



## Offering Statement for 20/20 Biolabs, Inc.

20/20 Biolabs, Inc. (“we,” “us,” “our” or the “Company”), formerly known as 20/20 GeneSystems, Inc., a Delaware C-Corp incorporated on May 1, 2000, is holding the following offering (the “Offering”):

*20/20 Biolabs, Inc. is offering securities in the form of convertible notes. A convertible note is a debt instrument used by emerging growth companies and startups that converts into equity during a future funding round or upon a merger, acquisition, or public listing, typically offering investors a discount and/or valuation cap to determine their share allocation. Below are the terms of the convertible note:*

**Type of Security:** Convertible Promissory Notes (the “Notes”)

**Minimum Raise Amount:** \$10,000

**Maximum Raise Amount:** \$350,000

**Maturity Date:** 24 months from the issuance date of the Notes (the “Loan Date”)

**Discount:** 20%

**Interest Rate:** 15.0%

**Repayment.** Unless otherwise converted, all unpaid principal, together with all unpaid and accrued interest, shall be due and payable within ten (10) days after the Maturity Date (as defined below).

**Interest Rate.** Interest shall accrue on the outstanding principal amount of the Notes from the Loan Date until payment in full, which interest shall be payable at the rate of fifteen percent (15%) per annum or the maximum rate permissible by Maryland law, whichever is less. Such interest shall be calculated based on a 365-day year for the actual number of days elapsed.

**Maturity Date.** Unless the Notes have been pre-paid or previously converted, the entire outstanding principal balance and all unpaid accrued interest shall be repaid within ninety (90) days of written demand from the holder; provided, however, that such written demand may not occur prior to the date that is twenty-four (24) months from Loan Date (the “Maturity Date”).

**Prepayment.** The obligations under the Notes may not be pre-paid by Company without the prior written consent of the holders of a majority of the then outstanding principal amount of the Notes (the “Majority Holders”).

**Application of Payments.** Any payments shall be applied first to accrued interest, and thereafter to the outstanding principal balance.

**Conversion.**

**(a) Automatic Conversion Upon Stock Exchange Listing.** If, prior to repayment or conversion of the Notes, the Company's (or a successor to the Company's) shares are listed on a national securities exchange, including, without limitation, through a firm underwritten initial public offering, merger, reverse merger, or direct-listing (the "Public Company Stock"), all of the principal and accrued interest then outstanding under the Notes shall be automatically converted, without any action by the holders, into a number of shares of Public Company Stock equal to the number that results from the following equation: dividing (i) all of the principal and accrued interest then outstanding under the Notes by (ii) a conversion price equal to (A) eighty percent (80%) of the price per share of the Public Company Stock sold to the public by the underwriters at the closing of the initial public offering, or (B) in the event of a merger, reverse merger, or direct-listing, the volume weighted average price of the Public Company Stock during the five (5) trading days following such merger, reverse merger, or direct-listing.

**(b) Conversion Upon Qualified Financing.** If, prior to repayment or conversion of the Notes, the Company consummates a financing transaction whereby any equity or equity-linked securities of the Company are sold to investors in exchange for cash in which the Company receives gross proceeds of at least four million dollars (\$4,000,000) (including the conversion of the Notes) (a "Qualified Financing"), then effective upon the closing of the Qualified Financing, all of the principal and accrued interest then outstanding under the Notes shall be automatically converted, without any action by the holders, into a number of shares or units, as applicable, that were sold in such Qualified Financing at a conversion price equal to eighty percent (80%) of the price per share or unit, as applicable, sold in such Qualified Financing.

**(c) Optional Conversion at non-Qualified Financing.** If, prior to repayment or conversion of the Notes, the Company consummates a financing transaction whereby any equity or equity-linked securities of the Company are sold to investors in exchange for cash in a transaction that does not constitute a Qualified Financing, then the Majority Holders shall have the option to treat such equity financing as a Qualified Financing on the same terms set forth herein.

The minimum individual investment amount for this Offering is \$500 (the "Minimum Individual Purchase Amount"). The Company must reach a target offering amount of \$10,000 (the "Target Offering Amount") by November 30, 2025 (the "Offering Deadline"). Unless the Company raises at least the Target Offering Amount by the Offering Deadline, no securities will be sold in this Offering, investment commitments will be cancelled, and committed funds will be returned.

This document is generated by PicMii Crowdfunding LLC ("PicMii"), which is not a registered broker-dealer. PicMii does not give investment advice, endorsement, analysis or recommendations with respect to any securities. All securities listed here are being offered by, and all information included in this document are the responsibility of, the applicable issuer of such securities. PicMii has not taken any steps to verify the adequacy, accuracy or completeness

of any information. Neither PicMii nor any of its officers, directors, agents or employees makes any warranty, express or implied, of any kind whatsoever related to the adequacy, accuracy or completeness of any information in this document or the use of information in this document.

All regulation CF offerings are conducted through PicMii Crowdfunding LLC, a FINRA/SEC registered funding-portal. For inquiries related to Regulation CF securities, contact PicMii Crowdfunding LLC:

Chandler Kline: [chandler.kline@picmiicrowdfunding.com](mailto:chandler.kline@picmiicrowdfunding.com)

PicMii does not make investment recommendations and no communication through this website or in any other medium should be construed as a recommendation for any security offered on or off this investment platform. Equity crowdfunding investments in private placements, Regulation A, D and CF offerings, and start-up investments in particular are speculative and involve a high degree of risk and those investors who cannot afford to lose their entire investment should not invest in start-ups. Companies seeking startup investments through equity crowdfunding tend to be in earlier stages of development and their business model, products and services may not yet be fully developed, operational or tested in the public marketplace. There is no guarantee that the stated valuation and other terms are accurate or in agreement with the market or industry valuations. Additionally, investors may receive illiquid and/or restricted stock that may be subject to holding period requirements and/or liquidity concerns. In the most sensible investment strategy for start-up investing, start-ups should only be part of your overall investment portfolio. Further, the start-up portion of your portfolio may include a balanced portfolio of different start-ups. Investments in startups are highly illiquid and those investors who cannot hold an investment for the long term (at least 5-7 years) should not invest.

### **Cautionary Note Concerning Forward-Looking Statements**

This Form C and any documents incorporated by reference herein contain forward-looking statements and are subject to risks and uncertainties. All statements other than statements of historical fact or relating to present facts or current conditions included in this Form C are forward-looking statements. Forward-looking statements give our current reasonable expectations and projections regarding our financial condition, results of operations, plans, objectives, future performance and business. You can identify forward-looking statements by the fact that they do not relate strictly to historical or current facts. These statements may include words such as "anticipate," "estimate," "expect," "project," "plan," "intend," "believe," "may," "should," "can have," "likely," and other words and terms of similar meaning in connection with any discussion of the timing or nature of future operating or financial performance or other events.

The forward-looking statements contained in this Form C and any documents incorporated by reference herein are based on reasonable assumptions we have made in light of our industry experience, perceptions of historical trends, current conditions, expected future developments and other factors we believe are appropriate under the circumstances. As you read and consider this Form C, you should understand that these statements are not guarantees of performance or results. Although we believe that these forward-looking statements are based on reasonable

assumptions, you should be aware that many factors could affect our actual operating and financial performance and cause our performance to differ materially from the performance anticipated in the forward-looking statements. Should one or more of these risks or uncertainties materialize or should any of these assumptions prove incorrect or change, our actual operating and financial performance may vary in material respects from the performance projected in these forward-looking statements.

Investors are cautioned not to place undue reliance on these forward-looking statements. Any forward-looking statements made in this Form C or any documents incorporated by reference herein is accurate only as of the date of those respective documents. Except as required by law, we undertake no obligation to publicly update any forward- looking statements for any reason after the date of this Form C or to conform these statements to actual results or to changes in our expectations.

## **About This Form C**

**In making an investment decision, investors must rely on their own examination of the Company 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.**

THESE SECURITIES INVOLVE A HIGH DEGREE OF RISK THAT MAY NOT BE APPROPRIATE FOR ALL INVESTORS. THERE ARE ALSO SIGNIFICANT UNCERTAINTIES ASSOCIATED WITH AN INVESTMENT IN OUR COMPANY AND THE SECURITIES. THE SECURITIES OFFERED HEREBY ARE NOT PUBLICLY TRADED. THERE IS NO PUBLIC MARKET FOR THE SECURITIES AND ONE MAY NEVER DEVELOP. AN INVESTMENT IN OUR COMPANY IS HIGHLY SPECULATIVE. THE SECURITIES SHOULD NOT BE PURCHASED BY ANYONE WHO CANNOT BEAR THE FINANCIAL RISK OF THIS INVESTMENT FOR AN INDEFINITE PERIOD OF TIME AND WHO CANNOT AFFORD THE LOSS OF THEIR ENTIRE INVESTMENT. SEE THE SECTION OF THIS FORM C TITLED "RISK FACTORS".

THE SECURITIES OFFERED HEREBY WILL HAVE TRANSFER RESTRICTIONS. NO SECURITIES MAY BE PLEDGED, TRANSFERRED, RESOLD OR OTHERWISE DISPOSED OF BY ANY INVESTOR EXCEPT PURSUANT TO RULE 501 OF REGULATION CF. YOU SHOULD BE AWARE THAT YOU WILL BE REQUIRED TO

BEAR THE FINANCIAL RISKS OF THIS INVESTMENT FOR AN INDEFINITE PERIOD OF TIME.

YOU ARE NOT TO CONSTRUE THE CONTENTS OF THIS FORM C AS LEGAL, ACCOUNTING OR TAX ADVICE OR AS INFORMATION NECESSARILY APPLICABLE TO YOUR PARTICULAR FINANCIAL SITUATION. EACH INVESTOR SHOULD CONSULT THEIR OWN FINANCIAL ADVISER, COUNSEL AND ACCOUNTANT AS TO LEGAL, TAX AND RELATED MATTERS CONCERNING THEIR INVESTMENT.

THIS OFFERING IS ONLY EXEMPT FROM REGISTRATION UNDER THE LAWS OF THE UNITED STATES AND ITS TERRITORIES. NO OFFER IS BEING MADE IN ANY JURISDICTION NOT LISTED ABOVE. PROSPECTIVE INVESTORS ARE SOLELY RESPONSIBLE FOR DETERMINING THE PERMISSIBILITY OF THEIR PARTICIPATING IN THIS OFFERING, INCLUDING OBSERVING ANY OTHER REQUIRED LEGAL FORMALITIES AND SEEKING CONSENT FROM THEIR LOCAL REGULATOR, IF NECESSARY. THE INTERMEDIARY FACILITATING THIS OFFERING IS LICENSED AND REGISTERED SOLELY IN THE UNITED STATES AND HAS NOT SECURED, AND HAS NOT SOUGHT TO SECURE, A LICENSE OR WAIVER OF THE NEED FOR SUCH LICENSE IN ANY OTHER JURISDICTION. THE COMPANY, THE ESCROW AGENT AND THE INTERMEDIARY, EACH RESERVE THE RIGHT TO REJECT ANY INVESTMENT COMMITMENT MADE BY ANY PROSPECTIVE INVESTOR, WHETHER FOREIGN OR DOMESTIC.

### **SPECIAL NOTICE TO FOREIGN INVESTORS**

IF YOU LIVE OUTSIDE THE UNITED STATES, IT IS YOUR RESPONSIBILITY TO FULLY OBSERVE THE LAWS OF ANY RELEVANT TERRITORY OR JURISDICTION OUTSIDE THE UNITED STATES IN CONNECTION WITH ANY PURCHASE OF THE SECURITIES, INCLUDING OBTAINING REQUIRED GOVERNMENTAL OR OTHER CONSENTS OR OBSERVING ANY OTHER REQUIRED LEGAL OR OTHER FORMALITIES. WE RESERVES THE RIGHT TO DENY THE PURCHASE OF THE SECURITIES BY ANY FOREIGN INVESTOR.

### **NOTICE REGARDING THE ESCROW AGENT**

ENTERPRISE BANK AND TRUST, THE ESCROW AGENT SERVICING THE OFFERING, HAS NOT INVESTIGATED THE DESIRABILITY OR ADVISABILITY OF AN INVESTMENT IN THIS OFFERING OR THE SECURITIES OFFERED HEREIN. THE ESCROW AGENT MAKES NO REPRESENTATIONS, WARRANTIES, ENDORSEMENTS, OR JUDGEMENT ON THE MERITS OF THE OFFERING OR THE SECURITIES OFFERED HEREIN. THE ESCROW AGENT'S CONNECTION TO THE OFFERING IS SOLELY FOR THE LIMITED PURPOSES OF ACTING AS A SERVICE PROVIDER.

## **Bad Actor Disclosure**

The Company is not subject to any bad actor disqualifications under any relevant U.S. securities laws.

## **Ongoing Reporting**

Following the first sale of the securities offered hereby, the Company will file a report electronically with the Securities and Exchange Commission annually and post the report on its website, no later than 120 days after the end of the Company's fiscal year.

Once posted, the annual report may be found on the Company's website at <https://2020biolabs.com>.

The Company must continue to comply with the ongoing reporting requirements until:

1. the Company is required to file reports under Section 13(a) or Section 15(d) of the Securities Exchange Act of 1934, as amended (the “Exchange Act”);
2. the Company has filed at least three annual reports pursuant to Regulation CF and has total assets that do not exceed \$10,000,000;
3. the Company has filed at least one annual report pursuant to Regulation CF and has fewer than 300 holders of record;
4. the Company or another party repurchases all of the securities issued in reliance on Section 4(a)(6) of the Securities Act of 1933, as amended (the “Securities Act”), including any payment in full of debt securities or any complete redemption of redeemable securities; or
5. the Company liquidates or dissolves its business in accordance with applicable state law.

# The Company

## **1. What is the name of the Company?**

20/20 Biolabs, Inc.

15810 Gaither Road, Suite 235 Gaithersburg MD 20877

# Eligibility

## **2. The following are true for 20/20 Biolabs, Inc.:**

1. Organized under, and subject to, the laws of a State or territory of the United States or the District of Columbia.
2. Not Subject to the requirement to file reports pursuant to Section 13 or Section 15(d) of the Securities Exchange Act of 1934.
3. Not an investment company registered or required to be registered under the Investment Company Act of 1940.
4. Not ineligible to rely on this exemption under Section 4(a)(6) of the Securities Act as a result of a disqualification specified in Rule 503(a) of Regulation Crowdfunding. (For more information about these disqualifications, see Question 30 of this Question and Answer Format).
5. Has filed with the Commission and provided 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 Company was required to file such reports).
6. 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 Company or any of its predecessors previously failed to comply with the ongoing reporting requirements of Rule 202 of Regulation Crowdfunding?**

No.

# Directors, Officers and Promoters of the Company

**4. The following individuals (or entities) represent the company as a director, officer or promoter of the Offering:**

## **Employee Name and Title**

Jonathan Cohen: CEO, President and Board Member

Mr. Cohen's primary position is with the Company.

## **Employee Background**

Mr. Cohen is the founder of the Company and has served as Chief Executive Officer, President, and a director since its inception. He is a co-inventor of two of our most successful products, OneTest and BioCheck, and has led the commercial launch and sales of both. He has also spearheaded license, research, technology transfer, investment, and sales and marketing agreements with Fortune 500 companies such as Eastman Kodak, Abbott Diagnostics, Johnson & Johnson, IBM, and Ping An, the largest health insurance company in China. Mr. Cohen has also been a leading advocate in Annapolis, MD and on Capitol Hill on behalf of small and emerging biotechnology and diagnostics companies. Before founding the Company, Mr. Cohen was patent and general counsel for two publicly traded companies, Ventana Medical Systems Inc. (acquired by Roche diagnostics in 2008), from 1999 to 2000, and Oncor Inc., from 1997 to 1999. Mr. Cohen is a registered patent attorney with more than 25 years of experience in biotechnology patents and licensing matters. Mr. Cohen has a Master of Science Degree in Biotechnology from Johns Hopkins University and a law degree from the American University.

## **3-Year Work History**

Primary Position: 20/20 Biolabs, Inc. | CEO | 2000 – present

## **Employee Name and Title**

Jiming Zhou: COO

Dr. Zhou's primary position is with the Company.

## **Employee Background**

Dr. Zhou has served as our Chief Operating Officer since August 2020. He is an expert in healthcare and biotech industries, with over 20 years of experience in both academia and industry. Dr. Zhou began his academic career as an associate professor at Sichuan University in China, where he received his PhD of Biology. Afterward, he moved to the United States to



conduct research at the University of Iowa, where he spent 7 years publishing over 30 peer-reviewed research papers and receiving numerous grants and patents. In 2005, Dr. Zhou transitioned into industrial R&D, where he led a joint pharmaceutical project that reached significant milestones totaling \$330 million. He then went on to manage multiple clinical labs and co-founded companies, collaborating with prominent healthcare institutes both in the US and China. Prior to joining us in July 2019, Dr. Zhou held various leadership roles, including serving as president and co-founder of Baltimore-based biotech firm Firefox Pharmaceuticals, LLC from April 2017 to July 2019, partner and co-founder of Virginia-based Fairfax Medical Consulting International, LLC from October 2013, and managing director of Diagnostic Operation and Strategic Alliance of the Genetics and IVF Institute, an international company based in Virginia, from September 2009 to September 2013. Dr. Zhou's extensive experience in the biotech industry.

### **3-Year Work History**

Primary Position: 20/20 Biolabs, Inc. | COO | 2020 – present

#### **Employee Name and Title**

Ron Baker: Chief Business Officer

Mr. Baker's primary position is with the Company.

#### **Employee Background**

Mr. Baker has served as our Chief Business Officer since October 2019 and previously served as our Director of Sales from October 2019 to January 2023. Prior to joining us, he held executive management positions in clinical research, operations, technical, sales, marketing and business development with international, national and start-up companies, all related to specialized oncology laboratory services, including as executive director of U.S. sales for SGS Life Sciences (Belgium) from December 2006 to March 2018. He previously worked with Roche Diagnostics and Roche Clinical Labs, International Clinical Labs and Molecular Oncology (start-up sold to Dianon). Mr. Baker earned his BS in Biology from Loyola University.

