.

Once a device obtains 510(k) clearance, any significant modification that could impact its safety or effectiveness or represents a major change in its intended use necessitates either a new 510(k) clearance, potential PMA approval, or de novo classification. Initially, the manufacturer is responsible for making this determination, but the FDA retains the authority to review such decisions. If the FDA disagrees with the manufacturer's choice not to seek a new 510(k) clearance for the modified device, the agency may retroactively require the manufacturer to pursue 510(k) clearance, de novo classification, or PMA approval. Additionally, the FDA can mandate the manufacturer to halt marketing and/or recall the modified device until it obtains 510(k) clearance or PMA approval.

De Novo Classification

Devices that are of a new type and have not been previously categorized by the FDA based on their risk level are automatically assigned to Class III, regardless of their actual risk level. To prevent the necessity of subjecting novel, low- to moderate-risk devices in Class III to a PMA review by default, Congress introduced a provision that empowers the FDA to reclassify such devices into Class I or II when there is no predicate device available to support a 510(k) clearance. The FDA assesses the safety and effectiveness of devices submitted for review through this de novo

pathway, and devices categorized as Class II can subsequently serve as predicate devices for future 510(k) applications. The de novo pathway may require the submission of clinical data.

The FDA sets a user fee goal for reviewing de novo requests within 150 calendar days. During the review process, the FDA may issue an Additional Information request, which pauses the review timeline. Applicants are granted 180 days to respond. Consequently, the total review period could extend up to 330 days, and in practice, it may take even longer. During the COVID-19 Public Health Emergency, applicants have been provided an additional 180 days to respond.

PMA Approval

Typically, a Class III product must undergo the PMA pathway. This PMA process necessitates the submission of substantial and valid scientific evidence, including data from clinical studies, to establish the safety and effectiveness of the device for its intended use(s). After comprehensive testing, a PMA application, comprising data from non-clinical and clinical studies, along with information on the device's marketing history, design, labeling, manufacturing, and controls, is compiled and submitted to the FDA.

The PMA approval process is generally more demanding, lengthy, expensive, and uncertain in comparison to the 510(k) premarket notification process and the de novo classification process. It requires the presentation of compelling evidence regarding the device's safety and effectiveness to satisfy the FDA. During the PMA review, the FDA typically conducts inspections of the manufacturer's facilities to assess compliance with the Quality System Regulation (QSR) requirements. These requirements encompass comprehensive testing, control, documentation, and other stringent quality assurance procedures.

The FDA sets a user fee goal for PMA review, targeting 180 calendar review days for submissions not requiring advisory committee input, or 320 review days for those requiring such input. The review timeline may be paused if the FDA issues a major deficiency letter, for which the applicant has up to 180 days to respond. Consequently, the total review period may extend up to 360 days (for submissions not needing advisory committee input) or 500 days (for those requiring advisory committee input), and in practice, it may take even longer. The COVID-19 pandemic has increased the FDA's workload due to the need to review emergency use authorization requests for In Vitro Diagnostic Devices (IVDs) and other regulated products, resulting in delays for some non-COVID-19 products.

Should the FDA's evaluation of the PMA application yield a favorable outcome, the FDA will grant a PMA for the approved indications, which may be more limited than initially sought by the manufacturer. The PMA may include post-approval conditions deemed necessary by the FDA to ensure the device's safety and effectiveness. These conditions could involve constraints on labeling, promotion, sale, distribution, or the requirement for postmarket surveillance or completion of postmarket studies. Non-compliance with these approval conditions can lead to significant enforcement actions, including the withdrawal or loss of approval and/or the imposition of sales restrictions on the device until the conditions are met.

Even after obtaining PMA approval, modifications to the device, its labeling, or its manufacturing process may necessitate a new PMA or PMA supplement. Supplements to a PMA typically entail the submission of similar information as required for an original PMA, albeit limited to the information relevant to supporting the proposed changes from the product covered by the initial PMA.

Clinical Trials

In general, the support for a PMA application typically involves the requirement of at least one clinical trial. Clinical studies may also be necessary for de novo classification or a 510(k) premarket notification. Furthermore, clinical trials may be conducted or continued to meet post-approval obligations for devices with PMAs. For investigational device studies involving significant risks, FDA regulations mandate that human clinical investigations conducted in the U.S. must be carried out under an approved investigational device exemption, or “IDE”. An IDE application is deemed approved within 30 days of FDA receipt, unless the FDA informs the sponsor otherwise, either by approving it,

approving it with conditions, or disapproving it. Nonsignificant risk investigational device studies do not necessitate FDA approval of an IDE. Certain types of device studies, including many IVD studies, are entirely exempt from IDE requirements.

All clinical trials, whether involving significant or nonsignificant risk devices, as well as exempt studies, must adhere to the principles of good clinical practice outlined in federal regulations and international guidelines. Additionally, clinical trials require approval from an institutional review board, or IRB, a formally designated body responsible for reviewing and overseeing biomedical research involving human subjects. The IRB has the authority to approve, request modifications to, or disapprove research to safeguard the rights, safety, and well-being of human research subjects.

The FDA retains the authority to order the temporary or permanent suspension of a clinical trial at any point or impose other penalties if it deems the trial to be in violation of FDA requirements or if it poses an unacceptable risk to the patients involved in the trial. Similarly, an IRB may instruct the temporary or permanent cessation of a clinical trial it has approved due to non-compliance with its stipulations or impose other conditions or penalties.

Although the Quality System Regulation, or QSR does not fully apply to investigational devices, the requirement for controls during the design and development stages does apply. Additionally, the sponsor must manufacture the investigational device in accordance with the quality controls detailed in the IDE application and any conditions of IDE approval imposed by the FDA with regard to manufacturing.

Postmarket Requirements

Once a device is available on the market, it becomes subject to a range of general regulatory controls. These encompass:

1. The QSR
2. Labeling regulations
3. Medical device reporting regulations, which necessitate manufacturers to inform the FDA if their device may have caused or contributed to a death, serious injury, or malfunctions likely to cause such outcomes if they were to recur.
4. Regulations concerning reports of corrections and removals, which mandate manufacturers to report recalls, removals, and field corrections to the FDA if initiated to mitigate health risks posed by the device or to rectify a violation of the FDCA.

Failure to appropriately identify reportable incidents or submit timely reports, as well as the inability to address the FDA's concerns to its satisfaction, can expose manufacturers to warning letters, recalls, and other forms of sanctions and penalties.

Moreover, advertising, marketing, and promotional activities related to devices are subject to FDA oversight and must adhere to the statutory standards set forth in the FDCA and the FDA's implementing regulations.

Manufacturers of medical devices are allowed to promote their products solely for the uses and indications specified in the approved or cleared product labeling. Actions have been taken against manufacturers who promote products for "off-label" uses, which refers to uses not described in the approved or cleared labeling.

Violations of the FDCA related to improper promotion of medical devices may also result in investigations alleging breaches of federal and state healthcare fraud and abuse laws, as well as other regulations, along with state consumer protection laws.

For devices with PMA, Class II 510(k), or de novo classifications, the FDA may also mandate postmarketing testing, surveillance, or other measures to monitor the effects of an approved or cleared product. The FDA might impose conditions on a PMA-approved device that limit its distribution or use. Furthermore, manufacturers must continue to ensure that their quality control, manufacturing, packaging, and labeling procedures align with the QSR after approval or clearance, and they remain subject to periodic inspections by the FDA. Consequently, manufacturers must continue to invest resources, including time and money, in production and quality control to maintain compliance with the QSR and other applicable regulatory requirements. Failure to comply with regulatory demands could lead to the withdrawal of product approvals or result in the FDA recommending or requiring product recalls.

Clinical Trial Information Disclosure

Sponsors conducting clinical trials of FDA-regulated products, including drug products, must adhere to the requirement of registering and disclosing specific clinical trial information on the website www.clinicaltrials.gov. This registration includes details about the product, patient demographics, investigation phase, trial locations, investigators involved, and various other aspects of the clinical trial. This information is subsequently made accessible to the public.

Sponsors also have an obligation to share the results of their completed clinical trials. However, under certain circumstances, the disclosure of these results may be delayed for up to two years after the trial's completion date. Competitors may utilize this publicly available information to gather insights into the progress of clinical development programs and the design of clinical trials.

HIPAA and Other Privacy Regulations

The Health Insurance Portability and Accountability Act of 1996, as amended by the Health Information Technology for Economic and Clinical Health Act, or HIPAA, established comprehensive safeguards for the privacy and security of healthcare information. These HIPAA standards are applicable to three categories of organizations known as "Covered Entities": health plans, healthcare clearinghouses, and healthcare providers that conduct specific healthcare transactions electronically. Covered Entities, along with their business associates, are required to implement administrative, physical, and technical measures to protect against the improper use of personally identifiable health data. Our activities may fall under HIPAA's purview, as we embark on providing clinical laboratory testing services and engage in certain relationships with Covered Entities and their business associates. Violations of HIPAA can result in civil and criminal penalties.

In addition to HIPAA, our operations must also adhere to other pertinent privacy laws, which impose limitations on accessing, using, and disclosing personal information. Numerous state and international privacy regulations have been enacted, with many state laws not preempted by HIPAA, either because they are more rigorous or have a broader scope than HIPAA. One such regulation is the California Consumer Privacy Act of 2018, or CCPA, which includes expansions and amendments under the California Privacy Rights Act, effective as of January 1, 2023. CCPA safeguards personal information that falls outside the scope of HIPAA and grants California consumers specific data access, erasure, and restriction rights, particularly for sensitive personal information. Similar state laws have also been passed in Utah, Colorado, Virginia, and Connecticut. Furthermore, compliance with international, national, and provincial data protection laws and regulations is mandatory, including the European Union's General Data Protection Regulation, or “GDPR”. These regulations are highly prescriptive and grant significant authority to public bodies to penalize and halt the use of personal data. Adherence to the GDPR and other related national or provincial laws, both within and outside Europe, necessitates substantial efforts and expenses to ensure compliance. These laws may have an impact on our operations and are subject to periodic changes, which could potentially harm our business operations. Failure to comply with these privacy laws or significant modifications in the laws that restrict our ability to obtain patient samples and associated patient information may have a significant impact on our business, potentially leading to a temporary inability to offer tests to patients in the European Union or other markets.

European Union Regulation

To sell a medical device or diagnostic test in the EU, it must bear the CE mark. The EU's In Vitro Diagnostic Regulation, or "IVDR", outlines the prerequisites for obtaining the CE mark for in vitro diagnostic tests and medical devices in the EU. Manufacturers of these tests and devices must ensure compliance with all relevant regulatory requirements specified in the IVDR. Prior to introducing a test to the EU market, the manufacturer must provide substantiating evidence demonstrating compliance with these requirements.

Manufacturers are mandated to establish a comprehensive Quality Management System ("QMS") and implement processes for various activities, including manufacturing, importation, distribution, post-market surveillance, and vigilance. Additionally, rigorous documentation of the product is essential. Furthermore, it is highly likely that our test falls into a risk category necessitating a review by an external entity known as a "Notified Body" before the test can be placed on the EU market. This review process is anticipated to take an additional 6-12 months following the establishment of the requisite documents and systems. It is important to note that there is currently a shortage of designated Notified Bodies for IVDR devices in the EU, which could extend the time required for the review process. Additionally, we will be required to engage a European Authorized Representative, or "EAR", who will act as the legal representative of our Company within the EU. Medical devices must also be registered with the competent authority in the country where they are based. In addition to obtaining the CE mark and the EAR's registration, administrative notifications with specific EU member states are necessary.

European Data Collection

The gathering and utilization of personal data, including health data, within the European Economic Area (EEA), are subject to regulation by the EU General Data Protection Regulation and corresponding national laws in EEA Member States. The EU GDPR is applicable to businesses established within the EEA, as well as to entities outside the EEA that process personal data linked to offering goods or services to EEA data subjects or monitoring the behavior of EEA data subjects.

The EU GDPR imposes stringent prerequisites on the handling of personal data, encompassing rigorous conditions for obtaining data subjects' consent, increased transparency regarding data usage, mandatory assessments for "high-risk" data processing, limitations on data retention, specific provisions for "special categories of personal data" such as health and genetic information, mandatory reporting of data breaches under certain circumstances, requirements for implementing "privacy by design," and direct obligations for service providers acting as data processors.

Moreover, the EU GDPR prohibits the international transfer of personal data from the EEA to non-EEA countries unless the recipient country is considered to have adequate data privacy laws approved by the European Commission or if a data transfer mechanism is established. Non-compliance with EU GDPR and related national data protection laws in EEA Member States may result in significant fines, reaching up to 20 million euros or 4% of a company's global annual revenue for the preceding financial year, whichever is higher.