### **3-Year Work History**

Primary Position: 20/20 Biolabs, Inc. | Chief Business Officer | 2019 – present

#### **Employee Name and Title**

Michael Lebowitz: Chief Scientific Officer

Mr. Lebowitz's primary position is with the Company.

#### **Employee Background**

Dr. Lebowitz has served as our Chief Scientific Officer since January 2020 and was previously our Director of Research & Development from 2009-2012. Dr. Lebowitz has more than 30 years of research experience, including 27 years in our industry and more than 25 years in research management. He has been directly involved in the commercial launch of six LDTs for the early detection of cancer and the establishment of two CLIA-certified labs. He has also spearheaded the R&D supporting an anti-cancer vaccine from discovery through phase I clinical development. He is concurrently chief scientific officer of Athanor Biosciences, Inc., a cancer therapeutics company he cofounded in 2020. Prior to his current positions, he was senior director and vice president of research at Sensei Biotherapeutics from 2014-2019. Dr. Lebowitz holds a Ph.D. from the Johns Hopkins University School of Medicine in biochemistry, cellular, and molecular biology where he subsequently completed a three-year fellowship in immunology in the department of pathology, division of immunopathology. He is currently an adjunct faculty at both Johns Hopkins University and University of Maryland, Baltimore County teaching in their respective Biotechnology programs.

### **3-Year Work History**

Primary Position: 20/20 Biolabs, Inc. | Chief Scientific Officer | 2020 – present

### **Employee Name and Title**

John G. Compton: Chairman of the Board of Directors

Mr. Compton is retired and he serves on multiple boards. His primary position is as Mayor of Washington Grove, MD.

### **Employee Background**

Dr. Compton has served as Chairman of the Board since July 2016. He has over 30 years of experience in the development and application of molecular biological techniques to answer questions about genetics and epidermal differentiation and has authored more than 80 publications in the field. Dr. Compton served as vice-president of BioReference Laboratories from 2007 to 2013. Previously, Dr. Compton was founder, and served as scientific director and co-president of GeneDx Inc, from 2000 to 2006, the assets of which were acquired by BioReference Laboratories (now part of Opko) in September 2006. Dr. Compton also serves as Mayor of the Town of Washington Grove, MD (2000-2008, 2018-present), on the Board of Directors of Quertle Inc. and chairs the Boards of the non-profit BlackRock Center for the Arts and the Pinkney Center for Science and Technology at Montgomery College Germantown Campus. Dr. Compton holds B.S. degrees in Physics and Biology from the Massachusetts Institute of Technology, received his Ph.D. from the University of California, Berkeley, in Biophysics, and was a Staff Scientist at the NIAMS, National Institutes of Health, Bethesda, from 1991-2000. In 2003, he was awarded the Entrepreneur of the Year award by the Technology Council of Maryland.

### **3-Year Work History**

20/20 Biolabs, Inc. | Board Member | 2016-present

Primary position: Mayor of Washington Grove, MD | Chairman of the Board of Directors

**Employee Name and Title**

Richard M. Cohen: Board Member

Mr. Cohen's primary position is with Richard M Cohen Consultants as director.

**Employee Background**

Mr. Cohen has served as a member of our board of directors since July 2016. He is an experienced CEO/CFO at public and private companies. His professional experience includes biotech, financial services and diversified media and he maintains excellent contacts with capital financing sources on and off Wall Street. He has been the president of Richard M Cohen Consultants since 1995, a company providing financial consulting services to both public and private companies. From March 2012 to July 2015, he was the founder and managing partner of Chord Advisors, a firm providing outsourced CFO services to both public and private companies. He was the chief executive officer and chief financial officer of CorMedix Inc., a publicly traded medical device/biotechnology company with an intrapericardial therapy product targeted to markets in the U.S. and Europe, from 2010 to 2013. He has served on the board of directors and audit committees of Ondas Holdings Inc. (2018 to present), Helix BioMedix, Inc. (2006 to present), CorMedix Inc. (2010 to 2013), and Rodman & Renshaw (2008 to 2012). Mr. Cohen's academic credentials include an MBA from Stanford University and B.S. with honors from Wharton School, University of Pennsylvania.

**3-Year Work History**

20/20 Biolabs, Inc. | Board Member | 2016-present

Primary Position: Richard M Cohen Consultants | Director

**Employee Name and Title**

Wei Lu: Board Member on behalf of Ping An.

Ms. Lu's primary position is with Ping An Ventures

**Employee Background**

Ms. Lu has served as a member of our board of directors since June 2023. Ms. Lu has over 10 years of experience in private equity investment and post investment management. She has served as the Vice President of Ping An Ventures since January 2019, where she is mainly responsible for post investment management of medical investments, including biotechnology,

medical devices, medical services, etc. Ms. Wei Lu holds Master's degree in Finance from Chongqing University.

### **3-Year Work History**

20/20 Biolabs, Inc. | Board Member | 2023-present

Primary Position: Ping An Ventures | Director

#### **Employee Name and Title**

Prasanth Reddy: Board Member

Dr. Reddy's primary position is with Labcorp as SVP, Global Enterprise Oncology Head.

#### **Employee Background**

Dr. Reddy has served as a member of our board of directors since November 2023. He is triple board-certified in internal medicine, medical oncology, and hematology, and practiced medicine and served in leadership positions for more than 14 years in various clinical settings including academia, private practice, managed care, and life sciences. Dr. Reddy was most recently senior vice president, global enterprise oncology head of Labcorp from January 2021 to July 2023. Previously he served as vice president of medical affairs at Foundation Medicine from February 2018 to December 2020. He currently serves in the Air Force Reserve as a Lt Colonel. Dr. Reddy earned a bachelor's degree in microbiology and psychology from Kansas State University, and a medical degree from the University of Kansas Medical Center, where he also completed his internal medicine residency and clinical hematology and oncology fellowship. Dr. Reddy has a master's degree in public health and is an alumnus of Harvard Business School. Additionally, he is a fellow of the American College of Physicians and is a Certified Physician Executive.

### **3-Year Work History**

Primary Position: AdventHealth | Self-Employed | September 2016-present

20/20 Biolabs, Inc. | Board Member | 2023-present

#### **Employee Name and Title**

John W. Rollins: Board Member

Mr. Rollins' is retired with no primary position. He serves part time on the board of 20/20 BioLabs.

#### **Employee Background**

Mr. Rollins has served as a member of our board of directors since November 2017. He has served on multiple boards and chairs the board of directors of the MedStar Southern Maryland Hospital Center (2014 to present). From 2001 to 2010, he taught Entrepreneurship at the George Washington University School of Business and founded the GW New Venture Competition and served as its Director from 2007 to 2014. In 2003, Mr. Rollins founded StreamCenter, Inc., a firm that pioneered online education using video streaming, and served as chair of the board of directors from 2003 to 2008, and chief executive officer from 2008 to 2010. Prior to 2001, he founded and served for three decades as the chief executive officer and chairman of AZTECH Software Corporation, the nation's first specialized provider of information technology services to non-profit organizations. Mr. Rollins's board experience has included serving as Trustee of the National Park Trust (Vice Chair and Treasurer) (1990 to present), Director of the MedStar Georgetown University Hospital (Vice Chair) (2002 to 2013), the Washington Hospital Center (Vice Chair and Treasurer) (1977 to 2002), and the U.S. Association for Small Business & Entrepreneurship (2004 to 2006). Mr. Rollins earned his A.B. in Mathematics from Dartmouth and his M.B.A. in Finance from the Stanford University Graduate School of Business.

### **3-Year Work History**

20/20 Biolabs, Inc. | Board Member | 2017-present

MedStar Southern Maryland Hospital Center | Board Chair | September 2014-October 2022

National Park Trust | Founding Trustee | 1990-June 2022

### **Employee Name and Title**

Michael A. Ross: Board Member

Mr. Ross's primary position is with Euclid Systems Corporation as a director.

### **Employee Background**

Dr. Ross has served as a member of our board of directors since July 2016. He has served as the chairman and chief executive officer of Euclid Systems Corporation since 2015, where he led the growth of this ophthalmic medical device company from \$3.1 million to over \$20 million in five years. The bulk of Euclid's sales are in China and East Asia where Dr. Ross visits 4-5 times per year. Prior to joining Euclid, he was chief executive officer of E-P Therapeutics from 2010 to 2012, and was a medical and scientific advisor to StemCyte, Inc. 2009 to 2010. He is Board-certified in Obstetrics and Gynecology and is a founding member of an OB-GYN-Infertility practice in Northern Virginia from 1980 to 2007. Dr. Ross has been a Clinical Professor of Obstetrics and Gynecology, George Washington University Medical Center since 1979, and has served on the boards of directors of several biotech and medical device companies. He has a B.S. in Chemistry and Biology from Dickinson College and an M.D. from George Washington University.

### **3-Year Work History**

20/20 Biolabs, Inc. | Board Member | 2016-present

Primary position: Euclid Systems Corporation | Director

# Principal Security Holders

**5. 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 Company's outstanding voting equity securities, calculated on the basis of voting power. To calculate total voting power, include all securities for which the person directly or indirectly has or shares the voting power, which includes the power to vote or to direct the voting of such securities. If the person has the right to acquire voting power of such securities within 60 days, including through the exercise of any option, warrant or right, the conversion of a security, or other arrangement, or if securities are held by a member of the family, through corporations or partnerships, or otherwise in a manner that would allow a person to direct or control the voting of the securities (or share in such direction or control - as, for example, a co-trustee) they should be included as being "beneficially owned." You should include an explanation of these circumstances in a footnote to the "Number of and Class of Securities Now Held." To calculate outstanding voting equity securities, assume all outstanding options are exercised and all outstanding convertible securities converted.**

As of the most recent practicable date, **no individual or entity beneficially owns 20 percent or more of the Company's outstanding voting equity securities, calculated on the basis of voting power.** This includes voting power that may be acquired within 60 days through options, convertible securities, or other arrangements.

# Business and Anticipated Business Plan

## 6. Describe in detail the business of the Company and the anticipated business plan of the Company.

### Overview

We develop and commercialize AI-powered, laboratory-based blood tests for the early detection and prevention of cancers and chronic diseases.

We offer two families of lab tests, both under our OneTest brand: (i) OneTest for Cancer, a multi-cancer early detection (“MCED”) blood test which has been our primary commercial focus and source of revenues since we wound down our COVID-19 testing business, and (ii) OneTest for Longevity, which measures inflammatory biomarkers, that we expect to launch in the second half of 2025. Both tests are run in our CAP (College of American Pathologists) accredited, CLIA (Clinical Laboratory Improvement Amendments) licensed laboratory in Gaithersburg, MD. That laboratory also hosts our Clinical Laboratory Innovation Accelerator (“CLIAx”), which we believe is the country’s first shared CLIA laboratory for overseas diagnostics start-ups seeking to launch novel lab tests in the U.S. without the expense of establishing and operating their own, independent lab.

As noted above, during the COVID-19 pandemic, we also provided COVID-19 viral testing using polymerase chain reaction (“PCR”) analytical equipment in our clinical laboratory. Our legacy business also includes a pioneering field test kit for screening suspicious powders for bioterror agents known as BioCheck.

As of the date hereof, we generate revenue from three sources: OneTest for Cancer (primarily as a lab test in the U.S. but we also license our algorithms to overseas labs), BioCheck and from the CLIAx. For the years ended December 31, 2024 and 2023, sales of OneTest for Cancer accounted for approximately 85% and 65% of our revenues, respectively, sales of BioCheck accounted for approximately 10% and 13% of our revenues, respectively, our CLIAx accounted for approximately 5% and 4% of our revenues, respectively, and COVID-19 testing accounted for approximately 0% and 18% of our revenues, respectively.

### Products

#### *OneTest for Cancer*

##### The Problem

Of the ten deadliest cancers in the U.S., only three — breast, colon, and prostate — have widely adopted screening modalities. This is despite growing evidence that early detection saves or extends lives for cancers of the lung, liver, pancreas, esophagus, and ovaries, which are not yet the subject of widespread asymptomatic screening. The survival rate for the deadliest cancers is closely linked to the stage at the time of diagnosis. With lung cancer, for example, some studies show a five-year survival rate approaching 90% for screen-detected Stage 1 cancers (see



Henschke, et al. “Survival of patient with Stage 1 Lung Cancer Detected on CT Screening,” *N. Engl. J. Med.* 355 (2006)). That survival plummets to under 5% for cancers first diagnosed in Stage 4.

To address this void, a few MCEDs have entered the market in recent years and are generating significant enthusiasm among many medical practitioners, policymakers, employers, and consumers. MCEDs gained significant attention in 2022 as the White House included MCEDs as a core component of its “Cancer Moonshot” program and bi-partisan legislation has been introduced in Congress to make it easier for these types of screening tests to achieve reimbursement by government payers. See H.R.842 — *Nancy Gardner Sewell Medicare Multi-Cancer Early Detection Screening Coverage Act* reintroduced in the current 119<sup>th</sup> Congress (February 2025). The same bill was cosponsored by 319 House Members and over 60 Senators in the 118<sup>th</sup> Congress which ended December 2024.

Additionally, on February 26, 2025, the “*Firefighter Investments to Recognize Exposure to Cancer Act of 2025*” was reintroduced as H.R. 1610. If enacted, the legislation would allocate \$700 million in grants to American firefighters to receive MCED tests through the Federal Emergency Management Administration (“FEMA”). FEMA and several states, including Maryland, New Hampshire, Louisiana, Vermont, and New Jersey, already reimburse their firefighters for obtaining MCEDs, including our OneTest (firefighters have proven higher incidence and death rates for several cancers and are a major segment of our customer base). We expect many more states to appropriate funding to reimburse their fire departments for MCED tests like OneTest in 2025 and 2026.

This focus on MCEDs has been further bolstered by the activities of high-profile companies offering or developing circulating tumor DNA (“ctDNA”), based tests, such as Grail’s Galleri test, following technological advances in next-generation DNA sequencing and machine learning techniques. While ctDNA-based tests are newer and are seeing growing use by scientists, clinicians, and self-insured employers, they are significantly more expensive, are lacking in the level and number of analytical and clinical validation studies to support them and generally have not performed any better than protein-based technologies in terms of sensitivities for early-stage cancers in asymptomatic populations. Additionally, ctDNA tests require larger quantities of blood that require venipuncture whereas proteomic-based MCEDs work well with smaller volumes of capillary blood that can be easily collected in retail locations or at home without a phlebotomist.

### Our Solution

To address this market, we are offering what we believe to be the first MCED blood tests to enter the American market based mainly on a panel of protein tumor markers (“PTMs”). PTMs have been extensively validated and are widely utilized in certain regions of the world for cancer screening (the Premium version of OneTest also includes inflammatory and metabolic biomarkers). Our patented approach improves upon the use of these biomarkers with various algorithms and is powered by AI. We believe that ours is the first and only MCED on the market in the U.S. that (i) is available at a starting price of under \$200, (ii) can be accessed at home without painful needles, and (iii) has been demonstrated in studies conducted in 2024 by the U.S. National Cancer Institute (the “NCI”) to correctly identify significant numbers of otherwise

deadly cancers at early stages. These cancers include those of the lung, pancreas, and ovaries, which, when detected at an earlier stage, give the best chance of survival.

The OneTest algorithm combines the levels of protein biomarkers such as carcinoembryonic antigen (“CEA”), alpha-fetoprotein (“AFP”), prostate specific antigen (“PSA”) and others, with patient information (e.g., age, gender, smoking history, etc.). We report the values of the biomarkers along with a proprietary score indicating the likelihood of being diagnosed with cancer within a year of the test date (a sample lab report for OneTest Standard is shown below).



OneTest (Multi-Cancer Early Detection) Report

Female OneTest Panel

<b>Patient</b> Name: Jane Doe Patient ID: 136648 DOB: 1990-01-18 Gender: Female Email:	<b>Sample</b> Accession #: 373537 Specimen Source: serum Collect Date: 01/20/2023 8:01AM Received Date: 01/20/2023 10:01AM Report Date: 01/20/2023 1:01AM	<b>Ordering Provider</b> 2020 Gene Systems R&D Name: Research Development Phone: (240) 453-6339 Address: 15810 Gaither Drive Suite 235 Gaithersburg, MD 20877
---	--	--



Low Risk:

The tumor biomarker patterns in your blood sample showed low risk. In our database, only 0.3% of individuals with similar results were projected to have cancer within 12 months.

Tumor Marker	Result	Unit	Flag	Reference Range
AFP	1.61	ng/mL		0.0 - 8.3
CA125	9.10	U/mL		0.0 - 38.0
CA15-3	5.30	U/mL		0.0 - 25.0
CA19-9	5.00	U/mL		0.0 - 35.0
CEA	0.60	ng/mL		0.0 - 4.7
CYFRA21-1	1.42	ng/mL		0.0 - 2.37

Explanation

The OneTest algorithm analyzed your biomarkers based on a dataset of >27,000 asymptomatic individuals who were followed for at least one year after testing. Only 0.3% of individuals in our dataset with biomarker patterns similar to yours were diagnosed with cancer within one year of having their biomarkers tested. This places you in a low-risk category. You should continue to monitor your general health status under the guidance of a healthcare professional and adhere to standard cancer screening protocols as directed. According to the National Cancer Institute, the standard incidence rates of cancer range from 0.35%-2.2% from 40-85+ years of age, suggesting that your risk is not elevated over the general population.

Notes

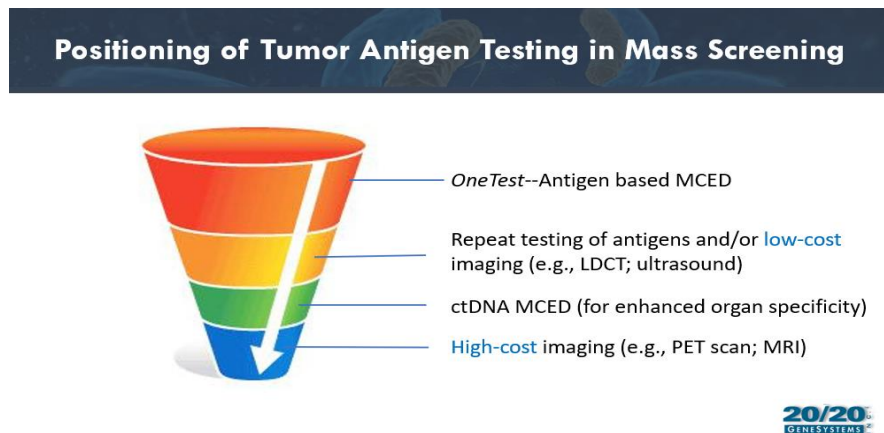
Reported tumor marker values were derived from Roche Elecsys chemiluminescence immunoassay kits approved by the US FDA for use in cancer prognosis or monitoring, but by regulators in several regions outside the US for use in cancer screening. OneTest is a Laboratory-Developed Test (LDT) that predicts risk of being identified as having cancer within 12-months of the test by using biomarker values together with subject age and gender. Percent risk can range, with low risk categorized as a 0.3% risk; mildly elevated risk categorized as a 2.2% risk; and moderately elevated risk categorized as a 10.2% risk. The algorithm for risk prediction was developed using data from populations outside of the US. The OneTest algorithm does NOT consider standard biomarker reference values and instead sets internal thresholds based on the training dataset. FDA does not currently clear or approve LDTs in the US; certification of the laboratory is required under CLIA to ensure quality and validity of tests. Genesys Biotech, a division of 20/20 GeneSystems, Inc. is a CAP-accredited lab to perform high complexity testing.  
The National Cancer Institute data link: <https://www.cancer.gov/about-cancer/causes-prevention/risk/age>

Laboratory Director: Chih-Ling Zuo, PhD, HCLD (ABR)  
Genesys Biotech, a division of 20/20 GeneSystems, Inc., 15810 Gaither Drive, Suite 235, Gaithersburg, MD 20877  
CLIA#: 21D037411, CAP#: 898355

OneTest Premium, introduced in late 2023, also includes inflammatory and metabolic biomarkers, which are essentially probing the effected individual’s immune and metabolic response to the cancer. Exclusively licensed from BioInfra Life Science, Inc. (“BioInfra”), OneTest Premium calculates the likelihood of eight specific tumor types rather than a pan-cancer likelihood score as is presented with OneTest Standard.

Since all the biomarkers tested in Standard are included in Premium, consumers of Premium, which comprise more than two-thirds of all OneTest customers, also get the Standard Report page.

We have positioned OneTest as a “top of funnel” first screening test due to its relatively low cost, higher sensitivity for earlier stage cancers, and ease of access due to the small amount of blood required. Those with abnormal OneTest results should receive follow-up, which in many cases may be limited to repeat testing to establish biomarker baselines and assess changes in biomarker values over time. Significantly high values or concerning changes in these values can subsequently, under the auspices of a healthcare provider, be followed up by imaging and ctDNA based MCEDs, which can better pinpoint location and type of possible malignancies. By way of example, suspicious results on a “top of funnel” first screening test might be used to indicate a second screening test which could be a molecular (ctDNA sequencing) or imaging modality which in turn might lead to biopsy as the definitive diagnostic. This approach very much differentiates OneTest from competing tests, including other MCED tests, whether based on ctDNA, protein biomarkers or other modalities. Most of these other screening tests are placed further down in the funnel and lead directly to more expensive and more invasive definitive diagnostic tests. As such, these competing modalities focus more on achieving the highest levels of specificity in order to reduce the number of false positive results that could lead directly to an expensive and invasive test. Because OneTest is positioned at the “top of the funnel,” meaning that immediate follow-up tests are less expensive and generally not invasive (beyond a second blood draw), the performance characteristics of OneTest are more focused on sensitivity, the detection of true positives, while accepting a lower specificity, as false positives will be removed further down the funnel.



### Key Competitive Advantages

Our patented MCED approach, based on PTMs versus ctDNA, provides the following advantages (we refer to these advantages as our Straight A's): Affordability, Accuracy, Accessibility, Acceleration Over Time, AI Powered Algorithms from Large Data Sets, Assists Imaging, and Advisory Expertise.

**Affordability.** Since the instruments and reagents we utilize in our lab are widely used around the world and adapted for automated analyzers, the costs to run these tests are quite low compared to DNA sequencing. Since our labor and reagent costs are lower, we can pass these savings on to the customer. In most cases, follow-up testing of high biomarkers is covered by insurance if prescribed by the customer's own healthcare provider and can be run by other labs in-network

with the customer's health insurance plan. Our OneTest Standard is priced at under \$200 versus \$950 for Grail's Galleri, the only other MCED being widely marketed in the U.S. at this time.

*Accuracy.* Evidence suggests that tumor antigens are more readily detectable in the blood at earlier stages than ctDNA. PTMs are produced in large quantities by living cancer cells as a part of their normal biological function. These proteins are subsequently released into the surrounding tissue and blood. On the other hand, ctDNA is derived from dying tumor cells at single copy number per cell and one would expect minimal cell death in early-stage cancers which consist of relatively few cells as the tumor is still quite small. While DNA detection methods are very sensitive, given the very low amount of ctDNA released into blood, a very large blood sample would need to be collected to expect the sample to actually contain the ctDNA. Indeed, clinical studies have demonstrated that the sensitivity of ctDNA-based MCEDs for early-stage cancers is less than 20% (see (i) Pons-Belda OD, Fernandez-Uriarte A, Diamandis EP. "Can Circulating Tumor DNA Support a Successful Screening Test for Early Cancer Detection? The Grail Paradigm." *Diagnostics* (Basel). 2021 Nov 23;11(12):2171. doi: 10.3390/diagnostics11122171. PMID: 34943407; PMCID: PMC8700281; (ii) Pons-Belda OD, Fernandez-Uriarte A, Diamandis EP. "Multi Cancer Early Detection by Using Circulating Tumor DNA-The Galleri Test." Reply to Klein et al. *The Promise of Multicancer Early Detection. Comment on 'Pons-Belda et al. Can Circulating Tumor DNA Support a Successful Screening Test for Early Cancer Detection? The Grail Paradigm. Diagnostics* 2021, 11, 2171'. *Diagnostics* (Basel). 2022 May 17;12(5):1244. doi: 10.3390/diagnostics12051244. PMID: 35626399; PMCID: PMC9141547; and (iii) Bittla P, Kaur S, Sojitra V, Zahra A, Hutchinson J, Folawemi O, Khan S. "Exploring Circulating Tumor DNA (CtDNA) and Its Role in Early Detection of Cancer: A Systematic Review." *Cureus*. 2023 Sep 22;15(9):e45784. doi: 10.7759/cureus.45784. PMID: 37745752; PMCID: PMC10516512).

BioInfra, the developer of OneTest Premium, published data for their related test offered in Korea, iFINDER, which is only slightly different from the test we offer ("Diagnostic value of combining tumor and inflammatory biomarkers in detecting common cancers in Korea" (2021) *Clinica Chimica Acta*, 516, 169-178). At our request, the data was recalculated, restricting the biomarkers to those used in OneTest Premium and resetting the individual cutoffs to achieve greater than 98% specificity for each cancer type. This data is from case-control (retrospective) cohorts including 1199 subjects (607 cases and 592 controls). Resulting data from these training/validation cohorts are reported in the table below:

Cancer	Stage	% Sensitivity @98% Specificity	Cancer	Stage	% Sensitivity @98% Specificity
Lung	Overall	51	Prostate	Overall	75.5
	Stage I	33.3		Stage I	100
	Stage II	61.1		Stage II	58.3
	Stage III	52.9		Stage III	88.9
	Stage IV	90.5			
Liver	Overall	88.6	Ovary	Overall	73.7
	Stage I	85.7		Stage I	25
	Stage II	90.9		Stage II	100
	Stage III	100		Stage III	100

Colorectal	Stage IV	100	Gastric	Stage IV	80
	Overall	72.1		Overall	33.3
	Stage I	64.3		Stage I	27.3
	Stage II	80		Stage II	50
Pancreas	Stage III	75.9	Breast	Stage III	80
	Stage IV	100		Overall	18.8
	Overall	92.7		Stage I	15.4
	Stage I	85.7		Stage II	15.4
	Stage II	95.7		Stage III	57.1
	Stage III	100			
	Stage IV	85.7			

In the first quarter of 2023, BioInfra conducted a real-world analysis of their test performance based on data from Korean governmental cancer registries. It looked at results of the BioInfra test as reported in the health records of individual clients who purchased the test over several years (n=42,364) and correlated these results to health outcomes (cancer diagnoses) in the ensuing 12 months. The test performance was excellent compared to testing individual biomarkers alone, without our algorithms. BioInfra in their peer-reviewed publication, “Diagnostic value of combining tumor and inflammatory biomarkers in detecting common cancers in Korea” (2021) *Clinica Chimica Acta*, 516, 169-178, directly compared the area under the curve (“AUC”) of the receiver operating characteristic curve for the MCED to that of single tumor markers (CEA for colon cancer, AFP for liver cancer, Cyfra 21.1 or CEA for lung cancer, PSA for prostate cancer). Note that a higher AUC indicates better performance and that the best possible AUC is 1.0.

<b>Cancer</b>	<b>MCED AUC</b>	<b>Single Marker AUC</b>
Colon	0.9603	0.7183
Liver	0.9685	0.7943
Lung	0.9424	0.7609
Prostate	0.9848	0.9635

Based on the retrospective (newly diagnosed cases) and prospective (pre-diagnostic cases) data available to date, the premium version is expected to have improved sensitivity and better organ specificity to help identify the tumor of origin. The following table summarizes the data available to date.

<b>Cancer</b>	<b>Sensitivity</b>	<b>Specificity</b>
Liver	47.1%	98.7%
Lung	45.5%	94.9%
Pancreatic	42.9%	99.2%
Prostate	42.2%	98.3%
Colorectal	34.0%	97.8%
Ovarian	29.7%	97.5%
Breast	20.2%	96.5%

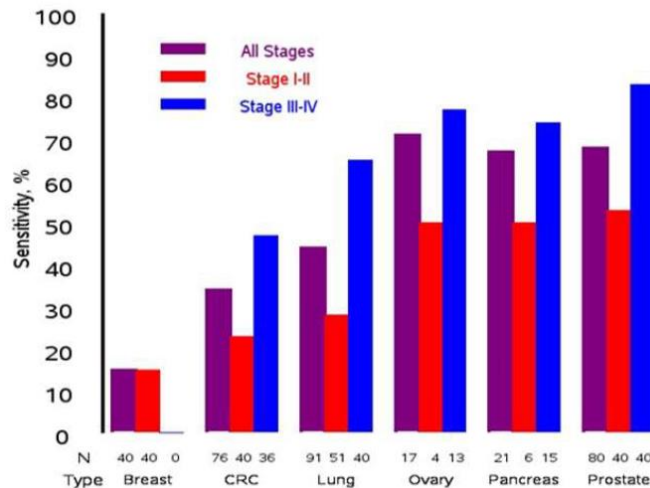
Stomach      8.6%      98.4%

Typically, data generated from a pre-diagnostic cohort (i.e. specimens collected before a diagnosis) such as that shown above is less compelling data from newly diagnosed patients. It should also be noted that reducing the specificity to around 85% would substantially boost the sensitivity in a manner that would avoid missing many cancers while not a consequential number of false positives. We believe that with the “funnel” approach described above (i.e., repeating high biomarkers and utilizing ultrasound and other low-cost imaging technologies), a specificity of around 85% would identify most early stage cancer without causing too much expense to the healthcare system.

The following table compares the performance of OneTest Premium to Grail’s Galleri test. The data for OneTest Premium is from case-control data provided by BioInfra (limiting to only the biomarkers used in OneTest Premium and holding the specificity for each cancer type at >98%) and the data for Galleri is taken from Klein EA, et al. “Clinical validation of a targeted methylation-based multi-cancer early detection test using an independent valuation set” *Ann Oncol.* 2021 Sep;32(9):1167-1177. For this comparison, only OneTest Premium specificity was held at >98% and Galleri specificity was at 99.5%. Both studies utilized data from blood collected at or shortly after the time of diagnosis rather than before diagnosis. The specificity of the commercial Galleri test is set at 99.5%. The specificity of our commercial test is approximately 95%, resulting in higher sensitivity than shown here. The data for Galleri is derived from a cohort of 4,077 individuals while the OneTest Premium data is from a cohort of 1,199 individuals. Please also note that sensitivity is for single time point testing only. The sensitivity of most biomarkers in OneTest (CEA, CA125, CA 19.9, AFP, PSA) have been shown in different studies to improve by 10-15% (absolute values) with serial (repeat) testing for cancers of the lung, ovaries, pancreas, liver and prostate.

<b>Sensitivity (@ &gt;98% Specificity)</b>		
<b>Stage</b>	<b>OneTest</b>	<b>Galleri</b>
All	62%	52%
I	44%	17%
II	61%	40%
III	77%	77%
IV	86%	90%

The OneTest data cited above was from an East Asian population. To assess our performance in an American cohort, in 2024, we participated in a blinded validation study of OneTest Premium conducted by the NCI to compare the performance of various MCEDs. We were informed by several NCI staff scientists that our test was among the best performers in terms of sensitivity and specificity. Using blood specimens collected 18-30 years ago in healthy individuals up to six months prior to diagnosis as part of a prostate, lung, colorectal, and ovarian clinical trial, we correctly identified half of early stage pancreatic and ovarian cancers. The following graph was prepared by NCI’s new cancer screening research network team in May 2024. NCI estimated that the effective specificity of OneTest Premium was approximately 95%.



A more complete description of the study design can be found in LeeVan,E., *et al.*, “Framework to Select Multi-Cancer Detection Assays in the National Cancer Institute’s Vanguard Study.” *Cancer Epidemiol Biomarkers Prev* (2025). We do not know which other companies were involved in this study, nor do we have access to the data from the other MCED tests to perform our own direct head-to-head comparison of the results. For the purposes of this study, capillary collected samples were not available and as such the NCI study does not directly fall within the referenced categorization. That said, we have demonstrated equivalence in our labs between the use of capillary and venipuncture samples and as such the NCI study does inform on the performance of the capillary test by inference. Thus, we believe that the NCI study contributes to the validation of OneTest Standard and Premium.

**Accessibility.** In 2024, our scientific and laboratory personnel successfully demonstrated equivalency in the performance of OneTest using capillary blood with that of venous blood. The requirement of engaging with a phlebotomist adds cost and burden to many of our customers, especially those who purchase OneTest online. Since our test requires only a fraction of the blood typically collected through venipuncture, we have shown that the test can function comparatively with capillary blood collected from fingerstick or the upper arm. Fortunately, several new devices are entering the market to improve capillary collection. Obviating the need for a phlebotomist should permit our test to be more easily accessed at pharmacy counters and even at home, thereby increasing uptake and adoption.





The small quantities of blood required permits capillary (upper arm) blood collection that can be easily self-administered at home, at retail outlets including pharmacies, and at workplaces (e.g., fire stations), avoiding the need for special appointments with phlebotomists and painful needles. Ease of access boosts compliance with follow-up testing which aids in the earlier detection of more cancers.

*Acceleration Over Time.* Many studies suggest that annual screening with PTMs boosts sensitivity for many cancer types (lung, pancreatic, liver, etc.), as described in more detail in the table below.

<b>Tumor Antigen</b>	<b>Cancer Type</b>	<b>Evidence of Improvement in Detecting Early-Stage Cancers</b>
CA125	Ovarian	Early-stage detection improves from 10% to 50% in high-risk women if tested quarterly and from 25% to 40% in normal risk postmenopausal women if tested yearly. See Skates et al. Skates et al. CCR 2017, Rosenthal et. al. JCO 2017, Jacobs Menon et. al. Lancet 2015.
CA19-9	Pancreatic	In a pre-diagnostic cohort (PLCO), levels of CA19-9 increased exponentially starting at 2 years prior to diagnosis with sensitivities reaching 60% at 99% specificity within 0-6 months prior to diagnosis for all cases and 50% at 99% specificity for cases diagnosed with early-stage disease. See Hanash et al. Lead-Time Trajectory of CA19-9 as an Anchor Marker for Pancreatic Cancer Early Detection - PubMed (nih.gov).
CA19-9 & CEA	Pancreatic	In a pre-diagnostic cohort (PLCO), levels of CA 19-9 and CEA demonstrated significant velocity related to time to diagnosis suggesting that serial measurements of these biomarkers may enhance panel performance. See Prediagnostic serum biomarkers as early detection tools for pancreatic cancer in a large prospective cohort study - PubMed (nih.gov).



CA-19-9	Biliary Tract	CA19-9 remained stable in patients who were cancer-free but increased early in those who developed biliary tract cancer. See Regular CA19-9 measurement might improve early detection of these malignancies. <a href="https://doi.org/10.1111/apt.15146">https://doi.org/10.1111/apt.15146</a>
AFP	Liver	Most studies to date have evaluated AFP using a fixed threshold. We have found that algorithms that incorporate patient screening history increased the likelihood of earlier detection of hepatocellular carcinoma. The sensitivity of AFP alone was 59%. When we incorporate the trajectory, the sensitivity improves to 81%. See Tayob et al., Abstract #69, 11 <sup>th</sup> NCI Early Detection Research Network Scientific Workshop (2019).
PSA	Prostate	The Maximum Likelihood Estimation-PSA (“MLE-PSA”) model with a 50% cut-off probability has a sensitivity of 87%, specificity of 85%, positive predictive value (“PPV”) of 89%, and negative predictive value (“NPV”) of 82%. By contrast, a single PSA value with a 4ng/ml threshold has a sensitivity of 59%, specificity of 33%, PPV of 56%, and NPV of 36% using the same population of patients used to generate the MLE-PSA model. Based on serial PSA measurements, the use of the MLE-PSA model significantly (p-value < 0.0001) improves prostate cancer detection and reduces the need for prostate biopsy. See JDS-1173.pdf (jds-online.com).
CEA	Colorectal	In a study in the United Kingdom, CEA levels increased towards diagnosis in a significant proportion (1/3) of colorectal cancer cases (half of late-stage cases), whereas longitudinal profiles were static in both benign and non-cancer controls. Combining CEA with other biomarkers (e.g. CA-19.9) further improves detection capabilities for colorectal cancer according to various studies. See <a href="https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4506388/">https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4506388/</a> .