Furthermore, the EU GDPR grants individuals various data protection rights, including the right to request the erasure of personal data in specific circumstances, as well as the ability for data subjects to claim both material and non-material damages stemming from EU GDPR infringements. Given the extensive and comprehensive nature of the changes in data protection obligations, maintaining compliance with the EU GDPR will demand substantial investments of time, resources, and finances. Additional measures may also be necessary to ensure ongoing compliance with evolving data protection regulations. This could impose burdens and potentially have adverse effects on our business, financial standing, operational outcomes, and prospects.

Rest of the World Regulation

In countries beyond the EU (or in some cases, EEA) and the United States, such as Japan, India, and Australia, the rules governing the execution of clinical trials, product licensing, pricing, and reimbursement can differ significantly from one nation to another. Furthermore, these clinical trials must adhere to Good Clinical Practice, or "GCP", standards, meet the relevant regulatory prerequisites, and adhere to ethical principles rooted in the Declaration of

Helsinki. Failure to adhere to the pertinent foreign regulatory criteria could potentially result in various consequences, including but not limited to fines, the suspension or revocation of regulatory approvals, product recalls, confiscation of products, operational restrictions, and even criminal prosecution.

RISK FACTORS

A crowdfunding investment involves risk. You should not invest any funds in this offering unless you can afford to lose your entire investment.

In making an investment decision, investors must rely on their own examination of the issuer and the terms of the offering, including the merits and risks involved. These securities have not been recommended or approved by any federal or state securities commission or regulatory authority. Furthermore, these authorities have not passed upon the accuracy or adequacy of this document.

The U.S. Securities and Exchange Commission does not pass upon the merits of any securities offered or the terms of the offering, nor does it pass upon the accuracy or completeness of any offering document or literature.

These securities are offered under an exemption from registration; however, the U.S. Securities and Exchange Commission has not made an independent determination that these securities are exempt from registration.

8. **Discuss the material factors that make an investment in the issuer speculative or risky:**

Investing in Securities involves a high degree of risk and may result in the loss of your entire investment. Before making an investment decision with respect to the Securities, we urge you to carefully consider the risks described in this section and other factors set forth in this Form C. In addition to the risks specified below, the Issuer is subject to the same risks that all companies in its business, and all companies in the economy, are exposed to. These include risks relating to economic downturns, political and economic events and technological developments (such as hacking and the ability to prevent hacking). Additionally, early-stage companies are inherently riskier than more developed companies. Prospective Investors should consult with their legal, tax and financial advisors prior to making an investment in the Securities. The Securities should only be purchased by persons who can afford to lose all of their investment.

Risks Related to Our Business and Industry

We are a breath diagnostics company with a limited operating history, which makes it difficult to evaluate our current business and future prospects.

We are a company with limited operating history, and our operations are subject to all of the risks inherent in establishing a new business enterprise. We have not yet commercially launched our first cancer diagnostic test and to date have generated no revenue. The likelihood of our success must be considered in light of the problems, expenses, difficulties, complications, and delays frequently encountered in connection with the formation of a new business, the development of new technologies and those subject to clinical testing, and the competitive and regulatory environment in which we will operate. To date, we have not generated any revenue from the OneBreath test. There can be no assurance that we will be able to successfully begin our commercialization efforts or that we will obtain the necessary regulatory approvals that will allow us to expand our marketing efforts. We may not be able to receive certification of our OneBreath test as a Laboratory Developed Test, or "LDT", in accordance with CAP/CLIA guidance and regulations or obtain approval of our diagnostic tests in development by the CMS, the FDA, European Medicines Agency, or Chinese National Medical Products Administration. Even if we do so and are also able to commercialize our diagnostic tests, we may never generate revenue sufficient to become profitable. Our failure to generate revenue and profit would likely cause our securities to decrease in value or become worthless.

We have incurred losses since our inception, and we may not be able to manage our business on a profitable basis.

We have generated losses since inception and have relied on cash on hand, sales of securities, external bank lines of credit, grants, and issuance of third-party and related party debt to support our operations. For the year ended December 31, 2023, we generated an operating loss of $932,824 and a net loss of $1,077,002. For the year ended December 31, 2024 we generated an operating loss of $819,321 and a net loss of $941,466. The revenue and income potential of our business and the market for our product are unproven. This makes an evaluation of our Company and its prospects difficult and highly speculative. There can be no assurances that we will be able to develop products or services on a timely and cost effective basis, that will be able to generate any increase in revenues, that we will have

adequate financing or resources to continue operating our business and to provide products to customers, that we will earn a profit, that we can raise sufficient capital to support operations by attaining profitability, or that we can satisfy future liabilities.

We will spend a substantial amount of our capital on test validation, biomarker and data acquisitions, and data analytics development, but our products might not succeed in gaining widespread market acceptance.

We have developed and will continually refine new biomarker test panels for our diagnostic test. The main focus of our product is on early detection of lung cancer. Our technology may not prove to be sufficiently efficacious or medically useful to gain widespread adoption or market share. The OneBreath diagnostic test that we plan to introduce to the market is still in the developmental stage and is not currently available on the market; thus, it has not yet generated any revenues for our Company. Without diagnostic test sales or revenues, we will not be able to operate at a profit, and we will not be able to cover our operating expenses without raising additional capital.

Medical organizations, physicians and employers may be reluctant to try a new diagnostic test due to the high degree of risk associated with the application of new technologies and diagnostic tests in the field of human medicine, especially if the new test differs from the current standard of care for detecting cancer in patients. Competing tests for the screening or initial diagnosis of lung cancer are being developed by more established and significantly better financed diagnostics or biotech companies and by academic laboratories.

There also is a risk that our competitors may succeed in developing more accurate or more cost-effective diagnostic tests that could render our diagnostic tests and technologies obsolete or noncompetitive. Even if our tests are technically superior, we may not be able to differentiate our products sufficiently from our competition.

We will require additional financing to accomplish our business strategy.

We will require substantial working capital to fund our business development plans, and we expect to experience significant negative cash flow from operations. We also anticipate the possibility of having to raise additional funds in order to achieve our plans and accomplish our immediate and longer-term business strategy. These additional funds may likely be raised through the issuance of our securities in debt and/or equity financings. If we are unable to raise these additional funds on terms acceptable to us, we will be required to limit our expenditures for our product development activities and our sales and marketing operations or to find alternatives to fund our business on terms that are not as favorable to us. Any such actions would impair our product development and expansion plans, reduce potential revenues, increase operating losses, and adversely affect the value of our Company.

Our revenues will depend almost entirely on continued successful testing, approvals and marketing of our OneBreath lung cancer test and, potentially, the development of additional new tests for other diseases or chronic conditions. The commercial success and our ability to generate revenues will depend on a variety of factors, including the following:

- competitive advantages;
- successful continued testing of the OneBreath test;
- receipt of all necessary regulatory certifications and approvals for the OneBreath test in the U.S. and other potential markets;
- patient acceptance of and demand for our tests;
- acceptance in the medical community;
- successful sales, marketing, and educational programs, including successful direct-to-patient marketing such as online advertising;
- the amount and nature of competition from other similar cancer screening products and procedures;
- the ease of use of our ordering process for physicians;

- maintenance of relevant patent protection of our intellectual property; and
- our ability to establish and maintain adequate commercial manufacturing, distribution, sales and CLIA laboratory testing capabilities.

If we are unable to develop and maintain substantial sales of our tests or if we are significantly delayed or limited in doing so, our business prospects, financial condition and results of operation will be adversely affected.

The success of our OneBreath diagnostic test depends on the degree of market acceptance by physicians, patients, government agencies and others who influence medical decision making.

The value of our OneBreath diagnostic product is largely unproven as it has not been sold; and there is no assurance that real world evidence or future clinical results will be sufficient to gain wide acceptance by the medical establishment or regulators in the countries in which we conduct business.

Our OneBreath test and any future diagnostics tests that we develop may not gain market acceptance by physicians and others in the medical community. The degree of market acceptance of our OneBreath test will depend on a number of factors, including:

- demonstrated sensitivity and specificity for detecting lung cancer;
- price;
- the availability and attractiveness of alternative screening methods;
- the willingness of physicians to recommend or prescribe our tests;
- the ease of use of our ordering process for physicians; and
- evidence that our tests confer a mortality benefit rather than merely shifting the stage of cancer at time of diagnosis.

If our diagnostics tests do not achieve an adequate level of acceptance, we may not generate the substantial revenues we need to generate in order to remain profitable.

If our OneBreath diagnostic tests do not perform as expected, are misused or misinterpreted, or the reliability of the technology is questioned, we could experience delayed or reduced market acceptance of the tests, increased costs, and damage to our reputation. False positives or false negatives could cause harm to patients and could result in action taken against our Company.

Our success depends on our ability to provide reliable, high-quality lung cancer diagnostic tests. As of now, we have not sold the OneBreath tests to the public or provided such tests to the market. We believe that customers are likely to be particularly sensitive to product defects and errors. Our reputation and the public image of our lung cancer diagnostic OneBreath test may be impaired if it fails to perform as expected or is perceived as difficult to use. Despite clinical verification studies, quality control and quality assurance testing, defects or errors could occur with tests.

In the future, if our diagnostic tests experience a material defect or error, this could result in loss or delay of revenues, damaged reputation, diversion of development resources, legal claims and increased insurance costs, any of which could harm our business. Such defects or errors could also prompt us to amend certain warning labels or narrow the scope of the use of our diagnostic tests, either of which could hinder our success in the market. Even after any underlying concerns or problems are resolved, any widespread concerns regarding our technology or any manufacturing defects or performance errors in the tests could result in lost revenue, delayed market acceptance, damaged reputation, increased costs and claims against us.

Our inability to manage growth could harm our business.

We expect to add additional personnel in the areas of sales and marketing, laboratory operations, billing and collections, quality assurance and compliance. As we develop our commercialization efforts and expand research and development activities, the scope and complexity of our operations will increase significantly. As a result of such growth, we expect that our operating expenses and capital requirements will also increase significantly. Our ability to manage our growth effectively requires us to forecast expenses accurately, and to properly forecast and expand operational and testing facilities, if necessary, to expend funds to improve our operational, financial and management controls, our reporting systems and our procedures. As we move forward to begin commercializing our tests, we will also need to effectively manage our growing manufacturing, laboratory operations and sales and marketing needs. If we are unable to manage our anticipated growth effectively, our business could be harmed.

Our suppliers may experience development or manufacturing problems or delays that could delay our clinical testing and clinical approval process prior to commercialization.

We may encounter unforeseen situations in the development and manufacturing of our diagnostic tests that could result in delays or shortfalls in production. Suppliers may also face similar delays or shortfalls. In addition, suppliers' production processes may have to change to accommodate any significant future expansion of manufacturing capacity, which may increase suppliers' manufacturing costs, delay production of our diagnostic tests, delay our ability to receive clinical approvals, and adversely impact our business.

The sizes of the markets for our OneBreath test and any future diagnostic tests and services may be smaller than we estimate and may decline.

Our estimates of the annual total addressable market for our OneBreath tests are based on a number of internal and third-party estimates and assumptions, including, without limitation, the assumed prices at which we can sell our products in the market. While we believe our assumptions and the data underlying our estimates are reasonable, these assumptions and estimates may not be correct and the conditions supporting our assumptions or estimates may change at any time, thereby reducing the predictive accuracy of these underlying factors. As a result, our estimates of the annual total addressable market for our products in different market segments may prove to be incorrect. If the actual number of patients who would benefit from our diagnostic tests, the price at which we can sell them or the annual total addressable market for them is smaller than we have estimated, it may impair our sales growth and negatively affect our business, financial condition and results of operations.

The success of our business is substantially dependent upon the efforts of our senior management team and our ability to attract additional personnel.

Our success depends largely on the skills, experience, and performance of key members of our senior management team who are critical to directing and managing our growth and development in the future. Our success is substantially dependent upon our senior management's ability to lead our Company, implement successful corporate strategies and initiatives, develop key relationships, including relationships with collaborators and business partners, and successfully commercialize products and services. While our management team has significant experience developing diagnostic products, we have considerably less experience in commercializing these products or services. The efforts of our management team will be critical to us as we develop our technologies and seek to commercialize our tests and other products and services.

Our success also depends in large part on our ability to attract and retain managerial personnel. Competition for desirable personnel is intense, and there can be no assurance that we will be able to attract and retain the necessary staff. The failure to maintain management or to attract sales personnel could materially adversely affect our business, financial condition, and results of operations.

Risks Related to our Diagnostic Tests

Until we secure LDT certification or FDA clearance for our OneBreath test, our marketing efforts are limited.

In order to market and begin to commercialize the OneBreath test, we will need to have appropriate certifications for the sale of our test, which we may never receive. If we fail to obtain such a certification, we will not be able to market and sell the OneBreath test.

To market our OneBreath test, we must receive the proper designation classification as a medical device from the FDA. We intend to launch a pivotal trial in 2026/2027 in an effort to attain such classification; however, there can be no assurance that the trial will have favorable results or that it will generate the results necessary to obtain such classification. Until such time as we receive an FDA classification, which we may never receive, our marketing efforts will be limited to any other existing certification that we are able to obtain.

In parallel to seeking classification as a medical device, we may pursue offering the OneBreath test as a Laboratory Developed Test ("LDT") through a CLIA-certified laboratory. Under the Clinical Laboratory Improvement Amendments ("CLIA"), a laboratory may develop, validate, and offer an in-house diagnostic assay as an LDT if it performs the test entirely within that single laboratory. While this approach could enable us to begin limited commercialization of the OneBreath test before receiving FDA medical device classification, the regulatory landscape for LDTs is evolving. See "*Laboratory Developed Tests*" for more information.

Based on a recent federal court ruling on March 31, 2025, which vacated the FDA's final rule which attempted to regulate Laboratory Developed Tests (LDTs) as medical devices, the FDA's proposed plan to phase out enforcement discretion for LDTs has been invalidated. As a result, the FDA currently lacks the authority to enforce such regulations under the Federal Food, Drug, and Cosmetic Act (FDCA). However, if the lower court's ruling is overturned on appeal or if new legislation is enacted that explicitly grants the FDA regulatory authority over LDTs or imposes additional requirements, we may still be required to seek FDA clearance or approval even for tests offered as LDTs.

We are very early in our development efforts and are substantially dependent on our only product, the OneBreath diagnostic test.

We are very early in our development efforts. Our OneBreath diagnostic test is still in pre-clinical development. Our ability to generate product revenues, which we do not expect will occur for many years, if ever, will depend heavily on the successful clinical development and eventual commercialization of our only current diagnostic test, the OneBreath test. The success of our lead product will depend on several factors, including the following:

- successful completion of pre-clinical studies;
- approval for our planned clinical trials or future clinical trials;
- successful initiation of clinical trials;
- successful patient enrollment in and completion of clinical trials; and
- efficacy profiles for our product that are satisfactory to the FDA or any other regulatory authority for marketing approval;

There is no guarantee that the results obtained in future pre-clinical trials of the OneBreath test will be sufficient to obtain regulatory approval or marketing authorization for it. Negative results in the development of our test may also impact our ability to obtain regulatory approval for any enhanced or future tests, either at all or within anticipated timeframes because there would be certain similarities in the underlying technology platform for all of our future products. Accordingly, a failure for any one product may affect the ability to obtain regulatory approval to continue or conduct clinical programs for other products.

In addition, because we have limited financial and personnel resources and are placing significant focus on the development of our lead product, we may forgo or delay pursuit of opportunities with other future products that later prove to have greater commercial potential. Our spending on current research and development programs may not yield any commercially viable future products.

If we do not achieve our projected development and commercialization goals in the timeframes we announce and expect, the commercialization of our OneBreath diagnostic test may be delayed, and our business will be harmed.

We sometimes estimate the timing of the accomplishment of various scientific, clinical, regulatory, and other product development objectives or milestones for planning purposes. These milestones may include our expectations regarding the commencement or completion of scientific studies and clinical trials, the submission of regulatory filings, or commercialization objectives. From time to time, we may announce the expected timing of some of these milestones, such as the completion of an ongoing clinical trial, the initiation of other clinical programs, receipt of regulatory approval, or a commercial launch of a product. The achievement of many of these milestones may be outside of our control. All of these milestones are based on a variety of assumptions which may cause the timing of achievement of the milestones to vary considerably from our estimates, including:

- our available capital resources or capital constraints we experience;
- our receipt of approvals, if any, by the FDA and other comparable foreign regulatory authorities and the timing thereof;
- the rate of progress, costs and results of our clinical trials and research and development activities, including the extent of scheduling conflicts with participating clinicians and collaborators, and our ability to identify and enroll patients who meet clinical trial eligibility criteria;
- other actions, decisions or rules issued by regulators;
- our ability to access sufficient, reliable and affordable supplies of compounds used in the manufacture of our diagnostic tests;
- the efforts of our collaborators with respect to the commercialization of our products; and
- the securing of, costs related to, and timing issues associated with, product manufacturing, as well as sales and marketing activities.

If we fail to achieve announced milestones in the timeframes we expect, the commercialization of our diagnostic test may be delayed, and our business and results of operations may be harmed.

If we experience delays or difficulties in the enrollment of patients in clinical trials, our receipt of necessary regulatory approvals could be delayed or prevented.

We may not be able to initiate clinical trials if we are unable to locate and enroll a sufficient number of eligible patients to participate and remain in these trials as required by the FDA or similar regulatory authorities outside the United States, such as the European Medicines Agency.

Patient enrollment is affected by many other factors, including:

- the severity of the disease under investigation;
- the patient eligibility criteria for the study in question;
- the efforts to facilitate timely enrollment in clinical trials;
- our payments for conducting clinical trials; and
- the patient referral practices of physicians.

We are unable to forecast with precision our ability to enroll patients. Our inability to enroll a sufficient number of patients for our clinical trials would result in significant delays and could require us to abandon one or more clinical trials altogether. Enrollment delays in our clinical trials may result in increased development costs, which would cause the value of our Company to decline and limit our ability to obtain additional financing.

Legislative or regulatory reforms in the United States may make it more difficult and costly for us to obtain regulatory clearances or approvals for our products or to manufacture, market or distribute our products after clearance or approval is obtained. Additionally, unpredictability within the U.S. regulatory agencies may result in unforeseen delays and costs.

From time to time, legislation is drafted and introduced in Congress that could significantly change the statutory provisions governing the regulatory clearance or approval, manufacture and marketing of regulated products or the reimbursement thereof. In addition, the FDA regulations and guidance are often revised or reinterpreted by the FDA in ways that may significantly affect our business and our products. Currently, there is ongoing upheaval and uncertainty within U.S. regulatory agencies, which could lead to unpredictable delays and heightened scrutiny of our operations. Any new regulations or revisions or reinterpretations of existing regulations may impose additional costs or lengthen review times of our products. We cannot determine what effect changes in regulations, statutes, legal interpretation or policies, when and if promulgated, enacted or adopted may have on our business in the future. Such changes could, among other things, require:

- changes to manufacturing methods;
- changes in protocol design;
- recall, replacement, or discontinuance of one or more of our products; and
- additional recordkeeping.

Adverse market, economic and political conditions, recent trade disputes and other events or circumstances beyond our control could have a material adverse effect on us.

Another economic or financial crisis or rapid decline of the consumer economy, significant concerns over energy costs, geopolitical issues, including the ongoing conflict between Ukraine and Russia, recent events in the Middle East, recent trade disputes between the U.S. and other countries resulting in the imposition of increased tariffs on products imported into the U.S., and the availability and cost of credit can contribute to increased volatility, diminished expectations for the economy and the markets, and high levels of structural unemployment by historical standards. Market, political and economic challenges, including dislocations and volatility in the credit markets, general global economic uncertainty, uncertainty or volatility from matters such as the implementation of the governing agenda of President Donald J. Trump, and changes in governmental policy on a variety of matters such as trade, tariffs and manufacturing policies may adversely affect the economy and financial markets, our financial condition, results of operations, and the trading price of our ordinary shares.

Changes to U.S. trade policy, tariff and import/export regulations may adversely affect our operating results.

The United States has recently enacted and/or proposed to enact significant new tariffs on goods imported from numerous countries, including our suppliers. Additionally, President Trump has directed various federal agencies to further evaluate key aspects of U.S. trade policy and there has been ongoing discussion and commentary regarding potential significant changes to U.S. trade policies, treaties and tariffs. There continues to exist significant uncertainty about the future relationship between the U.S. and other countries with respect to such trade policies, treaties and tariffs.

If the U.S. continues to impose new tariffs, this may cause supply chain disruptions and could further escalate our costs. We may determine to increase our sales prices in order to pass these increased costs to our customers. In the event we determine to pass increased costs to our customers, our customers may reduce their orders from us, which

could negatively affect our business, profitability and operating results. We are closely monitoring these developments and evaluating strategies to mitigate potential impacts.

Furthermore, as a result of policy changes and government proposals, there may be greater restrictions and economic disincentives on international trade in general. The new tariffs and other changes in U.S. trade policy could trigger retaliatory actions by affected countries, and foreign governments have instituted or are considering imposing trade sanctions on U.S. goods. Such changes have the potential to adversely impact the U.S. economy or sectors thereof, our industry and the demand for our products, and as a result, could have a negative impact on our business, financial condition and results of operations.

Interim top-line and preliminary data from studies or trials that we announce or publish from time to time may change as more data become available and are subject to audit and verification procedures that could result in material changes in the final data. Adverse differences between preliminary or interim data and final data could materially harm our business, financial condition, results of operations and prospects.

From time to time, we may publish interim top-line or preliminary data from pre-clinical studies or clinical trials. Interim data are subject to the risk that one or more of the outcomes may materially change as more data become available. We may also make assumptions, estimations, calculations and conclusions as part of the analyses of data, and we may not have received or had the opportunity to fully evaluate all data. As a result, the top-line results that we report may differ from future results of the same studies, or different conclusions or considerations may qualify such results, once additional data have been received and fully evaluated. Preliminary or top-line data also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data we previously published. As a result, interim and preliminary data should be viewed with caution until the final data are available. Additionally, interim data from clinical trials that we may complete are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data become available. Adverse differences between preliminary or interim data and final data could materially harm our business prospects.

Further, regulatory agencies may not accept or agree with our assumptions, estimates, calculations, conclusions or analyses or may interpret or weigh the importance of data differently, which could impact the value of the particular program, the approvability or commercialization of the particular product and our Company in general. In addition, the information we choose to publicly disclose regarding a particular study or clinical trial is based on what is typically extensive information, and you or others may not agree with what we determine is the material or otherwise appropriate information to include in our disclosure. Any information we determine not to disclose may ultimately be deemed significant by you or others with respect to future decisions, conclusions, views, activities or otherwise regarding a particular product or our business. If the top-line data that we report differ from actual results, or if others, including regulatory authorities, disagree with the conclusions reached, our ability to obtain approval for, and commercialize, our diagnostic test may be harmed, which could significantly harm our business prospects.

If clinical testing of OneBreath does not yield successful results, then we will be unable to commercialize that test candidate.

We must demonstrate the product efficacy of our candidate, the OneBreath test, for diagnostic tests in humans through extensive clinical testing. Our research and development programs are at an early stage of development. We may experience numerous unforeseen events during, or as a result of, the testing process that could delay or prevent commercialization of any test or product, including the following:

- the results of pre-clinical studies using our OneBreath test may be inconclusive, or they may not be indicative of results that will be obtained in human clinical trials;

- efficacy results attained in early human clinical trials may not be indicative of results that are obtained in later clinical trials;

- after reviewing test results, we may abandon projects that we might previously have believed to be promising;

- we or our regulators may suspend or terminate clinical trials because the participating subjects or patients are being exposed to unacceptable health risks; and

- our test may not have the desired effects or may include or other characteristics that preclude regulatory approval or limit their commercial use if approved.

Even if our OneBreath diagnostic test receives marketing approval, it may fail to achieve the degree of market acceptance by physicians, patients, third-party payors and others in the medical community necessary for commercial success.

Even if our OneBreath test receives marketing approval, it may nonetheless fail to gain sufficient market acceptance by physicians, patients, third-party payors, and others in the medical community. If we do not generate significant product revenues, we may not become profitable. The degree of market acceptance of our tests, if approved for commercial sale, will depend on a number of factors, including:

- their efficacy and other potential advantages compared to alternative tests;

- our ability to offer them for sale at competitive prices;

- their convenience and ease of administration compared to alternative diagnostics;

- the willingness of the target patient population to try new diagnostic tests and of physicians to order these tests;

- the strength of marketing and distribution support; and

- the availability of governmental agencies and third-party medical insurance and adequate reimbursement for our diagnostic tests.

If we are unable to address and overcome these and similar concerns, our business and our results of operations could be substantially harmed.