Throughout East Asia, tumor antigens are routinely tested as part of yearly health checkups. We obtained real-world data from a cohort 135,236 individuals tested with at least for tumor markers (AFP, CEA, PSA, CA19-9, and CA 125) at Chongqing Hospital (CHQ) in China, of which 433 were subsequently diagnosed with cancer.

### Improving risk prediction with Time Series Data

- For a small subset of patients more than one time point for certain TMs was available in the CHQ dataset. A second LSTM model was trained and tested using this data. The performance of the model in predicting cancer risk, improves with greater numbers of timepoints.

Time points	Biomarkers	AUROC	Sensitivity	Specificity
1	AFP, CEA, PSA, CA199, CA125	0.888	0.833	0.827
2	AFP, CEA, PSA, CA199, CA125	0.908	0.833	0.837
3	AFP, CEA, PSA, CA199, CA125	0.921	0.867	0.863
4	AFP, CEA, PSA, CA199, CA125	0.931	0.867	0.883

*Computers in Biology and Medicine 144 (2022) 105362*

Furthermore, repeat testing of slightly high biomarkers at ~2-month intervals substantially lowers false positive rates, according to the medical directors of health checkup centers at Chang Gung Memorial Hospital in Taiwan and Seoul National University Hospital in Korea. Both of these reputable medical institutions have at least two decades of experience offering PTMs for screening.

*AI Powered Algorithms from Large Data Sets.* In certain regions of the world, especially East Asia, an aggressive cancer screening posture is commonplace. Tens of millions of individuals in Japan, Korea, China, and Taiwan undertake 3-5 hour “health checks” each year that usually include blood tests for an array of cancers. Typically, these blood tests measure the levels of between three to eight tumor antigens, which are proteins secreted by tumors that can be detected using antibodies. Large-scale observational studies by our collaborators in Taiwan using data from cancer registries demonstrate that these tests are useful for detecting even early-stage cancers (see Y.-H. We et al., “Cancer screening through a multi-analyte serum biomarker panel during health check-up examinations: Results from a 12-year experience,” *Clinica Chimica Acta* 450 (2015)). However, using our patented methodology, this screening approach can be rendered significantly more accurate using machine learning algorithms that integrate the outcomes of tens of thousands of tested individuals together with clinical factors (e.g., age, gender, smoking history, etc.) with the biomarker levels (see “Improving Multi-Tumor Biomarker Health Check-up Tests with Machine Learning Algorithms,” *Cancers*, 2020 Jun 1;12(6):1442).

We have directly demonstrated this advantage in real-world population studies including 27,938 individuals performed in collaboration with researchers in East Asia, where tumor antigens are currently used to test millions of individuals without the added value of our AI-enhanced methods (see “Cancers Screening in an Asymptomatic Population by Using Multiple Tumour Markers.” *PLoS One*. 2016;11(6) and “Improving Multi-Tumor Biomarker Health Check-up Tests with Machine Learning Algorithms” *Cancers* 2020 Jun 1;12(6):1442). These studies/publications indicate clear and significant improvements in AUC, sensitivity, and specificity for overall cancers as well as individual cancers. This research and development collaboration was pursuant to an exclusive license, technology transfer and commercialization agreement that we entered into with Taiwan-based Chang Gung Medical Memorial Hospital, Linkou (“CGMH”) on November 21, 2018, and an option agreement to obtain this license that

we entered into with CGMH on April 17, 2017. Pursuant to this agreement, we obtained an exclusive license to make, have made, use, sell, import, commercialize and otherwise distribute any product or service, including but not limited to subscriptions to cloud-based software as a service, that contains, relies on or was developed by CGMH's technology, which includes CGMH's raw data (including biomarker values and clinical information from individuals screened for cancer with a blood test at CGMH's facilities), code, software, algorithms, know-how and methodology associated with a multi-biomarker approach for the screening of at least three cancer types developed in part or entirely by the CGMH Department of Laboratory Medicine, as well as improvements and derivatives thereof; provided that CGMH has the right to improve and use its technology for experimental use and/or management of human patients at any CGMH facility in Taiwan. As consideration for this license, we paid an option fee of \$75,000 and a license fee of \$150,000 in cash and \$300,000 in common stock (through the issuance of 92,025 shares of common stock) upon exercise of the option. As further consideration, we agreed to pay CGMH royalties in the amount of 6% of Net Sales (as defined in the agreement); provided that if we are required to pay royalties to a third party, then the royalty due to CGMH shall be reduced by 1% for each 1% due to such third party; and provided further, that such royalty shall not in any event be less than 3%. We also agreed to pay CGMH \$100,000 in cash upon the earlier of (i) our reaching \$2 million in net sales of the licensed products or (ii) when the cumulative profit margin due to sales directly attributable to CGMH's technology is at least \$450,000. Neither of these milestones has been met. This agreement also includes a transitional assistance project involving the provision of clinical data (including prospective data), algorithm improvements, serum sample testing services, and clinical consulting. The term of this agreement is for twenty years commencing on February 1, 2018 (the date that the option was exercised).

State-of-the-art machine learning and other AI based programs require large amounts of data. Because PTMs are widely used for screening and early used in East Asia there is much published and unpublished data that can be leveraged without the burden and expense of running our own large scale clinical trials. This advantage is covered in several of our issued patents and pending patent applications.

*Assists Imaging.* Published studies conclude that PTMs like AFP, CEA, and CA 19.9 can help resolve ambiguous findings on an ultrasound or CT scan to aid in the early detection of liver, testicular, lung, and pancreatic cancers. This phenomenon would be especially helpful where customers are offered MCEDs, ultrasound, and LDCT scans. For example, a team led by Sam Hanash at the MD Anderson Cancer Center has demonstrated how the levels of CEA, CA-125, and Cyfra (all part of OneTest) can help determine whether a pulmonary nodule found on a low-dose CT scan is likely benign or malignant. Ostrin, E. J., *et al.* (2021). "Contribution of a Blood-Based Protein Biomarker Panel to the Classification of Indeterminate Pulmonary Nodules." *Journal of Thoracic Oncology*, 16(2), 228–236. Additionally, a meta-analysis concluded that the addition of AFP to ultrasound significantly increases sensitivity for the early detection of liver cancer. Tzartzeva K, *et al.* (2018) "Surveillance Imaging and Alpha Fetoprotein for Early Detection of Hepatocellular Carcinoma in Patients With Cirrhosis: A Meta-analysis. *Gastroenterology*." 154(6):1706-1718.e1.

*Advisory Expertise.* Unlike novel ctDNA targets, PTMs have been used clinically and in research studies for decades. This allows us to offer expert medical consultants who have vast experience

in using these biomarkers over many years to help advise patients and their doctors. For example, our Medical Director Sean Wang, MD has over a decade of experience evaluating thousands of PTM screening reports in Taiwan.

### *The OneTest Machine Learning Algorithm*

OneTest is built around the installed base of existing FDA-approved tumor marker detection kits which run on automated instruments available from companies like Roche Diagnostics, Abbott Diagnostics, Siemens Diagnostics, and others. In the U.S., approval for most of these kits, except PSA, is for monitoring of disease recurrence, not screening. While we are using these approved kits in an off-label manner, this practice is permitted under the laboratory-developed test CLIA framework. One advantage to using these kits is that the analytical performance of these kits has been fully vetted by regulatory authorities ensuring the accuracy of individual marker value results. Furthermore, these tests and instruments are used in thousands of clinical testing labs worldwide, thereby permitting us to obtain data from around the world. Throughout East Asia in particular, millions of individuals have their tumor antigen levels tested each year at physical examination or health checkup centers. In many cases these tumor markers are tested using the same kits and instrumentation that we use in our CLIA laboratory. This has permitted us to develop machine learning algorithms based on historical outcome data from cancer registries that would otherwise require long and expensive prospective clinical trials if novel biomarkers are incorporated. One further advantage is that these markers are known and are meaningful to clinicians and specifically to oncologists. While their use in an MCED test is novel and proprietary, the individual marker values are always listed as a part of the OneTest standard report, and these values can help healthcare professionals to better guide follow-up testing and year-over-year monitoring.

In short, our unique technical approach involves the following three elements: (i) obtain “real-world” data from tens of thousands of apparently healthy individuals (i.e. no apparent signs of symptoms of cancer when tested) who are screened for cancer using blood tests that are routine in certain parts of the world (e.g. East Asia), (ii) use this data to build machine learning algorithms that improve the accuracy of those tests by integrating cancer outcomes and clinical factors (age, gender, etc.), and (iii) introduce those tests and algorithms worldwide, even in parts of the world where this testing approach is less common (e.g. North America), while examining variability across patient populations.

AI and machine learning are expected to transform healthcare by helping physicians diagnose and treat patients with greater accuracy and precision. As we continue to collect reliable outcome data (i.e., whether cancer was diagnosed) from individuals tested with the OneTest biomarkers (either from our customers or from research collaborators), our ability to leverage the latest and most powerful forms of machine learning will increase.

On April 4, 2023, U.S. Patent No. 11,621,080 titled “Methods and Machine Learning Systems for Predicting the Likelihood or Risk of Having Cancer” was issued to us. Additionally, in January 2024 we received a Notice of Allowance from the United States Patent and Trademark Office (the “USPTO”) for a second patent covering OneTest. Similar notices of patentability have also been received in early 2024 from patent offices in Japan and China. Our inventors were among the first to apply machine learning and AI to prospective outcome data from

thousands of persons tested with protein tumor markers to predict a newly tested individual's likelihood of having cancer. We expect to continue to build out our patent estate in this arena.

### *MCED Research, Development and Product Improvements*

In October 2023, we introduced a “premium” version of OneTest at a higher price point. In connection with the development of OneTest Premium, in August 2022, we executed a technology license and access agreement with Korean-based BioInfra. BioInfra commercializes an MCED in Korea primarily based on the levels of tumor antigens, such as CEA, CA-125, etc. However, their panel also includes several inflammatory markers such as C-reactive protein, Transthyretin, Beta-2-Microglobulin, etc. that BioInfra has demonstrated to result in improved accuracy. This data is reported in the peer-reviewed journal article “Diagnostic value of combining tumor and inflammatory biomarkers in detecting common cancers in Korea,” *Clinica Chimica Acta* 516 (2021) 169–178. The license covers software, algorithms, and know-how, but no U.S. patents were or need to be licensed to us from BioInfra.

Under the terms of our agreement with BioInfra, we have the exclusive right to commercialize BioInfra's test panel and algorithm in the United States, having paid the requisite up-front license fee of \$300,000 and commenced bridging studies to validate those algorithms on a Western population. In addition, we have agreed to pay per-test royalty fees in the range of \$12-\$25 per test for sales of our products using BioInfra's technology. Our agreement with BioInfra is for a term of three (3) years and may be extended for an additional three (3) years if certain minimum royalties are met or if we conduct, or arrange for another party to conduct, a prospective clinical trial in the U.S. (we believe that the blinded validation study we conducted in 2024 with the NCI using prospectively collected blood specimens meets the criteria for a three year extension, but the agreement has not yet been formally extended). To date, we have not paid any royalties under this agreement.

### ***OneTest for Longevity***

#### *The Problem*

According to the U.S. Centers for Disease Control and Prevention (the “CDC”), chronic diseases are the leading cause of premature death in America, responsible for eight out of the ten most common causes of mortality. These diseases, including cancer, type 2 diabetes, cardiovascular ailments, and dementia, are closely linked to chronic inflammation. A significant contributor to this inflammation is the consumption of processed foods, which are often high in sugars, unhealthy fats, and additives. We believe that new tools to measure and track chronic inflammation to inform and encourage better food and lifestyle choices are urgently needed.

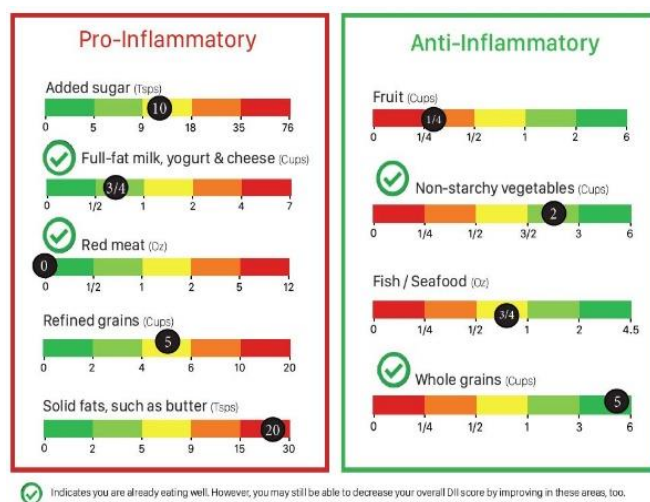
#### *Our Solution*

In the second half of 2025, we expect to introduce OneTest for Longevity, a blood test to measure and track biomarkers associated with chronic inflammation which, according to the CDC, is associated with 8 of 10 leading causes of death in America. The test will offer specific and personalized diet and exercise changes proven to lower biomarker levels and the associated risk of type 2 diabetes, cancer, cardiovascular disease, dementia, mental health, and diseases associated with aging.

For this product, we are partnering with James R. Hébert, Ph.D. and his colleagues from the University of South Carolina. Hébert, a nutritional epidemiologist for over 30 years, is the author of *Diet, Inflammation, and Health* and the developer of the Dietary Inflammatory Index (the “DII”), a numerical score that assesses a diet for its effect on several biomarkers linked to inflammation. The DII has been utilized in over 1,300 peer reviewed studies and validated in studies involving over 187,000 subjects.

On February 14, 2025, we obtained exclusive rights to utilize, incorporate and report the DII score together with inflammatory biomarkers measured in a lab. Specifically, pursuant to a license agreement that we entered into with Connecting Health Innovations (“CHI”) on February 14, 2025, we were granted an exclusive license in North America for the data, algorithms, programs, software and intellectual property rights developed by Dr. Hébert or others employed by or under contract with CHI for which CHI has intellectual property rights that calculates or displays, for individuals who inflammatory biomarker levels have been measured, (i) a numerical score associated with chronic inflammation that is calculated based on the biomarker levels, and (ii) specific dietary changes that can be made to lower inflammatory biomarker levels and associated risk for multiple chronic diseases. The license is limited to use in connection with clinical laboratory tests for the levels of biomarkers of inflammation and does not include stand-alone portals, websites, apps, or software that are not integrated or marketed with a clinical laboratory test. The license covers software, algorithms and know-how, but no patents were included. In exchange for the license, we agreed to pay CHI (i) a license fee of \$30,000 payable within ten (10) business days of incorporation of the licensed subject matter into our laboratory information statement and (ii) royalties in the amount of ten percent (10%) of net sales of OneTest for Longevity. The term of the license is for three (3) years and may be terminated by us upon thirty (30) days’ notice; provided that either party may terminate the license immediately in the event of a material breach if such breach is not cured within thirty (30) days of written notice thereof. To date, we have paid the license fee of \$30,000, but no royalties have been paid.

Below is a sample lab report that we expect to provide.



#### SAMPLE LAB REPORT LANGUAGE

Specific recommendations based on association between DII® score and biomarkers (e.g., C-reactive protein (CRP):

“Your CRP value of 2.7 ng/dL = Elevated risk of mental health problems such as depression, chronic diseases such as cancer and stroke, aches and pains such as arthritis, and infectious diseases such as COVID-19. We recommend decreasing your DII® score by 1.8 points to get your CRP value to less than 1 ng/dL. The following dietary changes are recommended:  $\frac{1}{2}$  cup of almonds per day, 2½ cups of dark green leafy vegetables, ...

We expect to market this product widely to Americans of all ages and demographics both through mass marketing and through major supermarket chains beginning with Giant Food, the largest supermarket chain in the Washington Metro region, at which we already offer OneTest for Cancer.

In addition to providing biomarker levels and specific dietary recommendations, we also plan to offer electronic coupons for discounts for those suggested healthy food items. This has the dual benefit of motivating consumers to make better food selections while providing an ancillary revenue stream for both us and the participating supermarket (food manufacturers commonly remunerate distributors of redeemed coupons). A patent application has been filed covering this systematic approach.

### *Key Competitive Advantages*

Longevity tests on the market, such as those that measure telomere length or assess dozens of biomarkers or genetic mutations, tend to be expensive and rarely provide simple to understand, evidence based, practical and specific guidance for lifestyle changes proven to improve lifespan and healthspan. Microbiome testing has a further disadvantage in that it requires collecting stool specimens which many consumers disfavor. Many of the labs that offer these tests also promote and sell dietary supplements, the safety and efficacy of which is often questionable.

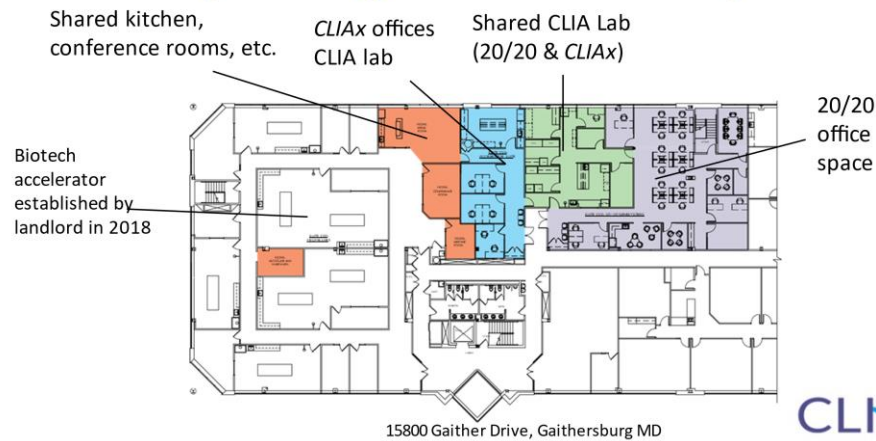
We believe that OneTest for Longevity fills a compelling unmet need for an affordable, easily accessible test with actionable, evidence-based recommendations to reduce inflammation and the risk of most major chronic diseases. Our exclusive access to the Dietary Inflammatory Index for use with clinical lab test reporting provides another level of distinctiveness.

### ***Clinical Laboratory Innovation Accelerator (CLIAx)***

To increase our menu of innovative tests faster and at a lower cost and risk than through internal development, in 2021 we established our CLIAx, which permits diagnostics start-up companies from around the world to launch their laboratory developed tests in our CLIA licensed laboratory using shared equipment and laboratory personnel. To date, we have enrolled one company in our CLIAx, Minomic International (“Minomic”), and helped it validate and launch its blood test to help determine whether PSA levels should be followed up with a biopsy. Our CLIAx, which we believe to be the first such shared CLIA laboratory facility in the U.S., reduces the costs and expense for start-up companies to launch their novel tests in the American market while providing us with sales and marketing rights to additional products. In 2022, it earned an “Honorable Mention” in *Fast Company* magazine’s list of “World Changing Ideas.



## Unique Design of Accelerator Space



In July 2021, we entered a lab services and marketing agreement with Minomic under which its testing technology and reagents were transferred to our CLIA lab, installed, and validated under CLIA regulations. Under the agreement, Minomic maintains its ownership of all intellectual property. Minomic compensates us on a “cost plus” basis (i.e., our fully burdened costs for labor, materials, space and testing analyzers plus a 10% profit). Furthermore, we have the right, but not the obligation, to help market their test with a 25% commission. We have not yet opted to promote the Minomic test since it does not target our typical consumer base. However, we believe this framework will be apt for other lab tests that address the early detection, disease prevention and wellness market. The agreement with Minomic is for a term of three years and may be terminated by either party upon 30 days’ written notice if there has been a material breach of the agreement that has not been cured with 60 days of notice of such breach. Either party may also terminate the agreement in the event of insolvency, bankruptcy, assignment for the benefit of creditors of the other party or an admission of the party’s inability to pay its debts as they become due.

We plan to create a new fund associated with our CLIAx. This would enable us to invest in, acquire, or transact with companies or academic medical centers that have tests that could add to our menu or technologies, products, testing components or intellectual property that strengthen our core business. We have identified a few companies that could be candidates for this CLIAx fund, but have no agreements, or letters of intent with any of them. Thus, there is no guarantee that we can identify or reach agreement in the near term with any such companies to meaningfully contribute to inorganic growth.

### ***Field Tests for Screening Suspicious Powders***

We have a longstanding business that makes and sells a proprietary test kit for screening suspicious powders called BioCheck. These kits are widely used by fire departments and other emergency responders to quickly screen unknown suspicious powders for compounds such as ricin, anthrax, and other bioweapon agents and to identify false alarms in minutes at the site of a suspected bioterror threat. The powder screening kit works by quickly identifying the presence or absence of protein, a biomolecule found in all living materials. It therefore provides a rapid



screen for the possible presence of multiple bioterrorism agents while ruling out most of the ordinary substances that citizens have frequently feared to be possible bio-agents of terror. Such ordinary substances include, for example, talc, ceiling tile dust, powdered sugar, etc., none of which are expected to contain detectable levels of protein.

### ***COVID-19 Tests***

In the third quarter of 2020, in response to a substantial and urgent demand for expanded pandemic-related testing in Maryland, we began to provide COVID-19 viral testing using PCR analytical equipment in our clinical laboratory. Initially, most of our customers were nursing/assisted living facilities. In the first quarter of 2021, we began receiving and testing specimens under contract with and collected by the Montgomery Department of Health and Human Services. In August of 2021, we were one of five CLIA-certified laboratories to be awarded a contract with the Maryland Department of Health to perform coronavirus screening at K-12 schools. However, following the expiration of the public health emergency in May 2023, all testing from both the State of Maryland and the Montgomery County Health Department has ceased, and we do not anticipate additional COVID-19 testing absent a new variant resulting in a significant increase in cases.

Profits from COVID-19 testing were deployed to grow our core cancer diagnostics business. Additionally, some of the commercial partnerships we entered for COVID-19 testing are being extended for non-pandemic-related testing.

### **Lab Facility**

We operate a high-complexity CLIA-licensed clinical laboratory facility where our lab tests are performed at our Gaithersburg facility. This clinical lab became accredited by CAP in 2022. Our CLIA lab is currently equipped with immunodiagnostic, clinic chemistry, and molecular (PCR) analyzers, extractors, and liquid-handling robots. CAP and CLIA regulations establish standards for proficiency testing, facility administration, general laboratory systems, preanalytic, analytic, and postanalytic systems, personnel qualifications and responsibilities, quality control, quality assessment, and specific cytology provisions for labs performing moderate to high complexity tests. Our laboratory is inspected biennially as part of its ongoing certification under the CLIA.

### **Supply Chain**

For both OneTest for Cancer and OneTest for Longevity, we rely on a supply chain through Roche Diagnostics IVD kits for Cobas E411, with all reagents used also available on other immunoassay platforms offered by major companies such as Abbott, Beckman, Siemens, and ThermoFisher, except for CYFRA and IL-6. CYFRA and IL-6 are only available in the United States on our current Roche equipment; however, as an alternative we could also source this assay on a Luminex system and various ELISA assay systems.

In addition to our OneTest, we also rely on a supply chain for general chemistry markers. Currently, these markers are run on Abbott Alinity C, but they are available through all major manufacturers, including Roche.

We have established reagent contracts with Roche and Abbott that guarantee pricing for all immunoassay and chemistry markers currently used in our diagnostic test panels. These contracts ensure that we can continue to provide our customers with high-quality diagnostic tests at predictable pricing. Additionally, these contracts provide us with supply chain stability and allow us to manage cost fluctuations associated with reagent pricing.

We depend on our suppliers and contract manufacturers to provide us and our customers with materials in a timely manner that meets our and their quality, quantity, and cost requirements. We have initiated a second source qualification process for most of these critical components, but we may not be successful in securing second sourcing for all of them on a timely basis. Moreover, while we are confident that other suppliers could meet our quality, quantity and cost requirements, the time required to transition to a new supplier could have negative impact on our ability to perform these tests until an alternative supplier could be validated. Our supply chain for OneTest is critical to our ability to deliver high-quality diagnostic tests to our customers.

Overall, we remain committed to building strong relationships with our suppliers and contract manufacturers to ensure that our supply chain for all our diagnostic tests is reliable, resilient, and able to meet the needs of our customers. We continuously monitor and improve our supply chain processes to minimize the risk of disruptions and ensure that we can provide high-quality diagnostic tests to our customers when they need them.

Please see “—*Risk Factors—Risks Related to Our Business and Industry*” for a description of the risks related to our supplier relationships.

## **Sales and Marketing Strategy**

### ***OneTest for Cancer***

Sales of OneTest have increased significantly in recent years, from \$323,414 in 2022 to \$1,490,881 in 2024. We sell to employers, medical practitioners and direct-to-consumers. For employers, the largest subgroup are fire departments due to the proven higher cancer incidences in that population. Several states and at least one federal agency provide grants to reimburse fire departments for our test. Iraq war veterans are another growing customer segment, and our largest order in 2024 was from an organization supporting that community.

Occupational health is our largest physician specialty group ordering our tests. Penetration of this large occupational health market will require significant business-to-business sales and marketing campaigns as well as consumer-initiated test campaigns that must be coupled with convenient access to phlebotomy services and telemedicine practitioners to provide guidance on the test and its results. Retail (walk-in) clinics such as urgent care centers and pharmacy chains present the best opportunities to grow the consumer-initiated test market for OneTest.

We currently have engagements in place with over 1,000 retail clinics located throughout the U.S., mostly urgent care centers, to conduct blood draws for OneTest products and include over 200 locations of AnyLabTestNow. These clinics, coupled with a dedicated telemedicine service, have made it practical for us to initiate a consumer-initiated test campaign. In the future we expect to offer capillary collection options at retail venues and at home.

Furthermore, on January 6, 2025, we entered into a participation agreement and an amended and restated statement of work No. 2. with Ahold Delhaize USA Services LLC, an affiliate of Giant of Maryland, LLC (“Giant Food”), the largest supermarket chain in the Washington, D.C. region. The participation agreement provides that we shall provide certain services as set forth in one or more statements of work. Pursuant to the amended and restated statement of work No. 2, we agreed to provide OneTest Standard and OneTest Premium testing to Giant Food customers at certain participating locations. We agreed to pay Giant Food \$35 per individual participant. The participation agreement is for a term of three (3) months and will be reassessed for renewal for additional three (3) month terms on each anniversary of the effective date. Either party may terminate the participation agreement upon thirty (30) days’ written notice. The parties are in discussions to extend the term of this agreement.

Several states are beginning to create large funds to reimburse their fire departments for multi-cancer screening tests. For example, New Hampshire’s program provides \$5 million in funding over two years and Maryland increased their grant program for multi-cancer screening tests to \$1 million for their fiscal year beginning July 2025 from \$400,000 in the prior year (typically, more than half of Maryland grants go to fire departments who elect to use our MCED). We expect more states to provide this type of reimbursement over the coming years. Additionally, in February 2025, the FIRE Cancer Act was reintroduced in Congress to provide \$700 million in federal funding (through FEMA) for MCED testing.

We believe that bipartisan legislation in Congress that would pave the way for Medicare reimbursement of MCEDs is likely to pass in the current Congress. As of July 2025, the Nancy Gardner Sewell Medicare Multi-Cancer Early Detection Screening Coverage Act has gained significant traction in Congress and is showing strong signs of momentum. The House Bill (H.R. 842) and Senate Bill (S. 339) were reintroduced in early 2025. The House version passed out of the Ways and Means Committee unanimously (38–0). The legislation has bipartisan support, with 319 House cosponsors and over 60 Senators backing it. It is also supported by over 500 organizations, including the American Cancer Society and the Oncology Nursing Society. Private insurance typically follows Medicare coverage determinations. This is expected to dramatically expand the MCED market over the next 4 or 5 years.

### ***OneTest for Longevity***

We believe that nearly all Americans, from children through seniors, could benefit from OneTest for Longevity. This product clearly aligns with the “Make America Healthy Again” initiatives of the new Administration as it provides a unique and innovative tracking tool to encourage healthier eating to combat chronic diseases. On February 13, 2025, President Trump issued Executive Order 14212 “Establishing the President’s Make America Healthy Again Commission.” It noted in relevant part, that “[n]inety percent of the Nation’s \$4.5 trillion in annual healthcare expenditures is for people with chronic and mental health conditions...To fully address the growing health crisis in America, **we must re-direct our national focus, in the public and private sectors towards drastically lowering chronic disease rates...**This includes **fresh thinking on nutrition**, physical activity, healthy lifestyles, over reliance on medication and treatments...[A]gencies shall ensure the...**flexibility for health insurance coverage to provide benefits that support beneficial lifestyle changes and disease prevention...**The Commission shall submit to the President a Make our Children Healthy Again Assessment,

which shall...assess the threat that certain food ingredients...pose to children with respect to **chronic inflammation** and identify and report on the best practices for preventing childhood health issues, including proper nutrition and the promotion of healthy lifestyles.” (*Emphasis added*)

Due to its broad market, we will utilize general advertising, both digital and traditional, to market the OneTest for Longevity. We also plan to leverage our channel partnership with Giant Food to market to their customers. If the pilot with Giant Food is successful, we intend to expand to other national supermarket chains.

Considering this profound change in public policy, we are hopeful that reimbursement or other government backed incentives will be forthcoming. In the meantime, we believe that offering this test for around \$150 (with subscription discounts) coupled with easy, pain-free capillary blood collection accessible at home or local pharmacies will be met with widespread adoption.

## Competition

Because of the substantial unmet medical need worldwide, many companies (and associated academic entities) are actively seeking to develop and commercialize tests of various types to detect cancers early, when it can be treated most effectively. Current approaches include *in-vivo* radiographic imaging as well as *in-vitro* tests using diverse bodily tissues and fluids including blood (serum or whole blood), urine, saliva, stool, sputum, and exhaled breath.

In the U.S., we know of no MCED blood tests that large numbers of Americans routinely utilize. Furthermore, there do not appear to currently be any companies in the U.S. that have adopted our approach of testing a panel of tumor antigens together with a machine learning algorithm. However, there is significant and growing competition in the MCED space with most tests using next-generation sequencing to analyze ctDNA. Most notably, Grail Inc., which was acquired by Illumina for \$8 billion in 2020, introduced its Galleri test in the second quarter of 2021 at a price of \$949. Additionally, Thrive, Inc. was acquired by Exact Sciences for \$2 billion, but they have not publicly announced when they plan to launch their test CancerGuard MCED. These tests may present both competitive threats but also opportunities for OneTest. The fact that our test measures well known biomarkers creates several important competitive advantages. Our lower cost OneTest Standard with a list price of under \$200 could be followed up with more expensive ctDNA tests and/or imaging for those individuals with high biomarkers levels or a high algorithm score.

In East Asia, where such biomarker tests are commonly offered as part of annual health check-ups, we are unaware of any widely used algorithms of the type we have developed, namely an algorithm built with real-world data from a large screening population with known cancer outcomes. However, there are many emerging companies seeking to use “liquid biopsy” and “next-gen sequencing” for pan-cancer testing. Furthermore, many companies are actively utilizing AI and machine learning to improve health outcomes, and at least some of those companies are likely seeking to use these techniques to improve cancer screening blood tests.

Regarding our longevity test, we are unaware of any labs offering a panel of inflammatory biomarkers together with specific dietary guidance directly linked to the biomarker levels. Some

labs offer vague and generalized suggestions such as “eat more fruits and vegetables” but we will offer specific, evidence-based, quantitative guidance on how to lower CRP and IL-6 levels and what that yields in terms of improving lifespan and health outcomes.

## **Growth Strategies and Path to Profitability**

We will strive to increase stockholder value by pursuing the following growth strategies:

- ***Exploit our compelling advantage of at-home and retail collections.*** We believe that COVID-19 testing caused a paradigm shift in the way Americans seek access to testing. Previously, most testing was done at doctor’s offices and at specialty patient service centers maintained by the large national lab chains. During the pandemic, testing was conducted at retail establishments and at home. OneTest for Cancer utilizes small volume, capillary collected blood specimens that can easily be accessed at home and at retail venues such as pharmacies, health clubs, etc. This is a big advantage over most known competitors which need to utilize traditional venipuncture to obtain sufficient blood volumes to permit DNA sequencing. Requiring an in-person visit to a specimen collection site is a potential barrier for a person who needs testing. Our at-home specimen collection option may help eliminate these barriers. One Test for Longevity also can utilize capillary collection. To date, we have demonstrated that this collection approach works well both at home and in retail environments (we are now offering our tests at pharmacies within Giant Food, the largest supermarket chain in the Washington, D.C. area). We also have a telemedicine provider available to authorize the test and be available to consult with the patient in the event of a high-risk score. We plan to expand direct-to-consumer marketing and build additional retail channel partnerships (supermarkets, pharmacies, health clubs, etc.) at which blood collection is not yet commonplace.
- ***Strategic partnerships and cooperative advertising.*** To facilitate scale while mitigating expenses, we have initiated an ambitious plan of marketing alliances and partnerships with an array of other companies, large and small, including suppliers, other clinical labs, and organizations that offer wellness and screening tests. In many cases we seek to introduce the cooperative advertising model where marketing expenses are shared pro-rata based on revenue allotments.
- ***Leverage trending federal health initiatives.*** As stated, the Make America Healthy Again campaign of the Trump Administration, which is dedicated to reducing chronic disease through healthier diet, is expected to create numerous opportunities for OneTest for Longevity. We will closely follow and seek to make recommendations to and engage with the Department of Health & Human Services (the “HHS”) and its constituent agencies throughout 2025 to identify opportunities for government contracts, research grants, and other forms of support.
- ***Targeting of higher-risk populations.*** We already target firefighters, due to their proven higher incidence and mortality rates for several types of cancer. Over 200 fire departments are OneTest customers to date, as are thousands of individual firefighters, and we expect to expand that number to over 2,500 fire departments, roughly 10 percent

of all departments in the U.S. Additionally, in 2024 we sold over 500 tests to military veterans who served in Iraq or Afghanistan as it is believed that they were exposed to cancer causing toxins during their deployments. We will continue to explore other high-risk populations to target for our tests.

- ***Strategic investments, acquisitions, and transactions.*** Utilizing our CLIAx as a platform, we plan to enter technology licensing and marketing agreements with companies that have IP that improve our current tests or marketable tests that can be offered to our customers. In some cases, we hope to be positioned to make equity investments or acquisitions with one or more of these companies.

## Facilities

On March 18, 2021, we entered into a lease agreement for a new office and laboratory space totaling 5,511 square feet in Gaithersburg, Maryland. The term of the lease commenced on December 8, 2021 and expires 88 months thereafter. The initial monthly rent is \$14,315 with annual increases to \$17,308 for the final year of the lease. We will also pay our 7.75% pro rata portion of the property taxes, operating expenses and insurance costs and are also responsible for paying for the utilities used on the premises.

We believe that all our properties have been adequately maintained, are generally in good condition, and are suitable and adequate for our business.

## Intellectual Property

The following table summarizes our patent portfolio. All of these patents and patent applications are owned by us.

Description		Serial No./Patent No.	Jurisdiction	Projected Expiry
<b>Methods, Systems, Algorithms and AI for the Early Detection of Multi-Cancer and Lung Cancer</b>				
1	Algorithm for assessing the likelihood a patient has lung cancer	USPN 9,753,043 USPN 10,156,575 USPN 11,733,249	US and CA	2032
2	Methods for aiding in distinguishing between benign and malignant pulmonary nodules	WO 2017/173428	US and CN	2037
3	Algorithm for assessing the likelihood a patient has cancer	USPN 11,621,080	US and CN	2035-37
4	Cancer Classifier Models	PCT/US19/40075	US, CN and JP	2039
5	Methods and algorithms for identifying a patient for follow-up cancer diagnostic testing	WO 2021/247577	US	2041
6	Pan cancer universal algorithm	WO 2022/015700	US and CN	2041

7	Use of multiple tumor markers in a machine learning model for cancer detection	US 2018/0173847	US and TW	2036
---	--	-----------------	-----------	------

No assurance is made that any pending patent applications within the portfolio will result in a granted patent.

To protect our intellectual property, we rely on a combination of laws and regulations, as well as contractual restrictions. We rely on Federal patent laws to protect our intellectual property, including our patented technology. We also rely on the protection of laws regarding unregistered copyrights for certain content we create and trade secret laws to protect our proprietary technology and know-how. To further protect our intellectual property, we enter into confidentiality agreements with our employees, executive officers and directors.