If we are unable to convince physicians of the benefits of our OneBreath tests, we may incur delays or additional expense in our attempt to establish market acceptance.

Broad use of our OneBreath tests may require pathology laboratories and physicians to be informed regarding the product and its intended benefits. Inability to carry out this physician education process may adversely affect market acceptance of the OneBreath test. We may be unable to timely educate physicians regarding our proposed diagnostic tests in sufficient numbers to achieve our marketing plans or to achieve acceptance of our diagnostic tests. Any delay in physician education may materially delay or reduce demand for our diagnostic tests. In addition, we may expend significant funds toward physician education before any acceptance or demand for our proposed diagnostic tests is created, if at all.

We face substantial competition, which may result in others discovering, developing, or commercializing competing diagnostic tests before or more successfully than we do.

The development and commercialization of new diagnostic technologies is highly competitive. We will always face competition with respect to any diagnostic technology that we may seek to develop or commercialize in the future from major diagnostic and pharmaceutical companies, LDT laboratories, smaller diagnostic and pharmaceutical companies, and biotechnology companies worldwide. In 2022, we evaluated more than 50 companies advancing tests for the early detection of lung cancer that provided at least a scientific foundation for their tests. These competitors are investigating lung cancer screening and diagnostic methods that use various types of collected samples (blood, breath, nasal epithelial cells, saliva, sputum, and urine) or imaging systems. Potential competitors also include academic institutions, government agencies, and other public and private research organizations that conduct research,

seek patent protection, and establish collaborative arrangements for research, development, manufacturing, and commercialization.

A substantial number of the companies against which we will be competing may have significantly greater financial resources, established presence in the market, and expertise in research and development, manufacturing, pre-clinical testing, conducting clinical trials, obtaining regulatory approvals, and marketing approved diagnostic tests. Mergers and acquisitions in the diagnostic, pharmaceutical, and biotechnology industries may result in even more resources being concentrated among a smaller number of our competitors.

Smaller and other early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These third parties compete with us in recruiting and retaining qualified scientific, sales, marketing, and management personnel, establishing clinical trial sites and patient registration for clinical trials, and acquiring technologies complementary to or necessary for our programs.

Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize diagnostic tests that are more accurate, more convenient, or less expensive than any diagnostic tests that we may develop. Our competitors also may obtain FDA or other regulatory approval for their diagnostic tests more rapidly than we may obtain approval for ours, which could result in our competitors establishing a stronger market position. In addition, our ability to compete may be affected in many cases by insurers or other third-party payors.

We may be unable to compete in our target marketplaces, which could impair our ability to generate revenues, thus causing a material adverse impact on our results of operations.

We are exposed to product liability and pre-clinical and clinical liability risks which could place a substantial financial burden upon us, should we be sued.

Our business exposes us to potential product liability and other liability risks that are inherent in the testing, manufacturing, and marketing of diagnostic tests. Such claims may be asserted against us. In addition, using diagnostic tests that may be developed with potential collaborators in our clinical trials and the subsequent sale of these tests and products by our potential collaborators may cause us to bear a portion of or all product liability risks. A successful liability claim, or series of claims, brought against us could have a material adverse effect on our business, financial condition, and results of operations.

In the future we may not be able to obtain or maintain adequate product liability insurance, when needed, on acceptable terms, if at all, or such insurance may not provide adequate coverage against our potential liabilities. Furthermore, potential partners with whom we intend to have collaborative or strategic agreements or our future licensees may not be willing to indemnify us against these types of liabilities and may not themselves be sufficiently insured or have sufficient liquidity to satisfy any product liability claims. Claims or losses in excess of any product liability insurance coverage that we may obtain could have a material adverse effect on our business, financial condition, and results of operations.

In addition, we may be unable to obtain or to maintain clinical trial liability insurance on acceptable terms, if at all. Any inability to obtain and/or maintain insurance coverage on acceptable terms could prevent or limit the commercialization of any tests or products we develop.

If we use hazardous chemicals in a manner that causes injury, we could be liable for damages.

Our diagnostic activities currently require the controlled use of potentially harmful chemicals. We cannot eliminate the risk of accidental contamination or injury to employees or third parties from the use, storage, handling or disposal of these materials. In the event of contamination or injury, we could be held liable for any resulting damages, and any liability could exceed its resources or any applicable insurance coverage it may have. Additionally, we would be subject to, on an ongoing basis, federal, state and local laws and regulations governing the use, storage, handling and disposal of these materials and specified waste products. The cost of compliance with these laws and regulations may become significant and could have a material adverse effect on its, and therefore our, financial condition, results of operations and cash flows. In the event of an accident or if we otherwise fail to comply with applicable regulations, we could lose our permits or approvals or be held liable for damages or penalized with fines.

Our collection, use and disclosure of personal information, including health and employee information, is subject to U.S. state and federal privacy and security regulations, and our failure to comply with those regulations or to adequately secure the information we hold could result in significant liability or reputational harm.

The privacy and security of personal information stored, maintained, received or transmitted, including electronically, is a major issue in the U.S. and abroad. Numerous federal and state laws and regulations, including state privacy, data security and breach notification laws, federal and state consumer protection and employment laws, the Health Insurance Portability and Accountability Act of 1996, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, and the Genetic Information Nondiscrimination Act of 2008, govern the collection, dissemination, use and confidentiality of personal information, including genetic, biometric and health information. These laws and regulations are increasing in complexity and number, may change frequently and sometimes conflict. Penalties for violations of these laws vary but can be severe.

While we strive to comply with all applicable privacy and security laws and regulations, including our own posted privacy policies, these laws and regulations continue to evolve, and any failure or perceived failure to comply may result in proceedings or actions against us by government entities or others or could cause us to lose customers, which could have a material adverse effect on our business. Recently, there has been an increase in public awareness of privacy issues in the wake of revelations about the data-collection activities of various government agencies and in the number of private privacy-related lawsuits filed against companies. Concerns about our practices with regard to the collection, use, retention, disclosure, or security of personal information or other privacy-related matters, even if unfounded and even if we are in compliance with applicable laws, could damage our reputation and harm our business.

Our business operations and current and future relationships with investigators, healthcare professionals, consultants, third-party payors and customers are subject, directly or indirectly, to federal and state healthcare fraud and abuse laws, transparency laws and other healthcare laws and regulations. If we are unable to comply, or have not fully complied, with such laws, we could face substantial penalties.

Healthcare providers and others play a primary role in the recommendation ordering and prescription of any diagnostic tests for which we obtain marketing approval. Our operations and current and future arrangements with investigators, healthcare professionals, customers, and third-party payors are subject to various U.S. federal and state healthcare laws and regulations, including, without limitation, U.S. federal Anti-Kickback Statute, the U.S. federal civil and criminal false claims laws, and the Physician Payments Sunshine Act and regulations. These laws may impact, among other things, our current business operations, including our clinical research activities, and proposed sales, marketing, and education programs and constrain the business of financial arrangements and relationships with healthcare providers and other parties through which we may market, sell, and distribute our diagnostic tests for which we obtain marketing approval. In addition, we may be subject to additional healthcare, statutory, and regulatory requirements and enforcement by foreign regulatory authorities in jurisdictions in which we conduct our business.

Ensuring that our internal operations and future business arrangements with third parties comply with applicable healthcare laws and regulations will involve substantial costs. It is possible that governmental authorities will conclude that our business practices, including certain arrangements with physicians who receive stock, warrants or stock options as compensation for services provided to us, do not comply with current or future statutes, regulations, agency guidance, or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of the laws described above or any other governmental laws and regulations that may apply to us, we may be subject to significant penalties, including civil, criminal and administrative penalties, damages, fines, exclusion from U.S. government-funded healthcare programs, such as Medicare and Medicaid, or similar programs in other countries or jurisdictions, disgorgement, imprisonment, contractual damages, reputational harm, diminished profits, additional reporting requirements and oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with these laws, and the delay, reduction, termination or restructuring of our operations. Further, defending against any such actions can be costly and time-consuming and may require significant financial and personnel resources. Therefore, even if we are successful in defending against any such actions that may be brought against us, our business may be impaired. If any of the physicians or other providers or entities with whom we expect to do business are found not to be in compliance with applicable laws, they may be subject to significant criminal, civil or administrative sanctions, including exclusions

from government-funded healthcare programs and imprisonment. If any of the above occur, it could adversely affect our ability to operate our business and our results of operations.

Risks Related to Intellectual Property

If we are unable to obtain and enforce patents and to protect our trade secrets, others could use our technology to compete with us, which could create undue competition and pricing pressures. There is no certainty that our pending or future patent applications will result in the issuance of patents or that our issued patents will be deemed enforceable.

The success of our business depends significantly on our ability to operate without infringing patents and other proprietary rights of others. If the technology that we use infringes a patent held by others, we could be sued for monetary damages by the patent holder or its licensee, or we could be prevented from continuing research, development, and commercialization of diagnostic tests that rely on that technology, unless we are able to obtain a license to use the patent. The cost and availability of a license to a patent cannot be predicted, and the likelihood of obtaining a license at an acceptable cost would be lower if the patent holder or any of its licensees is using the patent to develop or market a diagnostic test with which our diagnostic test would compete. If we could not obtain a necessary license, we would need to develop or obtain rights to alternative technologies, which could prove costly and could cause delays in diagnostic test development, or we could be forced to discontinue the development or marketing of any diagnostic tests that were developed using the technology covered by the patent.

We have issued patents and patent applications pending worldwide that are owned by or exclusively licensed to us. We and our collaborators expect to continue to file and prosecute patent applications covering the products and technology that we commercialize. However, there is no assurance that any of our licensed patent applications, or any patent applications that we have filed or that we may file in the future in the United States or abroad, will result in the issuance of patents.

Our success will depend in part on our ability to obtain and enforce patents and maintain trade secrets in the United States and in other countries. If we are unsuccessful in obtaining and enforcing patents, our competitors could use our technology and create diagnostic tests that compete with our diagnostic tests, without paying license fees or royalties to us.

The relatively recent Supreme Court decisions in *Mayo Collaborative Services v. Prometheus Laboratories*, Inc. and *Alice Corp. v. CLS Bank Int'l* may adversely impact our ability to obtain strong patent protection for some or all of our diagnostic tests and associated algorithms.

The preparation, filing, and prosecution of patent applications can be costly and time consuming.

The preparation and filing of patent applications, and the maintenance of patents that are issued, may require substantial time and money. A patent interference proceeding may be instituted with the United States Patent and Trademark Office, or USPTO, when more than one-person files a patent application covering the same technology, or if someone wishes to challenge the validity of an issued patent. Furthermore, our limited financial resources may not permit us to pursue patent protection of all of our technology and diagnostic tests throughout the world, even where we have legally binding patent protection and trade secret rights. Even if we are able to obtain issued patents covering our technology or diagnostic tests, we may have to incur substantial legal fees and other expenses to enforce our patent rights in order to protect our technology and diagnostic tests from infringing uses. We may not have the financial resources to finance the litigation required to preserve our patent and trade secret rights.

Obtaining and maintaining patent protection depends on compliance with various procedural, document submissions, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.

Periodic maintenance fees, renewal fees, annuities fees and various other governmental fees on patents and/or patent applications are due to be paid to the USPTO and foreign patent agencies in several stages over the lifetime of the patent and/or patent application. The USPTO and various foreign governmental patent agencies also require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. While an inadvertent lapse can in many cases be cured by payment of a late fee or by other means

in accordance with the applicable rules, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Non-compliance events that could result in abandonment or lapse of a patent or patent application include, but are not limited to, failure to respond to official actions within prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents. If we fail to maintain the patents and patent applications covering our diagnostic tests, our competitive position would be adversely affected.

Our patents may not protect our diagnostic tests from competition.

We might not be able to obtain any patents beyond our 13 existing patents (of which two are active, and nine are inactive) that have been issued by the USPTO, and any patents that we do obtain might not be comprehensive enough to provide us with meaningful patent protection. There will always be a risk that our competitors might be able to successfully challenge the validity or enforceability of any patent issued to us.

We may become involved in lawsuits to protect or enforce our patents or other intellectual property, which could be expensive, time-consuming, and ultimately unsuccessful.

Competitors may infringe our issued patents or other intellectual property. To counter infringement or unauthorized use, we intend to file infringement claims, which can be expensive and time-consuming. Any claims we assert against perceived infringers could provoke these parties to assert counterclaims against us alleging that we infringe their intellectual property. In addition, in a patent infringement proceeding, a court may decide that a patent of ours is invalid or unenforceable, in whole or in part, construe the patent's claims narrowly, or refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology in question. An adverse result in any litigation proceeding could put one or more of our patents at risk of being invalidated or interpreted narrowly, which could adversely affect us.