## **Employees**

As of December 31, 2024, we had a total of 20 employees, including 12 full-time employees.

We believe that we maintain a satisfactory working relationship with our employees, and we have not experienced any significant labor disputes or any difficulty in recruiting staff for our operations. None of our employees are represented by a labor union.

## **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.

## **Government Regulation**

The healthcare industry, and thus our business, is subject to extensive federal, state, local and foreign regulation. Some of the pertinent laws and regulations have not been definitively interpreted by the regulatory authorities or the courts, and their provisions are open to a variety of subjective interpretations. In addition, these laws and their interpretations are subject to change.

Both United States federal and state governmental agencies continue to subject the healthcare industry to intense regulatory scrutiny, including heightened civil and criminal enforcement efforts. As indicated by work plans and reports issued by these agencies, the federal government will continue to scrutinize, among other things, the marketing, labeling, promotion, manufacturing, and export of diagnostic healthcare products. The federal government also has increased funding in recent years to fight healthcare fraud, and various agencies, such as the United States Department of Justice, the Office of Inspector General of HHS and state Medicaid fraud control units, are coordinating their enforcement efforts.

## ***FDA and CLIA***

Based on widespread industry practice, we believe that our products do not require pre-market approval from the U.S. Food and Drug Administration (the “FDA”). In the U.S., our current products are laboratory developed tests (“LDTs”) regulated under the CLIA and the Maryland Department of Health. If in the future we elect to license or distribute software as a service those products would likely be deemed to be Clinical Decisions Support Software (“CDSS”). As explained below, products in both of those categories do not require FDA pre-market approval but could become subject to the FDA’s policy of “enforcement discretion.”

Laboratory Developed Tests. LDTs are tests run in the laboratory of the company that developed them. With very rare exceptions, LDTs are not regulated by the FDA but rather under a different regulatory regime called CLIA (Clinical Laboratory Improvement Amendments), state law and regulations, and organizations such as CAP. Our laboratory is fully certified and compliant with CLIA as a “High Complexity Lab.” Furthermore, as of 2023 our lab has been accredited by CAP.

Under current law there is no requirement for CLIA regulated LDTs to obtain approval or clearance from the FDA prior to being marketed (outside the context of tests used in response to a declared pandemic emergency under which the FDA has been given special statutory authorities). In November 2016, the FDA issued a formal statement clarifying that LDTs can be marketed without pre-market approval, but that the agency maintains “enforcement discretion” to require their approval for those LDTs that are marketed in a way that is unsafe or could mislead or cause harm to patients. Since November 2016, such enforcement discretion has been exercised very rarely, and when it has been exercised, the tests were not ordered by independent medical professionals. To reduce the likelihood that our tests will face enforcement discretion by the FDA, we request that our tests be ordered by a physician who is independent of the Company and that the physician aid the patient/consumer in interpreting the test results.

On April 29, 2024, the FDA issued a final regulation under which they would begin to regulate LDTs starting in late 2027. However, on March 31, 2025, a U.S. District Court in Texas ordered that FDA’s LDT final rule be vacated and set aside in its entirety. The FDA elected not to appeal the District Court decision. Thus, there is a consensus among legal experts that the FDA has no jurisdiction to regulate LDTs absent clear statutory authority from Congress. Heretofore bills to provide the FDA with this authority have failed to pass. However, there could be attempts in the future to reintroduce this legislation, especially if Democrats gain control of both Chambers. If passed into law, FDA regulation would impose substantial expenses and delays in our ability to introduce new LDTs.

CDSS. On December 13, 2016, the 21st Century Cures Act was signed into law. Among the many provisions of the Cures Act was the exclusion of certain medical decision support software from the FDA’s jurisdiction. On December 8, 2017, the FDA issued its first set of Draft Guidance to implement those provisions of the Cures Act relating to CDSS. Based on our reading of this Draft Guidance, we believe that there may be aspects of our current or planned OneTest software package that would be exempt from pre-market approval. If we elect to proceed with an independent software product in the U.S. (as we will likely do overseas), outside laboratories could run the OneTest biomarker panels (all of the detection instruments and kits are FDA approved).



Operating under the assumption that seeking FDA approval for our products is optional, but that approval could improve the adoption rates and permit greater scale, we may seek FDA approval when test volume exceeds the capacity of our CLIA laboratory. In so doing, we will present to the FDA real-world evidence, data from tens of thousands of individuals tested with our products in the U.S. and overseas. On August 31, 2017, the FDA issued Guidance on the “Use of Real-World Evidence to Support Regulatory Decision-Making for Medical Devices.” The Guidance provides that “in some cases, a ‘traditional’ clinical trial may be impractical or excessively challenging to conduct” and that use of real-world data “may in some cases provide similar information with comparable or even superior characteristics to information collected and analyzed through a traditional clinical trial.”

### ***Federal and State Fraud and Abuse Laws***

We are subject to federal fraud and abuse laws such as the federal Anti-Kickback Statute (the “AKS”), the federal prohibition against physician self-referral, commonly known as the Stark Law, the Eliminating Kickbacks in Recovery Act (“EKRA”), and the federal False Claims Act (the “FCA”). We are also subject to similar state and foreign fraud and abuse laws.

The AKS prohibits knowingly and willfully offering, paying, soliciting, or receiving remuneration, directly or indirectly, overtly or covertly, in cash or in kind, in return for or to induce such person to refer an individual, or to purchase, lease, order, arrange for, or recommend purchasing, leasing or ordering, any item or service that may be reimbursable, in whole or in part, under a federal healthcare program, such as Medicare or Medicaid. There are a number of statutory exceptions and regulatory safe harbors to the AKS that provide protection from AKS liability to arrangements that fully satisfy the applicable requirements.

EKRA prohibits knowingly and willfully soliciting, receiving, offering or paying remuneration, directly or indirectly, in return for the referral of a patient to, or in exchange for an individual using the services of certain entities, including laboratories, if the services are covered by a health care benefit program. The term “health care benefit program” is broadly defined such that EKRA extends to referrals reimbursed by both governmental and commercial third-party payers. EKRA includes a number of statutory exceptions that provide protection from EKRA liability if the applicable requirements are met.

The Stark Law generally prohibits, among other things, clinical laboratories and other so-called “designated health services” entities from billing Medicare for any designated health services when the physician ordering the service, or any member of such physician’s immediate family, has a financial relationship, such as a direct or indirect investment interest in or compensation arrangement with the billing entity, unless the arrangement meets an exception to the prohibition. The Stark Law also prohibits physicians from making such referrals to a designated health services entity. There are also similar state laws that apply where Medicaid and/or commercial payers are billed.

The FCA imposes penalties against individuals or entities for, among other things, knowingly presenting, or causing to be presented, claims for payment to the government that are false or fraudulent, or knowingly making, using or causing to be made or used a false record or statement material to such a false or fraudulent claim, or knowingly concealing or knowingly and

improperly avoiding, decreasing, or concealing an obligation to pay money to the federal government. This statute also permits a private individual acting as a “qui tam” whistleblower to bring actions on behalf of the federal government alleging violations of the FCA and to share in any monetary recovery. FCA liability is potentially significant in the healthcare industry because the statute provides for treble damages and mandatory penalties of \$13,508 to \$27,018 per false claim or statement for penalties assessed after January 30, 2023, with respect to violations occurring after November 2, 2015.

Other federal statutes pertaining to healthcare fraud and abuse include the civil monetary penalties statute, which prohibits, among other things, the offer or payment of remuneration to a Medicaid or Medicare beneficiary that the offeror or payer knows or should know is likely to influence the beneficiary to order or receive a reimbursable item or service from a particular provider, practitioner, or supplier, and contracting with an individual or entity that the person knows or should know is excluded from participation in a federal health care program. In addition, federal criminal statutes created by the Health Insurance Portability and Accountability Act of 1996 (“HIPAA”) prohibit, among other things, knowingly and willfully executing or attempting to execute a scheme to defraud any healthcare benefit program or obtain by means of false or fraudulent pretenses, representations or promises any money or property owned by or under the control of any healthcare benefit program in connection with the delivery of or payment for healthcare benefits, items or services.

In addition to these federal laws, there are often similar state anti-kickback and false claims laws that typically apply to arrangements involving reimbursement by a state-funded Medicaid or other health care program. Often, these laws closely follow the language of their federal law counterparts, although they do not always have the same exceptions or safe harbors. In some states, these anti-kickback laws apply with respect to all payers, including commercial payers.

A number of states have enacted laws that require pharmaceutical and medical device companies to monitor and report payments, gifts and other remuneration made to physicians and other healthcare providers, and, in some states, marketing expenditures. In addition, some state statutes impose outright bans on certain manufacturer gifts to physicians or other health care professionals. Some of these laws, referred to as “aggregate spend” or “gift” laws, carry substantial fines if they are violated.

Efforts to ensure that our business arrangements with third parties will comply with applicable healthcare laws and regulations will involve substantial costs and extensive annual trainings for all of our employees and contractors. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, fines, imprisonment, exclusion from participation in government-funded healthcare programs, such as Medicare and Medicaid, disgorgement, contractual damages, reputational harm, diminished profits and future earnings, additional reporting or oversight obligations if we become subject to a corporate integrity agreement or other agreement to resolve allegations of non-compliance with the law, and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our results of operations. If any of the physicians or other healthcare providers or entities with whom we do business is found to be not in compliance with applicable

laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government-funded healthcare programs.

### ***Anti-Corruption***

The Foreign Corrupt Practices Act of 1977 (the “FCPA”), and similar international bribery laws make it unlawful for persons or entities to make payments to foreign government officials to assist in obtaining and maintaining business. Specifically, the anti-bribery provisions of the FCPA prohibit any offer, payment, promise to pay, or authorizing the payment of money or anything of value to any person, while knowing that all or a portion of such money or thing of value will be offered, given or promised, directly or indirectly, to a foreign official to do or omit to do an act in violation of his or her duty, or to secure any improper advantage in order to assist in obtaining or retaining business for or with, or directing business, to any person. In addition to the anti-bribery provisions of the FCPA, the statute also contains accounting requirements designed to operate in tandem with the anti-bribery provisions. Covered companies are required to make and keep books and records that accurately and fairly reflect the transactions of the company and devise and maintain an adequate system of internal accounting controls. With our international operations through our third-party partnerships, we could incur significant fines and penalties, as well as criminal liability, if we fail to comply with either the anti-bribery or accounting requirements of the FCPA, or similar international bribery laws. Even an unsuccessful challenge of our compliance with these laws could cause us to incur adverse publicity and significant legal and related costs.

### ***Privacy and Data Protection Laws***

Numerous federal and state laws and regulations, including HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009 (“HITECH”), govern the collection, dissemination, security, use and confidentiality of protected health information (“PHI”) and personal information. In the course of performing our business we obtain personal information, including PHI. Laws and regulations relating to privacy, data protection, and consumer protection are evolving and, in some cases, particularly with regard to newer laws, may be subject to potentially differing interpretations. Under HIPAA and HITECH, the HHS, issues regulations that establish uniform standards governing the conduct of certain electronic healthcare transactions and requirements for protecting the privacy and security of PHI, used or disclosed by covered entities (“CEs”) and their authorized business associates (“Bas”). Because we electronically transmit health care information, and we also provide certain services to CEs and receive PHI from them, we are at times either a CE or a BA, as defined by HIPAA. Our subcontractors that create, receive, maintain, transmit or otherwise process PHI on our behalf are HIPAA BAs and must also comply with HIPAA, as applicable.

HIPAA and HITECH include the privacy and security rules, breach notification requirements and electronic transaction standards. The privacy rule governs the use and disclosure of PHI, generally prohibits the use or disclosure of PHI except as permitted under the rule, and mandates certain safeguards to protect the privacy of PHI. The privacy rule also sets forth individual rights, such as the right to access or amend certain records containing such individual’s PHI, or to request restrictions on the use or disclosure of such individual’s PHI. The security rule requires CEs and BAs to safeguard the confidentiality, integrity, and availability of electronically

transmitted or stored PHI (also referred to as ePHI) by implementing administrative, physical and technical safeguards. Under HIPAA's breach notification rule, a CE must notify individuals, the Secretary of HHS, and in some circumstances, the media of certain breaches of unsecured PHI or ePHI, and similar breach notification provisions apply to certain BAs under HITECH.

Penalties for failure to comply with a requirement of HIPAA and HITECH vary depending on the number and nature of the violations and any history of prior violations, but can be significant and include civil monetary or criminal penalties. HIPAA is enforced by the HHS, Office for Civil Rights, and HIPAA also authorizes state attorneys general to file suit on behalf of their residents for violations. Courts are able to award damages, costs and attorneys' fees related to violations of HIPAA in such cases. While HIPAA does not create a private right of action allowing individuals to file suit in civil court for violations of HIPAA, its standards have been used as the basis for duty of care cases in state civil suits such as those for negligence or recklessness in improper use, access to or disclosure of PHI. In addition, HIPAA mandates that the Secretary of HHS conduct periodic compliance audits of HIPAA CEs, such as us, and their BAs for compliance with the HIPAA privacy and security standards and breach notification rules. It also tasks HHS with establishing a methodology whereby harmed individuals who were the victims of breaches of unsecured PHI may receive a percentage of the civil monetary penalty paid by the violator.

In addition, we may be subject to state privacy, cybersecurity, and data breach notification laws, which may govern the collection, use, disclosure and protection of health-related and other personal information. California, for example, has enacted the Confidentiality of Medical Information Act, which, in addition to HIPAA and HITECH, sets forth standards with which all California health care providers must abide. Colorado has enacted the Colorado Privacy Act, and Virginia has enacted the Consumer Data Protection Act, both of which also have standards that must be complied with that supplement Federal data protection requirements. State laws may be more stringent, broader in scope or offer greater individual rights with respect to PHI than HIPAA, and state laws may differ from each other in regard to personal information treatment, which may complicate compliance efforts. For instance, the California Consumer Privacy Act ("CCPA") became effective on January 1, 2020 and was amended by the passage of the California Privacy Rights Act ("CPRA") in November of 2020, which amendments came into force on January 1, 2023. The CCPA, among other things, gives California residents expanded rights to access and delete their personal information, opt out of certain personal information sharing and receive detailed information about how their personal information is used by requiring covered companies to provide new disclosures to California consumers (as that term is broadly defined) and provide such consumers new ways to opt-out of certain sales of personal information. The CCPA provides for civil penalties for violations, as well as a private right of action for data breaches that is expected to increase data breach litigation. The CCPA has been amended from time to time, and it remains unclear what, if any, further modifications will be made to this legislation or how it will be interpreted. Although there are certain exemptions for PHI and clinical trial data, the CCPA's implementation standards and enforcement practices are likely to remain uncertain for the foreseeable future and the CCPA may increase our compliance costs and potential liability. Additionally, the CPRA imposes additional data protection obligations on companies doing business in California, including additional consumer rights processes and opt outs for certain uses of sensitive data. It also creates a new California data protection agency – the California Privacy Protection Agency – specifically tasked to enforce the

law, which would likely result in increased regulatory scrutiny of California businesses in the areas of data protection and security. Similar laws have been proposed in other states and at the federal level, and if passed, such laws may have potentially conflicting requirements that could continue to make compliance challenging and costly.

Additionally, the Federal Trade Commission (the “FTC”) and state attorneys general enforce consumer protection laws that prohibit unfair and deceptive acts and practices, including Section 5 of the FTC Act, which creates standards for the collection, use, dissemination and security of health-related and other personal information. Claims of unfair or deceptive trade practices regarding privacy and security can lead to significant liabilities and consequences, including regulatory investigations, penalties, fines and orders as well as civil claims, which could impact our data practices and operations or cause reputational damage.

We may also be subject to laws and regulations in foreign countries covering data privacy and other protection of health and employee information that may add additional compliance burden and complexity. For example, in the European Economic Area, the collection and use of personal data is governed by the European Union’s General Data Protection Regulation (the “GDPR”). In the United Kingdom, the GDPR has been adopted in substantially the same form, however the UK may potentially make revisions in the coming years. The GDPR, together with national legislation, regulations and guidelines of the European Union member states and the United Kingdom governing the processing of personal data, impose strict obligations and restrictions on the ability to collect, analyze, store, transfer and otherwise process personal data. European and United Kingdom data protection authorities may interpret the GDPR and national laws differently and impose additional requirements, which adds to the complexity of processing personal data in or from the European Economic Area or United Kingdom. Guidance on implementation and compliance practices is often updated or otherwise revised. The GDPR applies extra-territorially under certain circumstances and imposes stringent requirements on controllers and processors of personal data, including, for example, requirements to ensure a legal bases to process personal information, provide robust disclosures to individuals, facilitate data subject rights, provide data security breach notifications within 72 hours after discovering a breach in certain circumstances, limit retention of personal information and apply enhanced protections to health data and other categories of sensitive personal information. The GDPR also has requirements around international transfers of personal data. Requirements around transfers to the United States and other jurisdictions have increased since a July 2020 decision by the Court of Justice of the European Union invalidated the Privacy Shield as a basis to transfer personal data from Europe to the United States, and added requirements for reliance on Standard Contractual Clauses. Regulatory guidance on requirements for international transfers, and other GDPR compliance matters, continues to evolve. For example, the European Commission in December 2022 announced that it was beginning the process of drafting a new adequacy decision that would ease regulatory barriers for data transfers to the United States. However, it is widely expected that the new adequacy decision will itself face scrutiny from the Court of Justice, underscoring that GDPR compliance is an ongoing endeavor. Failure to comply with the requirements of the GDPR may result in fines of up to €20 million or up to 4% of the total worldwide annual turnover of our preceding fiscal year, whichever is higher, and other administrative penalties. To comply with the GDPR and other applicable international data protection laws and regulations, we may be required to put in place additional mechanisms ensuring compliance, which may result in other substantial expenditures.

## ***Cybersecurity***

Our business relies on secure and continuous processing of information and the availability of our IT networks and IT resources, as well as critical IT vendors that support our technology, research and other data processing operations. While we take steps to protect our systems and data, security incidents, data breaches, computer malware and computer hacking attacks have become more prevalent across industries, including the life sciences sector, and may occur on our systems or those of our third-party service providers. Unauthorized persons may in the future be able to exploit weaknesses in the security systems of our (or our third-party service providers) IT networks and gain access to PHI and other personal information, sensitive trade secrets, or other proprietary information. Any wrongful use or disclosure of PHI, other personal information, trade secrets or other proprietary information by us or our third-party service providers could subject us to regulatory fines or penalties, third-party claims or otherwise could adversely affect our business and results of operations. Although HIPAA and the regulations promulgated thereunder do not provide for a private right of action, failures to adequately protect PHI or our IT systems could be viewed as violations of the HIPAA security rule or violations of other applicable information security laws, regulations, contractual obligations or industry standards, and could further result in costly data breach notification obligations that negatively impact our reputation.

Moreover, data security incidents or data breaches, as well as attacks on our IT systems, could result in operational disruptions or data loss or corruption that could adversely impact our business and operations, resulting in substantial investment of resources to investigate, recover and remediate and subject us to heightened regulatory scrutiny.

## ***International Regulations***

Many countries in which we may offer any of our diagnostic tests in the future have anti-kickback regulations prohibiting providers from offering, paying, soliciting or receiving remuneration, directly or indirectly, in order to induce business that is reimbursable under any national health care program. In situations involving physicians employed by state-funded institutions or national healthcare agencies, violation of the local anti-kickback law may also constitute a violation of the FCPA.

The FCPA prohibits any United States individual, business entity or employee of a United States business entity to offer or provide, directly or through a third party, including any potential distributors we may rely on in certain markets, anything of value to a foreign government official with corrupt intent to influence an award or continuation of business or to gain an unfair advantage, whether or not such conduct violates local laws. In addition, it is illegal for a company that reports to the Securities and Exchange Commission (the “SEC”) to have false or inaccurate books or records or to fail to maintain a system of internal accounting controls. We will also be required to maintain accurate information and control over sales and distributors’ activities that may fall within the purview of the FCPA, its books and records provisions and its anti-bribery provisions.

The standard of intent and knowledge in anti-bribery cases is minimal. Intent and knowledge are usually inferred from that fact that bribery took place. The accounting provisions do not require

intent. Violations of the FCPA's anti-bribery provisions for corporations and other business entities are subject to a fine of up to \$2 million and officers, directors, stockholders, employees, and agents are subject to a fine of up to \$100,000 and imprisonment for up to five years. Other countries, including the United Kingdom and other OECD Anti-Bribery Convention members, have similar anti-corruption regulations, such as the United Kingdom Anti-Bribery Act.

When marketing our diagnostic tests outside of the United States, we may be subject to foreign regulatory requirements governing human clinical testing, prohibitions on the import of tissue necessary for us to perform our diagnostic tests or restrictions on the export of tissue imposed by countries outside of the United States or the import of tissue into the United States, and marketing approval. These requirements vary by jurisdiction, differ from those in the United States and may in some cases require us to perform additional pre-clinical or clinical testing. In many countries outside of the United States, coverage, pricing and reimbursement approvals are also required.

Market access, sales and marketing of medical devices in non-U.S. countries are subject to foreign regulatory requirements that vary widely from country to country. For example, in the European Economic Area, a medical device must meet the Medical Devices Directive's/In Vitro Medical Devices Directive's ("MDD/IVDD") Essential Requirements or, applicable on May 26, 2021, the Medical Devices Regulation's ("MDR"), or applicable on May 26, 2022, In Vitro Medical Devices Regulation's ("IVDR") General Safety and Performance Requirements which apply to it, taking into account its intended purpose as defined by the data supplied by the manufacturer on the label, in the instructions for use or in promotional or sales materials or statements and as specified by the manufacturer in the clinical evaluation. Before placing a medical device on the European Economic Area market, the manufacturer must draw up a declaration of conformity, certifying that the device complies with the MDD/IVDD/MDR/IVDR, and must then affix the CE mark. For medium and high-risk devices as well as low risk devices that are placed on the market in sterile condition, have a measuring function, or are reusable surgical instruments, the manufacturer must obtain a CE certificate from a notified body. The notified body typically audits and examines the device's technical documentation, including the clinical evaluation, and the quality system for the manufacture, design and final inspection of the relevant device before issuing a CE certificate. Following the issuance of this CE certificate, manufacturers may draw up the declaration of conformity and affix the CE mark to the devices covered by this CE certificate.

Manufacturers of medical devices must document in a clinical evaluation report (the "CER") the evaluation of the clinical data related to the device. The CER is part of the device's technical file. The evaluation shall document that the applicable Essential Requirements/General Safety and Performance Requirements are met and document the evaluation of the undesirable side-effects and the acceptability of the benefit-risk ratio. The CER must be updated based on information from the post-market surveillance and vigilance activities related to the device. The CER shall consist, *inter alia*, of analyzed clinical data collected from a clinical investigation of the device, or the results of other studies on substantially equivalent devices. Reliance on "substantially equivalent" devices is very restrictive and requires, *inter alia*, that the manufacturer has full access to the technical documentation of the equivalent device on an ongoing basis and, if the "equivalent device" is not its own, that the manufacturer has in place a contract with the manufacturer of the "equivalent device."

### ***Environmental, Health and Safety Regulations***

We are subject to various federal, state, local, and foreign environmental, health and safety laws and regulations and permitting and licensing requirements. Such laws include those governing laboratory practices, the generation, storage, use, manufacture, handling, transportation, treatment, remediation, release and disposal of, and exposure to, hazardous materials and wastes and worker health and safety. Our operations involve the generation, use, storage and disposal of hazardous materials, and the risk of injury, contamination or non-compliance with environmental, health and safety laws and regulations or permitting or licensing requirements cannot be eliminated. Compliance with environmental laws and regulations has not had a material effect on our capital expenditures, earning or competitive position.

### **Corporate History**

We were incorporated in the State of Delaware on August 7, 2000 under the name 20/20 BioSystems, Inc. On September 19, 2000, our name was changed to 20/20 Gene Systems, Inc., on June 27, 2021, our name was changed to 20/20 GeneSystems, Inc. and on March 19, 2025, our name was changed to 20/20 Biolabs, Inc. We do not have any subsidiaries.



# Risk Factors

Investing in our 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 our 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 Company is subject to 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 our securities. Our securities should only be purchased by persons who can afford to lose all of their investment.

## Risks Related to Our Business and Industry

*Prior to the establishment of our COVID-19 testing business, we incurred losses, and expect to continue to generate losses now that COVID-19 testing has ceased.*

While we achieved profitability in 2021 and 2022, such profitability was mainly a result of COVID-19 testing, which ceased in the second quarter of 2023. Prior to 2021, we incurred losses since inception. We have financed our operations through the sale of our securities, product revenues and government research grants and contracts. There is no assurance that we will be able to obtain adequate financing that we may need, or that any such financing that may become available will be on terms that are favorable to us and our stockholders. Ultimately, our ability to generate sufficient operating revenue to earn a profit depends upon our success in developing and marketing or licensing our diagnostic tests and technology. Any failure to do so could result in the possible closure of our business or force us to seek additional capital through loans or additional sales of our equity securities to continue business operations, which could dilute the value of any securities you hold, or could result in the loss of your entire investment.

*Now that the pandemic emergency has ended, our success will depend heavily on our cancer screening and longevity tests.*

Now that the pandemic emergency has ended, the bulk of our revenues depends almost entirely on the commercial success of our cancer tests unless we can also develop or acquire 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
- 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 multi- cancer screening products and procedures;
- the ease of use of our ordering process for physicians;
- maintaining and defending 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.

***We will need to attract additional capital to scale our business but have no assurance that we can do so successfully.***

We will be incurring significant sales and marketing costs as we commercialize our diagnostic test products. We will need to raise additional capital to pay operating expenses until we are able to generate sufficient revenues from diagnostic test sales, royalties, and license fees, and we will need to sell additional equity or debt securities to meet those capital needs. Our ability to raise additional equity or debt capital will depend not only on progress made marketing and selling our diagnostic tests, but also will depend on access to capital and conditions in the capital markets. There is no assurance that we will be able to raise capital at times and in amounts needed to finance the development and commercialization of our diagnostic tests, maintenance of our CLIA certified diagnostic laboratory, and general operations. Even if capital is available, it may not be available on terms that we or our stockholders would consider favorable. Furthermore, sales of additional equity securities could result in the dilution of the interests of our stockholders.

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

We have developed and will continually refine new biomarker test panels and associated algorithms. The main focus of these products is on early detection of cancer. Our technologies may not prove to be sufficiently efficacious or medically useful to gain widespread adoption or market share. The diagnostics tests and software that we have introduced to the market to date have not yet generated significant revenues. Without diagnostic test sales or licensing fee 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 cancer are being developed by more established and significantly better-financed diagnostics or biotech companies, and 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.

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

The value of our diagnostic products is thus far proven mainly with real world evidence, rather than traditional clinical trials; and there is no assurance that real world evidence will gain wide acceptance by the medical establishment or regulators in the countries in which we conduct business. Also, there is no assurance that data derived from East Asia will be accepted in Western nations and generating data from Western populations could be time consuming and expensive. The value of machine learning and AI in our algorithms is novel, not entirely proven, and might not be widely embraced by the medical establishment or regulators in the countries in which we conduct business.

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

- demonstrated sensitivity and specificity for detecting cancers;
- 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 to remain profitable.

***We are expecting patient self-pay to constitute a significant portion of our revenues for the foreseeable future and this revenue growth is contingent upon individuals' willingness to pay out of pocket for our diagnostic tests.***

We expect that a substantial portion of the patients for whom we will perform diagnostic tests will have Medicare as their primary medical insurance. Medicare coverage is not expected for

several years. Patients who are not covered by Medicare will generally rely on health insurance provided by private health insurance companies. If we are considered a “non-contracted provider” by a third-party payer, that payer may not reimburse patients for diagnostic tests performed by us or doctors within the payer’s network of covered physicians may not use our services to perform diagnostic tests for their patients. As a result, we may need to enter into contracts with health insurance companies or other private payers to provide diagnostic tests to their insured patients at specified rates of reimbursement which may be lower than the rates we might otherwise collect.

Until our diagnostic tests are covered by Medicare or private insurance, we expect that self-pay will constitute a significant portion of our revenues for the foreseeable future. This revenue growth will be contingent on individuals’ willingness to pay out of pocket for our diagnostic tests.

***The commercial potential of our longevity test is unknown and unproven.***

While OneTest for Cancer has been on the market for several years, OneTest for Longevity is in development and has not yet been offered for sale. We do not know the costs of customer acquisition or whether the test will be embraced by the market. Despite the emphasis on chronic disease mitigation by the Secretary of the HHS, we have no evidence that our test would ever be reimbursed or otherwise recommended by the Centers for Medicare & Medicaid Services (the “CMS”), or any of the agencies that make up HHS. Our plans to introduce a subscription model may fail to be embraced by the marketplace and, if it is, we do not yet know what monthly or quarterly fee most consumers would be willing to pay.

***The interface between the DII and our laboratory information system has not yet been implemented.***

An important feature of OneTest for Longevity is the interface between the DII and our laboratory reports. A laboratory version of the DII for this purpose remains in development by the team from CII. We cannot guarantee that it will be ready in time for our product launch or that it will function through our portal and laboratory information system without technical issues.

***The viability of offering automated, tailored coupons for grocery purchases is untested and unproven by us.***

Part of our value proposition to consumers and revenue model for OneTest for Longevity includes automated coupons delivered to the customers’ mobile app for the foods recommended for them to lower inflammation. This concept remains mere conjecture at this stage, and we do not know whether food suppliers would be willing to share revenues with us when their coupons are redeemed, nor do we know how consumers will view this feature and what percentage will redeem the coupons.

***Our CLIAx and CLIAx fund might not contribute to our growth.***

Part of our growth strategy is to create a fund associated with our CLIAx. This would enable us to invest in, acquire, or transact with companies that have tests that could add to our menu or

technologies, products, testing components or intellectual property that strengthen our core business. We have identified a few companies that could be candidates for this CLIAx fund but have no agreements or letters of intent with any of them. Thus, there is no guarantee that we can identify or reach agreement in the near term with any such companies to meaningfully contribute to inorganic growth.

***We face substantial competition.***

The development and commercialization of diagnostics tests, especially MCEDs, is highly competitive and subject to rapid technological advances. We face competition with respect to our current products and any product candidates we may seek to develop or commercialize in the future. Our competitors may develop comparable tests that are safer, more effective, more convenient or less costly than any products that we may develop or market or may obtain marketing approval for their products from the FDA or equivalent foreign regulatory bodies more rapidly than we may obtain approval for our product candidates. Our competitors may devote greater resources to market or sell their tests, research and development capabilities, adapt more quickly to new technologies, scientific advances or patient preferences and needs, initiate or withstand substantial price competition more successfully, or more effectively negotiate third-party licensing and collaborative arrangements. As a result, physicians and other key healthcare decision makers may choose other products over our products, switch from our products to new products or choose to use our products only in limited circumstances, which could adversely affect our business, financial condition, and results of operations.

Regarding our longevity test, we face many competitors that assess pathways of aging other than inflammation such as telomere length, methylation, microbiome, and others. Furthermore, many labs can test for C-reactive protein, the most important biomarker of inflammation. If consumers do not value the proprietary DII or grocery coupon components of our test, they may seek out alternative testing providers.

***If our diagnostics 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 the Company.***

Our success depends on the market's confidence that we can provide a reliable, high-quality diagnostic tests. We believe that customers are likely to be particularly sensitive to product defects and errors. Our reputation and the public image of our diagnostic tests may be impaired if they fail to perform as expected or are 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, delayed market acceptance, damaged reputation, diversion of development resources, legal claims, increased insurance costs or increased service and warranty 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 test could result in lost revenue, delayed market acceptance, damaged reputation, increased service and warranty costs and claims against us.

***Our inability to manage growth could harm our business.***

We have added, and expect to continue to add, additional personnel in the areas of sales and marketing, laboratory operations, billing and collections, quality assurance and compliance. As we build our commercialization efforts and expand research and development activities, the scope and complexity of our operations is increasing significantly. As a result of our growth, our operating expenses and capital requirements have also increased, and we expect that they will continue to 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, reporting systems and procedures. As we move forward with 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.

***We currently manufacture our tests predominantly in one facility and perform our testing in one laboratory facility. As demand for our tests grows, we may lack adequate facility space and capabilities to meet increased processing requirements. Moreover, if these or any future facilities or our equipment were damaged or destroyed, or if we experience a significant disruption in our operations for any reason, our ability to continue to operate our business could be materially harmed.***

We currently perform testing in a single laboratory facility in Gaithersburg, Maryland. Our headquarters and manufacturing facilities are also located in Maryland. As we expand sales and increase the number of tests processed by our laboratory facility, we may need to expand or modify our existing laboratory facility or acquire new laboratory facilities to increase our processing capacity. Any failure to do so on terms acceptable to us, if at all, may significantly delay our processing times and capabilities, which may adversely affect our business, financial condition, and results of operation.

If these, or any future facilities, were to be damaged, destroyed or otherwise unable to operate, whether due to fire, floods, storms, tornadoes, other inclement weather events or natural disasters, employee malfeasance, terrorist acts, power outages, or otherwise, our business could be severely disrupted. If our laboratory is disrupted, we may not be able to perform testing or generate test reports as promptly as patients and healthcare providers require or expect, or possibly not at all. If we are unable to perform testing or generate test reports within a timeframe that meets patient and healthcare provider expectations, our business, financial results, and reputation could be materially harmed.

We currently maintain insurance against damage to our property and equipment and against business interruption and research and development restoration expenses, subject to deductibles and other limitations. If we have underestimated our insurance needs with respect to an interruption, or if an interruption is not subject to coverage under our insurance policies, we may not be able to cover our losses.

***There are a limited number of manufacturers of molecular diagnostic equipment and related chemical reagents necessary for the provision of our diagnostic tests.***

The test panels and algorithms that we have developed and will continue to develop rely on certain analytic equipment. There are only a few manufacturers of the equipment we will need and the chemical reagents that are required for use with a particular manufacturer's equipment will be available only from that equipment manufacturer. If the manufacturer of the equipment we acquire discontinues operation or if we and other testing laboratories experience supply or quality issues with their equipment or reagents, it may become necessary for us to adjust our products for different analytic equipment, which would require additional experiments to ensure reproducibility of our test results using the new equipment. As a result, we may be unable to provide our diagnostic products for a period of time.

***Our suppliers may experience development or manufacturing problems or delays that could limit the growth of our revenue or increase our losses.***

We may encounter unforeseen situations in the 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 diagnostic tests, reduce our product gross margin and adversely impact our business. If we are unable to keep up with demand for tests by successfully securing supply and shipping our diagnostic tests in a timely manner, our revenue could be impaired, market acceptance for the tests could be adversely affected and our customers might instead purchase our competitors' diagnostic tests.

***To achieve widespread use of our diagnostic test and commercial scale, some individual consumers may need convenient access to blood draw services, but we cannot guarantee that these service providers will be willing to perform them.***

Currently, some of those who use our tests prefer traditional venous blood collected by a licensed phlebotomist. While our business customers, such as employers, typically have little difficulty finding phlebotomists, this can be a challenge for many of our individual consumers. To address this need, we have about 1,000 retail establishments that can draw blood for our test customers. These establishments perform these services based on contracts we have with the companies Any Lab Test Now and My One Medical Source. If those contracts were to terminate or expire or if they are unable to maintain their franchisees or networks of clinics willing to draw blood, this could limit our ability to serve our customers and grow.

***Our capillary blood collection devices are manufactured by other companies, and we cannot guarantee that we will have a continued supply of these devices or that the costs for them will not rise significantly.***

Since we began validating and offering capillary (upper arm) blood collection, about two-thirds of our customers have elected that approach over traditional venipuncture with high success and satisfaction rates. Currently, there are only three or four manufacturers with FDA cleared upper arm collection devices and not all reliably collect the required 0.5mL of whole blood needed for

OneTest. Thus, if these collection device suppliers go out of business, experience supply chain disruptions, or substantially raise their prices, this could significantly disrupt our business operations.