If we fail to meet our obligations under various license, license option, and technology transfer agreements, we may lose our rights to key technologies or data sources on which our business depends.

Our business will depend on several critical technologies and data sources that have licenses from various domestic and overseas companies and research centers, including an exclusive license agreement with the University of Louisville.

These and other license agreements typically impose obligations on us, including payment obligations and obligations to pursue development and commercialization of diagnostic tests under the licensed patents and technology. If licensors believe that we have failed to meet our obligations under a license agreement, they could seek to limit or terminate our license rights, which could lead to costly and time-consuming dispute resolution and, potentially, a loss of the licensed rights. During the period of any such litigation our ability to carry out the development and commercialization of potential diagnostic tests, and our ability to raise any capital that we might then need, could be significantly and negatively affected. If our license rights were restricted or ultimately lost, we would not be able to continue to use the licensed patents and technology in our business.

In the future, we may need to obtain additional licenses of third-party technology that may not be available to us or are available only on commercially unreasonable terms, which may cause us to operate our business in a more costly or otherwise adverse manner that was not anticipated.

We currently own intellectual property underlying our diagnostic test and related technologies. Other pharmaceutical companies and academic institutions may also have filed or are planning to file patent applications potentially relevant to our business. From time to time, in order to avoid infringing these third-party patents, we may be required to license technology from additional third parties to further develop or commercialize our diagnostic tests. Should we be required to obtain licenses to any third-party technology, including any such patents required to manufacture, use, or sell our diagnostic tests, such licenses may not be available to us on commercially reasonable terms, or at all. The inability to obtain any third-party license required to develop or commercialize any of our diagnostic tests could cause us to abandon any related efforts, which could seriously harm our business and operations. The licensing or acquisition of third-party intellectual property rights is a competitive area, and several more established companies may pursue strategies to license or acquire third-party intellectual property rights we may consider attractive or necessary. These

established companies may have a competitive advantage over us due to their size, capital resources, and greater clinical development and commercialization capabilities. In addition, companies that perceive us to be a competitor may be unwilling to assign or license rights to us. Even if we are able to obtain a license under such intellectual property rights, any such license may be non-exclusive, which may allow our competitors access to the same technologies licensed to us.

Risks Related to Healthcare Government Regulation, Product Safety, and Effectiveness

We must successfully maintain and/or upgrade our information technology systems, and our failure to do so could have a material adverse effect on our business, financial condition or results of operations.

We rely on various information technology systems to manage our operations. Recently, we have implemented, and we continue to implement, modifications and upgrades to such systems and acquired new systems with new functionality. These types of activities subject us to inherent costs and risks associated with replacing and changing these systems, including impairment of our ability to fulfill customer orders, potential disruption of our internal control structure, substantial capital expenditures, additional administration and operating expenses, retention of sufficiently skilled personnel to implement and operate the new systems, demands on management time and other risks and costs of delays or difficulties in transitioning to or integrating new systems into our current systems. These implementations, modifications and upgrades may not result in productivity improvements to a level that outweighs the costs of implementation, or at all. In addition, the difficulties with implementing new technology systems may cause disruptions in our business operations and have a material adverse effect on our business, financial condition or results of operations.

Our business and operations could suffer in the event of system failures.

Despite the implementation of security measures, our internal computer systems and those of our contractors and consultants are vulnerable to damage from computer viruses, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures. Such events could cause interruption of our operations. For example, the loss of data for our diagnostic test candidates could result in delays in our regulatory filings and development efforts and significantly increase our costs. To the extent that any disruption or security breach was to result in a loss of or damage to our data, or inappropriate disclosure of confidential or proprietary information, we could incur liability and the development of our diagnostic test candidates could be delayed.

We are required to comply with federal and state laws governing the privacy of health information, and any failure to comply with these laws could result in material criminal and civil penalties.

HIPAA sets forth security regulations that establish administrative, physical, and technical standards for maintaining the confidentiality, integrity and availability of protected health information in electronic form. We also may be required to comply with state laws that are more stringent than HIPAA or that provide individuals with greater rights with respect to the privacy or security of, and access to, their health care records. HITECH established certain health information security breach notification obligations that require covered entities to notify each individual whose protected health information is breached.

We may incur significant compliance costs related to HIPAA and HITECH privacy regulations and varying state privacy regulations and varying state privacy and security laws. Given the complexity of HIPAA and HITECH and their overlap with state privacy and security laws, and the fact that these laws are rapidly evolving and are subject to changing and potentially conflicting interpretation, our ability to comply with the HIPAA, HITECH and state privacy requirements is uncertain and the costs of compliance are significant. The costs of complying with any changes to the HIPAA, HITECH and state privacy restrictions may have a negative impact on our operations. Noncompliance could subject us to criminal penalties, civil sanctions and significant monetary penalties as well as reputational damage.

We may be unable to obtain regulatory approval for our diagnostic tests under applicable international regulatory requirements. The denial or delay of such approval would delay commercialization of our OneBreath diagnostic test in other countries and thus adversely impact our potential to generate revenue, which could materially harm our business, financial condition, results of operations and prospects.

Approval by the FDA in the United States, if obtained, does not ensure approval by regulatory authorities in other countries or jurisdictions. In order to eventually market our OneBreath or any future diagnostic test in any foreign jurisdiction, we must establish and comply with numerous and varying regulatory requirements on a jurisdiction-by-jurisdiction basis regarding safety and efficacy. In addition, clinical trials conducted in one country may not be accepted by regulatory authorities in other countries, and regulatory approval in one country does not guarantee regulatory approval in any other country. Approval processes vary among countries and can involve additional product testing and validation and additional administrative review periods.

Seeking regulatory approval in foreign jurisdictions could result in difficulties and costs for us and require additional pre-clinical studies or clinical trials, which could be costly and time-consuming. Regulatory requirements can vary widely from country to country and could delay or prevent the introduction of our products in those countries. The regulatory approval processes in place in the European Union, Australia and other jurisdictions involve all of the risks associated with FDA approval. We do not have any diagnostic test approved for sale in any jurisdiction, including international markets, and we do not have experience in obtaining regulatory approval in international markets. If we fail to comply with regulatory requirements in international markets or to obtain and maintain required approvals, or if regulatory approvals in international markets are delayed, our target market will be reduced and our ability to realize the full market potential of our products will be unrealized.

In the event that one or more lawsuits are filed against us, we could be subject to reputational risk.

Our OneBreath test is intended for use only as a screening device, the results of which may trigger more in-depth diagnostic procedures. If our tests failed and the patient sued us, we could incur reputational damage if doctors or patients were thereby dissuaded from using our tests. Repeated lawsuits could also precipitate regulatory scrutiny that could negatively impact our ability to sell our products.

Risks Related to This Offering and Ownership of Our Common Stock

The Securities will not be freely tradable under the Securities Act until one year from the initial purchase date. Although the Securities may be tradable under federal securities law, state securities regulations may apply, and each Investor should consult with their attorney.

You should be aware of the long-term nature of this investment. There is not now and likely will not ever be a public market for the Securities. Because the Securities have not been registered under the Securities Act or under the securities laws of any state or foreign jurisdiction, the Securities have transfer restrictions and cannot be resold in the United States except pursuant to Rule 501 of Regulation CF. It is not currently contemplated that registration under the Securities Act or other securities laws will be effected. Limitations on the transfer of the Securities may also adversely affect the price that you might be able to obtain for the Securities in a private sale. Investors should be aware of the long-term nature of their investment in the Issuer. Each Investor in this Offering will be required to represent that they are purchasing the Securities for their own account, for investment purposes and not with a view to resale or distribution thereof.

Your ownership of the shares will be subject to dilution.

If we conduct subsequent offerings of securities, issue shares pursuant to a compensation or distribution reinvestment plan or otherwise issues additional shares, investors who purchase securities in this offering who do not participate in those other stock issuances will experience dilution in their percentage ownership of our Company's outstanding shares. Furthermore, shareholders may experience a dilution in the value of their underlying shares depending on the terms and pricing of any future share issuances (including the underlying shares being sold in this offering) and the value of our assets at the time of issuance.

There can be no assurance that we will ever provide liquidity to investors through either a sale of our Company or a registration of the securities.

There can be no assurance that any form of merger, combination, or sale of our Company will take place, or that any merger, combination, or sale would provide liquidity for investors. Furthermore, we may be unable to register the securities for resale by investors for legal, commercial, regulatory, market-related or other reasons. In the event that

we are unable to effect a registration, investors could be unable to sell their securities unless an exemption from registration is available.

The securities will be equity interests in our Company and will not constitute indebtedness.

The securities will rank junior to all existing and future indebtedness and other non-equity claims on our Company with respect to assets available to satisfy claims on the Issuer, including in a liquidation of our Company. Additionally, unlike indebtedness, for which principal and interest would customarily be payable on specified due dates, there will be no specified payments of dividends with respect to the securities and dividends are payable only if, when and as authorized and declared by us and depend on, among other matters, our historical and projected results of operations, liquidity, cash flows, capital levels, financial condition, debt service requirements and other cash needs, financing covenants, applicable state law, federal and state regulatory prohibitions and other restrictions and any other factors our board of directors deems relevant at the time. In addition, there is no limit on the amount of debt or other obligations we may incur in the future. Accordingly, we may incur substantial amounts of additional debt and other obligations that will rank senior to the securities, which are the most junior securities of our Company.

We may issue shares of preferred stock that would have a liquidation preference to our common stock.

Our articles of incorporation currently authorize the issuance of 7,000,000 shares of our preferred stock, of which there are no shares of preferred stock issued and outstanding. We have previously authorized and issued Series Seed Preferred Stock, all of which was converted to common stock. The rights of the holders of common stock will be subject to, and may be adversely affected by, the rights of any holders of preferred stock that may be issued in the future. We presently have no commitments or contracts to issue any shares of preferred stock. Authorized and unissued preferred stock could delay, discourage, hinder or preclude an unsolicited acquisition of our Company, could make it less likely that shareholders receive a premium for their shares as a result of any such attempt, and could adversely affect the market prices of, and the voting and other rights, of the holders of outstanding shares of our common stock.

There is no minimum amount required to be raised in this Offering.

We may not have enough funds to sustain our business until it becomes profitable, as we may not accurately anticipate how quickly we may use the funds that are raised in the offering and whether such funds are sufficient to bring our business to profitability. If we fail to raise sufficient capital from this offering, we intend to seek additional financing either through the sale of equity or loans from third parties. However, there can be no assurance that we will be able to obtain any additional capital.

We expect to raise additional capital through equity and/or debt offerings to support our working capital requirements and operating losses.

To fund future growth and development, we will likely need to raise additional funds in the future by offering shares of our common stock and/or other classes of equity, or debt that convert into shares of common stock, any of which offerings would dilute the ownership percentage of investors in this offering. In order to issue sufficient shares in this regard, we may be required to amend our certificate of incorporation to increase our authorized capital stock, which would require us to obtain the consent of a majority of our shareholders. Furthermore, if we raise capital through debt, the holders of our debt would have priority over holders of common stock, and we may be required to accept terms that restrict its ability to incur more debt. We cannot assure you that the necessary funds will be available on a timely basis, on favorable terms, or at all, or that such funds, if raised, would be sufficient. The level and timing of future expenditures will depend on a number of factors, many of which are outside our control. If we are not able to obtain additional capital on acceptable terms, or at all, we may be forced to curtail or abandon our growth plans, which could adversely impact us, our business, development, financial condition, operating results or prospects.

The offering price in this offering may not represent the value of our securities.

The price of the securities being sold in this offering has been determined based on a number of factors and does not necessarily bear any relationship to our book value, assets, operating results or any other established criteria of value. Prices for our securities may not be indicative of the fair market value of our securities now or in the future.

There is no present market for the Securities and we have arbitrarily set the price.

The offering price was not established in a competitive market. We have arbitrarily set the price of the securities with reference to the general status of the securities market and other relevant factors. The offering price for the securities should not be considered an indication of the actual value of the securities and is not based on our asset value, net worth, revenues or other established criteria of value. We cannot guarantee that the securities can be resold at the offering price or at any other price.

If we cannot raise sufficient funds, we may not succeed.

We are offering common shares in this offering on a best-efforts basis and may not sell all of the common shares we are offering. Even if the maximum amount is raised, we are likely to need additional funds in the future to grow. The technology and products we are developing are highly sophisticated, and we may also encounter technical challenges that require more capital than anticipated by the management team to overcome. If we cannot raise those funds for whatever reason, including reasons relating to us or to the broader economy, we may not survive. If we raise a substantially lesser amount than the maximum raise, we will have to find other sources of funding for some of the plans outlined in "Use of Proceeds".

Our management has broad discretion as to the use of the net proceeds from this offering.

Our management will have broad discretion in the application of the net proceeds of this offering. Accordingly, you will have to rely upon the judgment of our management with respect to the use of these proceeds. Our management may spend a portion or all of the net proceeds from this offering in ways that holders of our common stock may not desire or that may not yield a significant return or any return at all. Our management not applying these funds effectively could harm our business. Pending their use, we may also invest the net proceeds from this offering in a manner that does not produce income or that loses value. Please see "*Use of Proceeds*" below for more information.

Certain provisions of our certificate of incorporation and bylaws, the Delaware General Corporation Law, and the subscription agreement you will sign as a condition to your participation in this offering may have the effect of discouraging or delaying a change in control of our company.

Certain provisions of our certificate of incorporation and bylaws may have the effect of making it more difficult for a third party to acquire, or of discouraging a third party from attempting to acquire, control of us, even if a change of control might be deemed beneficial to our stockholders. Such provisions could limit the price that certain investors might be willing to pay in the future for our securities. Our certificate of incorporation eliminates the right of stockholders to call special meetings of stockholders or to act by written consent without a meeting, and our bylaws require advance notice for stockholder proposals and director nominations, which may preclude stockholders from bringing matters before an annual meeting of stockholders or from making nominations for directors at an annual meeting of stockholders. Our certificate of incorporation authorizes undesignated preferred stock, which makes it possible for our board of directors, without stockholder approval, to issue preferred stock with voting or other rights or preferences that could adversely affect the voting power of holders of common stock. In addition, the likelihood that the holders of preferred stock will receive dividend payments and payments upon liquidation could have the effect of delaying, deferring or preventing a change in control.

Additionally, the subscription agreement for the shares offered in this offering includes a proxy provision that grants our Chief Executive Officer the authority to vote on your behalf as a shareholder. Under this provision, our Chief Executive Officer, or the successor thereto or assignee thereof to any Chief Financial Officer, if any, will have the power to vote all of your shares and the shares held by each other participant in this offering, execute consents, and take any action necessary as deemed appropriate in their sole discretion, which may include voting against a proposal which would result in an acquisition of our Company by a third party. These and other provisions may have the effect of deferring hostile takeovers or delaying changes in control or management of us.

We have never paid cash dividends on our common stock and we do not intend to pay dividends for the foreseeable future.

We have paid no cash dividends on our common stock to date, and we do not anticipate paying cash dividends in the near term. For the foreseeable future, we intend to retain any earnings to finance the development and expansion of

our business, and we do not anticipate paying any cash dividends on our stock. Accordingly, investors must be prepared to rely on sales of their common stock after price appreciation to earn an investment return, which may never occur. Investors seeking cash dividends should not purchase our common stock. Any determination to pay dividends in the future will be made at the discretion of our board of directors and will depend on our results of operations, financial condition, contractual restrictions, restrictions imposed by applicable law and other factors our board deems relevant.

There is no guarantee of a return on an Investor's investment.

There is no assurance that an investor will realize a return on their investment or that they will not lose their entire investment. For this reason, each investor should read this Form C and all exhibits carefully and should consult with their attorney and business advisor prior to making any investment decision.

Future issuances of our common stock or securities convertible into, or exercisable or exchangeable for, our common stock, or the expiration of lock-up agreements that restrict the issuance of new common stock or the trading of outstanding common stock, could cause the market price of our common stock to decline and would result in the dilution of your holdings.

Future issuances of our common stock or securities convertible into, or exercisable or exchangeable for, our common stock, or the expiration of lock-up agreements that restrict the issuance of new common stock or the trading of outstanding common stock, could cause the market price of our common stock to decline. We cannot predict the effect, if any, of future issuances of our securities, or the future expirations of lock-up agreements, on the price of our common stock. In all events, future issuances of our common stock would result in the dilution of your holdings. In addition, the perception that new issuances of our securities could occur, or the perception that locked-up parties will sell their securities when the lock-ups expire, could adversely affect the market price of our common stock. In connection with this offering, we and all of our directors, executive officers and holders of 5% or more of our outstanding common stock have agreed with the underwriters, subject to certain exceptions, not to sell, transfer or dispose of, directly or indirectly, any of our common stock or securities convertible into or exercisable or exchangeable for our common stock for a period of six months after the date of this prospectus. See "*Underwriting*." In addition to any adverse effects that may arise upon the expiration of these lock-up agreements, the lock-up provisions in these agreements may be waived, at any time and without notice. If the restrictions under the lock-up agreements are waived, our common stock may become available for resale, subject to applicable law, including without notice, which could reduce the market price for our common stock.

Future issuances of debt securities, which would rank senior to our common stock upon our bankruptcy or liquidation, and future issuances of preferred stock, which could rank senior to our common stock for the purposes of dividends and liquidating distributions, may adversely affect the level of return you may be able to achieve from an investment in our common stock.

In the future, we may attempt to increase our capital resources by offering debt securities. Upon bankruptcy or liquidation, holders of our debt securities, and lenders with respect to other borrowings we may make, would receive distributions of our available assets prior to any distributions being made to holders of our common stock. Moreover, if we issue preferred stock, the holders of such preferred stock could be entitled to preferences over holders of common stock in respect of the payment of dividends and the payment of liquidating distributions. Because our decision to issue debt or preferred stock in any future offering, or borrow money from lenders, will depend in part on market conditions and other factors beyond our control, we cannot predict or estimate the amount, timing or nature of any such future offerings or borrowings. Holders of our common stock must bear the risk that any future offerings we conduct or borrowings we make may adversely affect the level of return, if any, they may be able to achieve from an investment in our common stock.

Investors will not be entitled to any inspection or information rights other than those required by law.

Investors will not have the right to inspect the books and records of the Issuer or to receive financial or other information from the Issuer, other than as required by law. Other security holders of the Issuer may have such rights. Regulation CF requires only the provision of an annual report on Form C and no additional information. Additionally, there are numerous methods by which the Issuer can terminate annual report obligations, resulting in no information rights, contractual, statutory or otherwise, owed to Investors. This lack of information could put Investors at a

disadvantage in general and with respect to other security holders, including certain security holders who have rights to periodic financial statements and updates from the Issuer such as quarterly unaudited financials, annual projections and budgets, and monthly progress reports, among other things.

Anti-takeover provisions in our charter documents and under Delaware law could make an acquisition of our Company more difficult, and limit attempts by our stockholders to replace or remove our current management.

Provisions in our certificate of incorporation and bylaws may have the effect of delaying or preventing a change of control of our Company or changes in our management. Our authorized but unissued shares of common stock are available for our board of directors to issue without stockholder approval. We may use these additional shares for a variety of corporate purposes, including raising additional capital, corporate acquisitions and employee stock plans. The existence of our authorized but unissued shares of common stock could render it more difficult or discourage an attempt to obtain control of our Company by means of a proxy context, tender offer, merger or other transaction since our board of directors can issue large amounts of capital stock as part of a defense to a take-over challenge. In addition, we have authorized in our certificate of incorporation 7,000,000 shares of preferred stock. Our board acting alone and without approval of our stockholders, can designate and issue one or more series of preferred stock containing super-voting provisions, enhanced economic rights, rights to elect directors, or other dilutive features, that could be utilized as part of a defense to a take-over challenge.

In addition, various provisions of our bylaws may also have an anti-takeover effect. These provisions may delay, defer or prevent a tender offer or takeover attempt of our Company that a stockholder might consider in his or her best interest, including attempts that might result in a premium over the market price for the shares held by our stockholders. Our bylaws contain limitations as to who may call special meetings as well as require advance notice of stockholder matters to be brought at a meeting. Additionally, our bylaws also provide that no director may be removed by less than a majority of the issued and outstanding shares entitled to vote on the removal. Our bylaws also permit the board of directors to establish the number of directors and fill any vacancies and newly created directorships. These provisions will prevent a stockholder from increasing the size of our board of directors and gaining control of our board of directors by filling the resulting vacancies with its own nominees.

Our bylaws also establish an advance notice procedure for stockholder proposals to be brought before an annual meeting of our stockholders, including proposed nominations of persons for election to the board of directors. Stockholders at an annual meeting will only be able to consider proposals or nominations specified in the notice of meeting or brought before the meeting by or at the direction of the board of directors or by a stockholder who was a stockholder of record on the record date for the meeting, who is entitled to vote at the meeting and who has given us timely written notice, in proper form, of the stockholder's intention to bring that business before the meeting. Although our bylaws do not give the board of directors the power to approve or disapprove stockholder nominations of candidates or proposals regarding other business to be conducted at a special or annual meeting, our bylaws may have the effect of precluding the conduct of certain business at a meeting if the proper procedures are not followed or may discourage or deter a potential acquirer from conducting a solicitation of proxies to elect its own slate of directors or otherwise attempting to obtain control of our Company.

Moreover, Section 203 of the General Corporation Law of the State of Delaware may discourage, delay or prevent a change in control of our Company. Section 203 imposes certain restrictions on mergers, business combinations and other transactions between us and holders of 15% or more of our common stock. See "*Description of Capital Stock*" for additional information.

These provisions may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace members of our board of directors, which is responsible for appointing the members of our management.

IN ADDITION TO THE RISKS LISTED ABOVE, RISKS AND UNCERTAINTIES NOT PRESENTLY KNOWN, OR WHICH WE CONSIDER IMMATERIAL AS OF THE DATE OF THIS FORM C, MAY ALSO HAVE AN ADVERSE EFFECT ON OUR BUSINESS AND RESULT IN THE TOTAL LOSS OF YOUR INVESTMENT.

THE OFFERING

9. **What is the purpose of the offering?**

The purpose of the offering is to raise capital for research and development and working capital purposes. In addition, the proceeds from this offering will be used to pay for legal and accounting costs.

10. **How does the issuer intend to use the proceeds of this offering?**

Description	If Target Offering Amount is Sold	If Maximum Amount is Sold
Total Proceeds	$20,000	$3,000,000
Less: Offering Expenses		
(A) Intermediary Commissions (7%)	$1,400	$210,000
(B) Legal Fees	$400	$100,000
(C) Accounting Expenses	$80	$20,000
(D) Miscellaneous Offering Expenses	$20	$5,000
Net Proceeds	$18,100	$2,665,000
Operating Expenses:		
(A) Research & Development	$911	$400,000
(B) Operating & Administration	$3,506	$900,000
(C) Professional Fees	$554	$140,000
(D) Contract Labor	$316	$110,000
(E) Lab & Product Supplies	$1,990	$600,000
(D) FDA Related Submissions	$6,400	$200,000
(E) Product Development	$3,680	$600,000
(D) Marketing & Promotion	$683	$50,000

(1) We will accept proceeds in excess of the target offering amount of $3,000,000. We will allocate oversubscriptions on a first come first served basis. We will use the oversubscribed amount up to $3,000,000 in the manner described in the above table. In any event, we will not sell more than $5,000,000 of Common Stock in a rolling 12-month basis.

(2) The above figures represent only estimated costs. This expected use of net proceeds from this offering represents our intentions based upon our current plans and business conditions. The amounts and timing of our actual expenditures may vary significantly depending on numerous factors, including the status of and results from operations. As a result, our management will retain broad discretion over the allocation of the net proceeds from this offering. We may find it necessary or advisable to use the net proceeds from this offering for other purposes, and we will have broad discretion in the application of net proceeds from this offering. Furthermore, we anticipate that we will need to secure additional funding in order to fully implement our business plan. Please see the section entitled “Risk Factors.”

11. **How will the issuer complete the transaction and deliver securities to the investors?**

The transaction between the issuer and the investor will be completed through the EquiFund Crowd Funding Portal, Inc. online platform, located at www.EquiFund.com. EquiFund Crowd Funding Portal, Inc. will serve as the Intermediary.

Upon acceptance of your subscription by our Company and delivery of the subscription amount into the escrow account, you will be able to download a fully signed copy of the subscription agreement and a confirmation of your investment and the number of shares of our common stock acquired by you.

12. How can an investor cancel an investment commitment?

Investors may cancel an investment commitment at any time up to the cancellation deadline, which occurs at 5:00 p.m. New York time, 48 hours prior to the offering deadline identified on the cover page of this offering statement.

Cancellation instructions can be found in the EquiFund investor dashboard. Investors may cancel their investment commitment by sending an email to support@equifund.com stating their intent to cancel the investment commitment. The investment commitment will be considered cancelled at that time, and the investor will be contacted directly by EquiFund with further information. If an investor's investment commitment is cancelled, the corresponding investment shall be refunded to the investor without deduction for any fee, commission or expense, and without accrued interest with respect to any money received.

Early Closing

If the target amount is reached prior to the offering deadline, the issuer may conduct an early closing. In the event that the issuer conducts an early closing, investors shall receive notice of such early closing as well as the new closing date, or the Early Closing Date. Investors shall have the right to cancel their investment commitment at any time and for any reason up until 48 hours prior to the Early Closing Date. After the target amount has been raised, the intermediary and the issuer may agree to hold multiple closings on a rolling basis.

Material Changes

If there is a material change to the terms of the offering or to the information provided by the issuer in connection therewith, EquiFund will send notice to each investor of such material change and inform the investor that the investment commitment will be cancelled unless the investor reconfirms their investment commitment within five business days. If any Investor fails to reconfirm their investment commitment within the reconfirmation period, the investment commitment will be cancelled automatically and EquiFund will send to each investor, within five business days after initial notice of the material change, a notification that the investment commitment was cancelled and a direct the refund of the investment.

No Closings

If the Company fails to reach the target offering amount by the offering deadline, each investor's investment commitment will be cancelled automatically and EquiFund will direct refund of each cancelled investment to the investor within five business days.

NOTE: Investors may cancel an investment commitment until 48 hours prior to the deadline identified in these offering materials.

The intermediary will notify investors when the target offering amount has been met.

If the issuer reaches the target offering amount prior to the deadline identified in the offering materials, it may close the offering early if it provides notice about the new offering deadline at least five business days prior to such new offering deadline (absent a material change that would require an extension of the offering and reconfirmation of the investment commitment).

If an investor does not cancel an investment commitment before the 48-hour period prior to the offering deadline, the funds will be released to the issuer upon closing of the offering and the investor will receive securities in exchange for his or her investment.

If an investor does not reconfirm his or her investment commitment after a material change is made to the offering, the investor's investment commitment will be cancelled and the committed funds will be returned.

OWNERSHIP AND CAPITAL STRUCTURE

The Offering

13. **Describe the terms of the securities being offered.**

Terms of the Offering

We are offering up to 1,000,000 shares of our common stock for $3,000,000.00. We are attempting to raise a minimum amount of $20,001 in this offering, which we refer to as the minimum amount or target amount. We must receive commitments from investors in an amount totaling the minimum amount the offering deadline identified on the cover page of this offering statement, which we refer to as the offering deadline, in order to receive any funds. If the sum of the investment commitments does not equal or exceed the minimum amount by the offering deadline, no securities will be sold in the offering, investment commitments will be cancelled, and committed funds will be returned without interest or deductions. We have the right to extend the offering deadline at our discretion. We will accept investments in excess of the minimum amount up to $3,000,000.00, which we refer to as the maximum amount, and the additional securities will be allocated as set forth in Question 10 of this Form C.

The price of the securities does not necessarily bear any relationship to our Company's asset value, net worth, revenues or other established criteria of value, and should not be considered indicative of the actual value of the securities.

In order to purchase the securities, you must make a commitment to purchase by completing the subscription agreement. Investor funds will be held in escrow with Enterprise Bank & Trust, who we refer to as the escrow agent, until the minimum amount of investments is reached. Investors may cancel an investment commitment until 48 hours prior to the offering deadline or the applicable closing, whichever comes first, using the cancellation mechanism provided by the Intermediary. We will notify investors when the minimum amount has been reached. If we reach the minimum amount prior to the offering deadline, we may close the offering at least five (5) days after reaching the minimum amount and providing notice to the investors. If any material change (other than reaching the minimum amount) occurs related to the offering prior to the offering deadline, we will provide notice to investors and receive reconfirmations from investors who have already made commitments. If an investor does not reconfirm his or her investment commitment after a material change is made to the terms of the offering, the investor's investment commitment will be cancelled, and the committed funds will be returned without interest or deductions. If an investor does not cancel an investment commitment before the minimum amount is reached, the funds will be released to our Company upon closing of the offering, and the investor will receive the securities in exchange for his or her investment. Any investor funds received after the initial closing will be released to us upon a subsequent closing, and the investor will receive securities via digital registry in exchange for his or her investment as soon as practicable thereafter.

Subscription agreements are not binding on us until accepted by us. We reserve the right to reject, in whole or in part, in our sole and absolute discretion, any subscription. If we reject a portion of any subscription, the applicable prospective investor's funds will be returned without interest or deduction.

The price of the securities was determined arbitrarily. The minimum amount that an investor may invest in the offering is $501.

The offering is being made through EquiFund Crowd Funding Platform, Inc., the Intermediary.

Commission/Fees

7.0% of the amount raised in the offering.

Stock, Warrants and Other Compensation

The intermediary will receive a number of shares of our common stock equal to 7% of the shares sold in the offering.

Transfer Agent and Registrar

We will act as transfer agent and registrar for the securities, which will be set forth in a stock ledger. No physical certificates will be delivered.

Restrictions on Transfer

Any securities sold pursuant to Regulation CF being offered may not be transferred by any Investor of such securities during the one-year holding period beginning when the securities were issued, unless such securities are transferred: (1) to the Company, (2) to an accredited investor, as defined by Rule 501(d) of Regulation D promulgated under the Securities Act, (3) as part of an initial public offering, or (4) to a member of the family of the Investor or the equivalent, to a trust controlled by the Investor, to a trust created for the benefit of a member of the family of the Investor or the equivalent, or in connection with the death or divorce of the Investor or other similar circumstances. "Member of the family" as used herein means a child, stepchild, grandchild, parent, stepparent, grandparent, spouse or spousal equivalent, sibling, mother/father/daughter/son/sister/brother-in-law and includes adoptive relationships. Remember that although you may legally be able to transfer the securities, you may not be able to find another party willing to purchase them.

NOTE: The term "accredited investor" means any person who comes within any of the categories set forth in Rule 501(a) of Regulation D, or who the seller reasonably believes comes within any of such categories, at the time of the sale of the securities to that person.

14. **Do the securities offered have voting rights? [X] Yes [ ] No**

Holders of our common stock are entitled to one vote per share of common stock held.

The subscription agreement for this offering which you will sign if you participate also includes a proxy provision that grants our Chief Executive Officer the authority to vote on your behalf as a shareholder. Under this provision, our Chief Executive Officer, or the successor thereto or assignee thereof to any Chief Financial Officer, if any, as the case may be, will have the power to vote all of your shares and the shares held by each other participant in this offering, execute consents, and take any action necessary as deemed appropriate in their sole discretion, which may include voting against a proposal which would result in an acquisition of our Company by a third party. Moreover, the proxy is irrevocable and coupled with an interest, meaning it survives the death or incapacitation of the shareholder or the reorganization of an entity holding our shares. The proxy terminates upon the earliest of a public offering, registration of our shares under the Exchange Act, or five years from the execution of the subscription agreement. Additionally, our Chief Executive Officer is indemnified against any losses arising from actions taken in good faith under the proxy, with limited exceptions for gross negligence or willful misconduct.

15. **Are there any limitations on any voting or other rights identified above? [ ] Yes [X] No**

We do not have any voting agreements or shareholder/equity holder agreements in place.

16. **Explain how the terms of the securities being offered may be modified?**

The rights of the holders of common stock of our Company may only be modified by the majority vote of the shares of common stock of our Company outstanding and entitled to vote, unless a greater number of voting shares is required by applicable law.

Description of Issuer's Securities

17. **What other securities or classes of securities of the issuer are outstanding? Describe the material terms of any other outstanding securities or classes of securities of the issuer.**

The only securities of our Company that are outstanding are common stock, convertible promissory notes, and warrants.

The total amount of common stock issued and outstanding prior to this offering is 10,714,454 shares of common stock.

As of December 31, 2024, we have issued convertible promissory notes in the aggregate principal amount of $1,990,128. The convertible promissory notes are unsecured, bear interest at an annual rate between 5-10% and have varying maturity dates. The Notes are convertible at varying conversion prices. Our most recent round of Notes are convertible at a 25% discount to the price of our securities sold in an equity financing of $2,000,000 or more, and another set of Notes converts at a value of $3.215.

We may also offer other debt or equity securities, including derivative securities like options, warrants and convertible debentures or notes in the future.

We reserve the right to sell our securities in a private placement transaction that occurs concurrent with this offering. Those securities may be SAFE securities (simplified agreement for future equity), preferred stock, convertible notes or other securities. Any securities that we sell for cash to investors in a private placement while this offering is ongoing will have a conversion cap, liquidation preference, conversion price, price or similar valuation mechanism that is based upon a valuation for our Company equal to the valuation at which securities are being sold in this offering or higher. Investors should be aware that the securities that we sell in a concurrent private placement may have a liquidation preference, security interest, sinking fund, redemption provision or similar right that is senior to your rights as a common stockholder of this Company and, accordingly, such other securities may be superior to our common stock in various ways even though they are being sold at the same valuation as we are selling our common stock in this offering.

18. **How may the rights of the securities being offered be materially limited, diluted or qualified by the rights of any other class of security identified above?**

As noted above, we have outstanding convertible notes. In the event of the liquidation of our Company, the noteholders would have a preference in liquidation and would receive the return of their principal plus accrued, but unpaid, interest on such principal prior to any payment being made to holders of our common stock.

The shares of our common stock being issued in this offering do not have anti-dilution rights, which means that future equity financings or other issuances of securities will dilute the ownership percentage that the investor will have in the Company. It also means that if future financing rounds are done at a lower valuation, you will not receive the benefit of additional shares so that your valuation will remain the same. If we issue any shares of preferred stock or any debt securities in the future and, thereafter there is a liquidation of our Company or sale of our Company, the holders of such preferred stock or debt securities would have a preference in the payment of amounts owed to them such that you may not receive a large portion of (or any of) the assets, including any cash, to be distributed in liquidation.

19. **Are there any differences not reflected above between the securities being offered and each other class of security of the issuer?** [_] Yes [X] No

20. **How could the exercise of rights held by the principal shareholders identified in Question 6 above affect the purchasers of the securities being offered.**

If the principal shareholders exercise their voting rights, then the minority shareholders will have no ability to override the principal shareholders' votes. As a minority shareholder in the Company, you will have limited ability, if any, to influence our policies or any other corporate matters.

21. **How are the securities being offered being valued? Include examples of methods for how such securities may be valued by the issuer in the future, including during subsequent corporate actions.**

The securities being offered have been arbitrarily valued. Also, see the "The offering price in this offering may not represent the value of our securities" risk factor.

22. **What are the risks to purchasers of the securities relating to minority ownership in the issuer?**

As a minority shareholder in our Company, you will have limited ability, if any, to influence our policies or any other corporate matters such as amendments to our articles of incorporation, the creation of securities that are senior to the common stock being offered, mergers, the sale of all or substantially all of our assets, the election of board members, the liquidation or dissolution of our Company and all other major corporate events.

23. **What are the risks to purchasers associated with corporate actions including: additional issuances of securities, issuer repurchases of securities, a sale of the issuer or of assets of the issuer or transactions with related parties?**

The securities do not have anti-dilution rights, which means that corporate actions, including: additional issuances of securities, issuer repurchases of securities, a sale of the issuer or of assets, or transactions with related parties could dilute the ownership percentage that the Investor may eventually have in the Company. Furthermore, if future issuances of securities are accomplished at a lower valuation than the valuation used for this offering (i.e., a down round), your valuation will remain the same as you have no price-based anti-dilution protection.

24. **Describe the terms of any indebtedness of the issuer.**

As of December 31, 2024, we had outstanding convertible promissory notes in the aggregate principal amount of $1,990,128. As of the date of this offering statement, we have outstanding convertible promissory notes in the aggregate principal amount of $1,990,168. See the response to Question 17 above for a description of the terms of these convertible promissory notes.

25. **What other exempt offerings has the issuer conducted within the past three years?**

We issued a total of 2,256,384 shares of common stock for aggregate proceeds of $2,506,382 in a private placement in August 2022, relying on Regulation D, Rule 506(b) of the Securities Act.

In August of 2022, we also converted shares of Series Preferred Stock of our Company, into 277,422 common stock of our Company, and shares of outstanding convertible promissory notes into 283,497 shares of common stock. In October 2022, we converted outstanding convertible notes into 2,334 shares of common stock. Between December 2022 and February 2023, we converted outstanding convertible notes into 117,524 shares of common stock. Between the months of June & August 2024, we converted outstanding convertible notes into 783,467 shares of common stock. Each convertible security described above was issued pursuant to Regulation D, Rule 506(b) offerings. We issued 5,000,000 shares of common stock pursuant to a Regulation D, Rule 506(b) offering under the Securities Act for aggregate gross proceeds of $350,000.

As of December 31, 2024, we issued a total of $1,990,128 of convertible notes. Those notes were issued under Regulation D, Rule 506(b) of the Securities Act. For a description of the terms of these notes, please see our response to question 17 above.

26. **Was or is the issuer or any entities controlled by or under common control with the issuer a party to any transaction since the beginning of the issuer's last fiscal year, or any currently proposed transaction, where the amount involved exceeds five percent of the aggregate amount of capital raised by the issuer in reliance on Section 4(a)(6) of the Securities Act during the preceding 12-month period, including the amount the issuer seeks to raise in the current offering, in which any of the following persons had or is to have a direct or indirect material interest: (1) any director or officer of the issuer; (2) any person who is, as of the most recent practicable date, the beneficial owner of 20 percent or more of the issuer's outstanding voting equity securities, calculated on the basis of voting power; (3) if the issuer was incorporated or organized within the past three years, any promoter of the issuer; or (4) any immediate family member of any of the foregoing persons. If yes, for each such transaction, disclose the following:**

There are no transactions to disclose.

FINANCIAL CONDITION OF THE ISSUER

27. **Does the issuer have an operating history?** [**X**] Yes [ ] No

28. **Describe the financial condition of the issuer, including, to the extent material, liquidity, capital resources and historical results of operations.**

Financial Information

Please see the financial information listed on the cover page of this Form C and attached hereto in addition to the following information. Financial statements are attached hereto as Exhibit A.

Results of Operations

Revenues—We intend to generate revenue from the sale of our breath test. We have not generated any revenues to date and have incurred $1,077,002 and $941,466 in losses for the periods ending December 31, 2023 and 2024, respectively.

Compensation, benefits, and Taxes—Compensation, benefits and taxes consist of salaries, wages, performance incentives, employer payroll taxes, and benefits for venue and corporate personnel. We continually review such costs for efficiency opportunities. Total compensation expense was $2,463,155.87 for the period from January 12, 2018 (inception) to December 31, 2024. Included in the total compensation expense, accrued compensation expense for the periods ending December 31, 2023 and 2024 were $334,676 & $189,563, respectively.

General and Administrative Expenses—The general and administrative expenses associated with project development includes business insurance, accounting fees, formation costs, and other related expenses. General and administrative expenses for the periods ending December 31, 2023, and 2024 were $200,830 and $426,007, respectively.

Development Costs— Development costs may include, but are not limited to, costs associated with medical studies, surveys, engineering, design, procurement contracting, utility interconnection studies and applications, site control, and other permitting-related activities. Development costs are expensed as incurred. Development costs for the periods ending December 31, 2023, and 2024, were $376,396 and $180,971, respectively.

Other Expenses-Other expenses include taxes and amortization. Other expenses for the periods ending December 31, 2023 and 2024, were $20,922 and $22,778, respectively.

Interest Expense—Interest includes the cost of our debt obligations, including the amortization of loan fees and original issue discounts, net of any interest income earned, or interest expense capitalized. Interest expenses for the periods ending December 31, 2023, and 2024 were $144,178 and $122,147, respectively.

Off Balance Sheet Arrangements—We have no material off-balance sheet arrangements.

Liquidity and Capital Resources

We had a net loss from operating activities of $941,466 in fiscal year 2024 compared to a net loss of $1,077,002 in fiscal year 2023. This continued net loss is attributable to the factors described above under "Results of Operations."

We had cash flow from financing activities of $1,511,499 in fiscal year 2024 as compared to $625,035 in fiscal year 2023. In fiscal year 2024 we raised $952,857 through the sale of our convertible notes. For a description of our convertible notes, see our response to question 17 of this Form C.

Capital Expenditures and Other Obligations

The Company does not intend to make any material capital expenditures and has no other outstanding obligations pending over the course of the next twelve months.

Material Changes and Other Information

None.

Trends and Uncertainties

The number one factor that affects our financial performance is our development and possible future sales of our lung cancer diagnostic tests.

The second factor is the Company's ability to attain sufficient financing until regular cashflow is achieved, and the third factor is regulatory hurdles, including those of which are not yet foreseen, which would affect the Company's ability to attain necessary financing and operational independence.

The financial statements are an important part of this Form C and should be reviewed in their entirety. The financial statements of the Company are attached hereto as Exhibit A.

29. **Include the financial information specified below covering the two most recently completed fiscal years or the period(s) since inception, if shorter:**

Attached as Exhibit A to this offering statement are the unaudited reviewed financial statements for the fiscal years ended December 31, 2024 and 2023.

30. **With respect to the issuer, any predecessor of the issuer, any affiliated issuer, any director, officer, general partner or managing member of the issuer, any beneficial owner of 20 percent or more of the issuer's outstanding voting equity securities, calculated in the same form as described in Question 6 of this Question and Answer format, any promoter connected with the issuer in any capacity at the time of such sale, any person that has been or will be paid (directly or indirectly) remuneration for solicitation of purchasers in connection with such sale of securities, or any general partner, director, officer or managing member of any such solicitor, prior to May 16, 2016:**

(1) Has any such person been convicted, within 10 years (or five years, in the case of issuers, their predecessors and affiliated issuers) before the filing of this offering statement, of any felony or misdemeanor:

(i) in connection with the purchase or sale of any security? [__] Yes [X] No

(ii) involving the making of any false filing with the Commission? [__] Yes [X] No

(iii) arising out of the conduct of the business of an underwriter, broker, dealer, municipal securities dealer, investment adviser, funding portal or paid solicitor of purchasers of securities? [__] Yes [X] No

If Yes to any of the above, explain:_____

(2) Is any such person subject to any order, judgment or decree of any court of competent jurisdiction, entered within five years before the filing of the information required by Section 4A(b) of the Securities Act that, at the time of filing of this offering statement, restrains or enjoins such person from engaging or continuing to engage in any conduct or practice:

(i) in connection with the purchase or sale of any security? [__] Yes [X] No;

(ii) involving the making of any false filing with the Commission? [__] Yes [X] No

(iii) arising out of the conduct of the business of an underwriter, broker, dealer, municipal securities dealer, investment adviser, funding portal or paid solicitor of purchasers of securities? [__] Yes [X] No

If Yes to any of the above, explain:_____

(3) Is any such person subject to a final order of a state securities commission (or an agency or officer of a state performing like functions); a state authority that supervises or examines banks, savings associations or credit unions; a state insurance commission (or an agency or officer of a state performing like functions); an appropriate federal banking agency; the U.S. Commodity Futures Trading Commission; or the National Credit Union Administration that:

(i) at the time of the filing of this offering statement bars the person from:

(A) association with an entity regulated by such commission, authority, agency or officer? [__] Yes [X] No

(B) engaging in the business of securities, insurance or banking? [__] Yes [X] No

(C) engaging in savings association or credit union activities? [__] Yes [X] No

(ii) constitutes a final order based on a violation of any law or regulation that prohibits fraudulent, manipulative or deceptive conduct and for which the order was entered within the 10-year period ending on the date of the filing of this offering statement? [__] Yes [X] No

If Yes to any of the above, explain:_____

(4) Is any such person subject to an order of the Commission entered pursuant to Section 15(b) or 15B(c) of the Exchange Act or Section 203(e) or (f) of the Investment Advisers Act of 1940 that, at the time of the filing of this offering statement:

(i) suspends or revokes such person's registration as a broker, dealer, municipal securities dealer, investment adviser or funding portal? [__] Yes [X] No

(ii) places limitations on the activities, functions or operations of such person? [__] Yes [X] No

(iii) bars such person from being associated with any entity or from participating in the offering of any penny stock? [__] Yes [X] No

If Yes to any of the above, explain:_____

(5) Is any such person subject to any order of the Commission entered within five years before the filing of this offering statement that, at the time of the filing of this offering statement, orders the person to cease and desist from committing or causing a violation or future violation of:

(i) any scienter-based anti-fraud provision of the federal securities laws, including without limitation Section 17(a)

(1) of the Securities Act, Section 10(b) of the Exchange Act, Section 15(c)(1) of the Exchange Act and Section 206(1) of the Investment Advisers Act of 1940 or any other rule or regulation thereunder? [__] Yes [X] No

(ii) Section 5 of the Securities Act? [__] Yes [X] No

If Yes to either of the above, explain:_____

(6) Is any such person suspended or expelled from membership in, or suspended or barred from association with a member of, a registered national securities exchange or a registered national or affiliated securities association for any act or omission to act constituting conduct inconsistent with just and equitable principles of trade? [__] Yes [X] No

If Yes, explain:_____

(7) Has any such person filed (as a registrant or issuer), or was any such person or was any such person named as an underwriter in, any registration statement or Regulation A offering statement filed with the Commission that, within five years before the filing of this offering statement, was the subject of a refusal order, stop order, or order suspending the Regulation A exemption, or is any such person, at the time of such filing, the subject of an investigation or proceeding to determine whether a stop order or suspension order should be issued? [__] Yes [X] No

If Yes, explain:_____

(8) Is any such person subject to a United States Postal Service false representation order entered within five years before the filing of the information required by Section 4A(b) of the Securities Act, or is any such person, at the time of filing of this offering statement, subject to a temporary restraining order or preliminary injunction with respect to conduct alleged by the United States Postal Service to constitute a scheme or device for obtaining money or property through the mail by means of false representations? [__] Yes [X] No

If Yes, explain:_____

If you would have answered "Yes" to any of these questions had the conviction, order, judgment, decree, suspension, expulsion or bar occurred or been issued after May 16, 2016, then you are NOT eligible to rely on this exemption under Section 4(a)(6) of the Securities Act.

OTHER MATERIAL INFORMATION

31. **In addition to the information expressly required to be included in this Form, include:**

(1) any other material information presented to investors; and

(2) such further material information, if any, as may be necessary to make the required statements, in the light of the circumstances under which they are made, not misleading.

Please see the exhibits to this offering statement, all of which have been made available to the offerees in connection with this offering.

ONGOING REPORTING

We will file a report electronically with the SEC annually and post the report on its website, no later than April 30, 2026 (120) days after the end of each fiscal year covered by the report). Once posted, the annual report may be found on our website at http://breathdiagnostics.com/annualreports. We must continue to comply with the ongoing reporting requirements until (1) we are required to file reports under Section 13(a) or Section 15(d) of the Exchange Act; (2) we have filed at least one annual report pursuant to Regulation Crowdfunding and have fewer than 300 holders of record and has total assets that do not exceed $10,000,000; (3) we have filed at least three annual reports pursuant to Regulation Crowdfunding; (4) we or another party repurchases all of the securities issued in reliance on Section 4(a)(6) of the Securities Act, including any payment in full of debt securities or any complete redemption of redeemable securities; or (5) we liquidate or dissolve our business in accordance with state law.

SIGNATURE

Pursuant to the requirements of Sections 4(a)(6) and 4A of the Securities Act of 1933 and Regulation Crowdfunding (§ 227.100 et seq.), the issuer certifies that it has reasonable grounds to believe that it meets all of the requirements for filing on Form C and has duly caused this Form to be signed on its behalf by the duly authorized undersigned.

The issuer also certifies that the attached financial statements are true and complete in all material respects.

/s/ Ivan Lo

(Signature)

Ivan Lo

(Name)

Chief Executive Officer

(Title)

Pursuant to the requirements of Sections 4(a)(6) and 4A of the Securities Act of 1933 and Regulation Crowdfunding (§ 227.100 et seq.), this Form C has been signed by the following persons in the capacities and on the dates indicated.

/s/ Ivan Lo

(Signature)

Chief Executive Officer

(Title)

May 2, 2025

(Date)

Instructions.

1. The form shall be signed by the issuer, its principal executive officer or officers, its principal financial officer, its controller or principal accounting officer and at least a majority of the board of directors or persons performing similar functions.

2. The name of each person signing the form shall be typed or printed beneath the signature. Intentional misstatements or omissions of facts constitute federal criminal violations. See 18 U.S.C. 1001

EXHIBITS

Exhibit A	Financial Statements
Exhibit B	[Intentionally Omitted]
Exhibit C	Subscription Agreement
Exhibit D	Pitch Deck

EXHIBIT A
Financial Statements

EXHIBIT B
[Intentionally Omitted]

EXHIBIT C
Subscription Agreement

EXHIBIT D
Pitch Deck

You can view our pitch deck presentation here.