***We have limited sales and marketing resources and few distribution resources for the commercialization of any diagnostic tests that we have developed.***

We currently have limited sales and marketing resources. If we are successful in developing marketable diagnostic tests, we will need to build our own marketing and sales capability, which would require the investment of significant financial and management resources to recruit, train, and manage a sales force.

***The sizes of the markets for our diagnostic tests and services 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 diagnostic tests and services 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 diagnostic tests and services 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 diagnostic tests and services 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.

***If we fail to enter into and maintain successful strategic alliances for diagnostic tests that we elect to co-develop, co-market, or out-license, we may have to reduce or delay our diagnostic test development or increase our expenditures.***

To facilitate the development, manufacture, and commercialization of our diagnostic tests we may enter into strategic alliances with hospitals and biomedical research institutes, biotechnology and diagnostics companies, clinical testing reference laboratories, and marketing firms in many of the countries in which we do business. We will face significant competition in seeking appropriate alliances. We may not be able to negotiate alliances on acceptable terms, if at all. If we fail to create and maintain suitable alliances, we may have to limit the size or scope of, or delay, one or more of our product development or research programs, or we may have to increase our expenditures and may need to obtain additional funding, which may be unavailable or available only on unfavorable terms.

In some countries we may license marketing rights to diagnostics or clinical laboratory companies or to a joint venture company formed with those companies. Under such arrangements we might receive only a royalty on sales of the diagnostic tests developed or an equity interest in a joint venture company that develops the diagnostic test. As a result, our revenues from the sale of those diagnostic tests may be substantially less than the amount of



revenues and gross profits that we might receive if we were to market and run the diagnostic tests ourselves.

***We may become dependent on possible future collaborations to develop and commercialize many of our diagnostic test candidates and to provide the manufacturing, regulatory compliance, sales, marketing and distribution capabilities required for the success of our business.***

We may enter into various kinds of collaborative research and development, manufacturing, and diagnostic test marketing agreements to develop and commercialize our diagnostic tests. There is a risk that we could become dependent upon one or more collaborative arrangements. A collaborative arrangement, upon which we might depend might be terminated by our collaboration partner or they might determine not to actively pursue the co-development of our diagnostic tests. A collaboration partner also may not be precluded from independently pursuing competing diagnostic tests or technologies.

***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 the 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 for 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.

***Certain jurisdictions in which we may do business may not provide the same level of legal protections and enforcement of contract and intellectual property rights to which investors are accustomed in the United States.***

We may conduct business in China and other foreign jurisdictions. In order to do business in these countries, we will be required to comply with the laws of those countries, including restrictions on exporting currency, requirements for local partners, tax laws and other legal requirements. Doing business in such foreign jurisdictions also entails political risk over which we have no control and for which we are unable to obtain insurance on acceptable terms. These countries also have different judicial systems, which may not provide the same level of legal protections and enforcement of contract and intellectual property rights to which investors are accustomed in the United States. We can provide no assurance that the applicable laws of such

foreign jurisdictions will not be changed in ways unfavorable to us, or that applicable laws will be adequately enforced in order to provide the same levels of protection accorded to us in the United States.

***Adverse U.S. and global market, economic and political conditions, including the ongoing conflict between Ukraine and Russia, recent events in the Middle East 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, the availability and cost of credit, the U.S. mortgage market, or a declining real estate market in the U.S. 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, cash flows and our ability to pay distributions on, and the per share trading price of, our common stock.

The Russian invasion of Ukraine in February 2022 and the resulting global governmental responses, including international sanctions imposed on Russia and other countries that are supporting Russia's invasion of Ukraine, have led to volatility in global markets, disruptions in the energy, agriculture and other industries and have created worldwide inflationary pressures. While the conflict has not caused material disruptions to our operations to date, further escalation of the war between Russia and Ukraine could result in a significant decline in global economic activities and impact our business.

## **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 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.

***Our patents may not protect our diagnostic tests from competition.***

We might not be able to obtain any patents beyond those 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.

***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. Importantly, if we fail to meet our obligations under our technology access agreement with BioInfra, this would adversely

impact our ability to introduce an enhanced or premium version of our MCED test. 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.

## **Risks Related to Healthcare Government Regulation, Reimbursement, Product Safety and Effectiveness**

***We have relied on and expect to continue to rely on third parties to conduct studies of our diagnostics tests that will be required to meet our obligations under CLIA, CAP and/or other regulatory authorities and those third parties may not perform satisfactorily.***

We rely on third parties, such as academic, medical and commercial entities, to conduct studies for our diagnostics tests. These include, among others, the Chang Gung Memorial Hospital in Taiwan and BioInfra. Our reliance on these third parties will reduce our control over these activities. These third-party contractors may not complete activities on schedule or conduct studies in accordance with regulatory requirements or our study design. We cannot control whether they devote sufficient time, skill, and resources to our studies. Our reliance on third parties that we do not control will not relieve us of any applicable requirement to prepare, and ensure compliance with, various procedures required under good scientific and clinical practices. If these third parties do not successfully carry out their contractual duties or regulatory obligations or meet expected deadlines, if the third parties need to be replaced or if the quality or accuracy of the data they obtain is compromised due to their failure to adhere to our clinical protocols or regulatory requirements under the CLIA or the CAP, or for other reasons, our studies may be extended, delayed, suspended or terminated, and we may not be able to obtain regulatory approval for additional diagnostic tests.

***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 at 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.

***International operations could subject us to risks and expenses that could adversely impact the business and results of operations.***

To date, we have not undertaken substantial commercial activities outside the United States. We have evaluated commercialization in Asian countries. If we seek to expand internationally, or launch other products or services internationally, in the future, those efforts would expose us to risks from the failure to comply with foreign laws and regulations that differ from those under which we operate in the U.S., as well as U.S. rules and regulations that govern foreign activities such as the FCPA. In addition, we could be adversely affected by other risks associated with operating in foreign countries. Economic uncertainty in some of the geographic regions in which we might operate, including developing regions, could result in the disruption of commerce and negatively impact cash flows from our operations in those areas.

These and other factors may have a material adverse effect on any international operations we may seek to undertake and, consequently, on our financial condition and results of operations.

***Our business is subject to various complex laws and regulations. We could be subject to significant fines and penalties if we or our partners fail to comply with these laws and regulations.***

As a provider of clinical diagnostic products and services, we and our partners are subject to extensive and frequently changing federal, state, and local laws and regulations governing various aspects of our business. In particular, the clinical laboratory industry is subject to significant governmental certification and licensing regulations, as well as federal and state laws regarding:

- test ordering and billing practices;
- marketing, sales and pricing practices;
- the Eliminating Kickbacks in Recovery Act of 2018;

- HIPAA, as amended by HITECH, and comparable state laws;
- anti-markup legislation; and
- consumer protection.

We are also required to comply with FDA regulations, including with respect to our labeling and promotion activities. In addition, advertising of our tests is subject to regulation by the FTC. Violation of any FDA requirement could result in enforcement actions, such as seizures, injunctions, civil penalties and criminal prosecutions, and violation of any FTC requirement could result in injunctions and other associated remedies, all of which could have a material adverse effect on our business. Most states also have similar regulatory and enforcement authority for devices. Additionally, most foreign countries have authorities comparable to the FDA and processes for obtaining marketing approvals. Obtaining and maintaining these approvals, and complying with all laws and regulations, may subject us to similar risks and delays as those we could experience under FDA and FTC regulation. We incur various costs in complying and overseeing compliance with these laws and regulations.

Healthcare policy has been a subject of extensive discussion in the executive and legislative branches of the federal and many state governments and healthcare laws and regulations are subject to change. Development of the existing commercialization strategy for our tests have been based on existing healthcare policies. We cannot predict what additional changes, if any, will be proposed or adopted or the effect that such proposals or adoption may have on our business, financial condition and results of operations.

If we or our partners, including independent sales representatives, fail to comply with these laws and regulations, we could incur significant fines and penalties and our reputation and prospects could suffer. Additionally, our partners could be forced to cease offering our products and services in certain jurisdictions, which could materially disrupt our business.

***New FDA regulations of lab tests could significantly impact our commercial operations.***

Most of our products have the regulatory status of LDTs, which for several decades have been regulated federally by the CMS under the CLIA statute rather than by FDA. On April 29, 2024, the FDA issued a final regulation under which they would begin to regulate LDTs starting in late 2027. However, on March 31, 2025, a U.S. District Court in Texas ordered that FDA's LDT final rule be vacated and set aside, in its entirety. The FDA elected not to appeal the District Court decision. Thus, there is a consensus among legal experts that the FDA has no jurisdiction to regulate LDTs absent clear statutory authority from Congress. Heretofore bills to provide the FDA with this authority have failed to pass. However, there could be attempts in the future to reintroduce this legislation, especially if Democrats gain control of both Chambers. If passed into law, FDA regulation would impose substantial expenses and delays in our ability to introduce new LDTs.

If we unexpectedly are required to obtain regulatory approval of our diagnostic test products, it may take two years or more to conduct the clinical studies and trials necessary to obtain pre-market approval from the FDA. Even if our clinical trials are completed as planned, we cannot

be certain that the results will support our test claims or that the FDA will agree with our conclusions regarding our test results. Success in early clinical trials does not ensure that later clinical trials will be successful, and we cannot be sure that the later trials will replicate the results of prior clinical trials and studies. If we are required to conduct pre-market clinical trials, delays in the commencement or completion of clinical testing could significantly increase our test development costs and delay commercialization. Many of the factors that may cause or lead to a delay in the commencement or completion of clinical trials may also ultimately lead to delay or denial of regulatory clearance or approval. The clinical trial process may fail to demonstrate that our tests are effective for the proposed indicated uses, which could cause us to abandon a test candidate and may delay development of other tests.

***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 are subject to federal and state healthcare fraud and abuse laws and regulations and could face substantial penalties if we are unable to fully comply with such laws.***

We are subject to healthcare fraud and abuse regulation and enforcement by both the federal government and the states in which we conduct our business. These health care laws and regulations include the following:

- The Eliminating Kickbacks in Recovery Act of 2018;
- The federal Anti-Kickback Statute;
- The federal physician self-referral prohibition, commonly known as the Stark Law;
- The federal false claims and civil monetary penalties laws;

- The federal Physician Payment Sunshine Act requirements under the Affordable Care Act; and
- State law equivalents of each of the federal laws enumerated above.

Any action brought against us for violation of these laws or regulations, even if we are in compliance and successfully defend against it, could cause us to incur significant legal expenses and divert our management's attention from the operation of our business. If our operations are found to be in violation of any of these laws and regulations, we may be subject to applicable penalties associated with the violation, including, among others, administrative, civil and criminal penalties, damages and fines, and/or exclusion from participation in Medicare, Medicaid programs, including the California Medical Assistance Program (Medi-Cal—the California version of the Medicaid program) or other state or federal health care programs. Additionally, we could be required to refund payments received by us, and we could be required to curtail or cease our operations.

***If we become subject to claims relating to the receipt and handling of bio-hazardous materials (including infected blood), we could incur significant cost and liability.***

Our quality control quality assurance process might involve the receipt and handling of whole blood, serum, or plasma from one or more individuals. We are subject to Federal, state and local regulations governing the use, manufacture, storage, handling and disposal of biological materials and waste products. We may incur significant costs complying with both existing and future environmental laws and regulations. In particular, we are subject to regulation by the Maryland Department of Health, the CLIA, the Occupational Safety and Health Administration ("OSHA"), and the Environmental Protection Agency (the "EPA"), and to regulation under the Toxic Substances Control Act and the Resource Conservation and Recovery Act in the United States. OSHA or the EPA may adopt additional regulations in the future that may affect our research and development programs. The risk of accidental contamination or injury from hazardous materials cannot be eliminated completely. In the event of an accident, we could be held liable for any damages that result, and any liability could exceed the limits or fall outside the coverage of our workers' compensation insurance. We may not be able to maintain insurance on acceptable terms, if at all.

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

Our diagnostic tests are intended for use only as screening devices, which 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 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 Securities**

***Neither the Offering nor the securities offered hereby have been registered under federal or state securities laws.***

No governmental agency has reviewed or passed upon this Offering or the securities offered hereby. You should not rely on the fact that our Form C is accessible through the SEC's EDGAR filing system as an approval, endorsement or guarantee of compliance as it relates to this Offering. The SEC has not reviewed this Form C, nor any document or literature related to this Offering.

Furthermore, neither the Offering nor the securities have been registered under federal or state securities laws. Because the securities have not been registered under the Securities Act or under the securities laws of any state or foreign jurisdiction, the securities are subject to transfer restrictions and cannot be resold in the United States except pursuant to an applicable exemption from registration under the Securities Act and any applicable state securities laws. 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 Company. 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.

***There is no public market for our stock. You cannot be certain that an active trading market or a specific share price will be established, and you may not be able to resell your securities at or above the purchase price.***

There is currently no public market for our stock. We may apply for the listing of our common stock on a national securities exchange (i.e., NYSE or NASDAQ) or for the quotation of our common stock on the OTC markets maintained by OTC Markets Group Inc. However, an active trading market may not develop even if we are successful in arranging for our common stock to be listed or quoted. We also cannot assure you that the market price of our common stock will not fluctuate or decline significantly, including a decline below the offering price, in the future.

***If a market for our common stock develops, the market price of our common stock may fluctuate, and you could lose all or part of your investment.***

If our common stock is listed on a national securities exchange or quotation system, our financial performance, our industry's overall performance, changing consumer preferences, technologies and government regulatory action, tax laws and market conditions in general could have a significant impact on the future market price of our common stock. Some of the other factors that could negatively affect our share price or result in fluctuations in our share price include:

- actual or anticipated variations in our periodic operating results;
- increases in market interest rates that lead purchasers of our common stock to demand a higher yield;

- changes in earnings estimates;
- changes in market valuations of similar companies;
- actions or announcements by our competitors;
- adverse market reaction to any increased indebtedness we may incur in the future;
- additions or departures of key personnel;
- actions by stockholders; and
- speculation in the press or investment community.

***Our management has broad discretion in how we use the net proceeds of the Offering.***

Our management will have considerable discretion over the use of proceeds from the Offering. You may not have the opportunity, as part of your investment decision, to assess whether the proceeds are being used appropriately.

***We have the right to limit individual investor commitment amounts based on our determination of an investor's sophistication.***

We may prevent any investor from committing more than a certain amount in this Offering based on our determination of the investor's sophistication and ability to assume the risk of the investment. This means that your desired investment amount may be limited or lowered based solely on our determination and not in line with relevant investment limits set forth by the Regulation CF rules. This also means that other investors may receive larger allocations of the Offering based solely on our determination.

***We have the right to extend the Offering Deadline.***

We may extend the Offering Deadline beyond what is currently stated herein. This means that your investment may continue to be held in escrow while we attempt to raise the Target Amount even after the Offering Deadline stated herein is reached. While you have the right to cancel your investment in the event we extend the Offering Deadline, if you choose to reconfirm your investment, your investment will not be accruing interest during this time and will simply be held until such time as the new Offering Deadline is reached without the Company receiving the Target Amount, at which time it will be returned to you without interest or deduction, or the Company receives the Target Amount, at which time it will be released to the Company to be used as set forth herein. Upon or shortly after the release of such funds to us, the securities will be issued and distributed to you.

***We may also end the Offering early.***

If the Target Offering Amount is met after 21 calendar days, but before the Offering Deadline, we can end the Offering by providing notice to investors at least 5 business days prior to the end of the Offering. This means your failure to participate in the Offering in a timely manner, may

prevent you from being able to invest in this Offering, and it also means we may limit the amount of capital we can raise during the Offering by ending the Offering early.

***We have the right to conduct multiple closings during the Offering.***

If we meet certain terms and conditions, an intermediate closing of the Offering can occur, which will allow us to draw down on half of the proceeds committed and captured in the Offering during the relevant period. We may choose to continue the Offering thereafter. Investors should be mindful that this means they can make multiple investment commitments in the Offering, which may be subject to different cancellation rights. For example, if an intermediate closing occurs and later a material change occurs as the Offering continues, investors whose investment commitments were previously closed upon will not have the right to re-confirm their investment as it will be deemed to have been completed prior to the material change.

***The Notes have no voting rights.***

The Notes offered hereby have no voting rights. This means that you are trusting in management's discretion. You will also hold these non-voting securities as a minority holder. Therefore, you will have no say in the day-to-day operation of the Company and must trust management to make good business decisions that grow your investment. Holders of our preferred stock have liquidation preferences over holders of our common stock. If a liquidation event were to occur after your Note converts, then first all creditors and preferred stockholders will be paid out. If there is any cash remaining, then the common stockholders will be paid. However, if the Company were to liquidate prior to conversion, you would be treated as a creditor and paid out in cash pro-rata with other creditors before any stockholders.

***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.

***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.

***Future issuances of our common stock or securities convertible into, or exercisable or exchangeable for, our 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, could cause the market price of our common stock to decline. We cannot predict the effect, if any, of future issuances of our securities 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 could adversely affect the market price of 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.

***Anti-takeover provisions in our charter documents and under Delaware law could make an acquisition of the 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 the 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 the Company by means of a proxy contest, 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 20,000,000 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 the 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 the Company.

Moreover, Section 203 of the General Corporation Law of the State of Delaware may discourage, delay or prevent a change in control of the 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.

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.

***We are subject to ongoing public reporting requirements that are less rigorous than rules for more mature public companies, and our stockholders receive less information.***

We are required to publicly report on an ongoing basis under the reporting rules set forth in Regulation A for Tier 2 issuers. The ongoing reporting requirements under Regulation A are more relaxed than for public companies reporting under the Exchange Act. The differences include, but are not limited to, being required to file only annual and semiannual reports, rather than annual and quarterly reports. Annual reports are due within 120 calendar days after the end of the issuer's fiscal year, and semiannual reports are due within 90 calendar days after the end of the first six months of the issuer's fiscal year.

We may elect to become a public reporting company under the Exchange Act. If we elect to do so, we will be required to publicly report on an ongoing basis as an emerging growth company, as defined in Jumpstart Our Business Startups Act (the “JOBS Act”) under the reporting rules set forth under the Exchange Act. For so long as we remain an emerging growth company, we may take advantage of certain exemptions from various reporting requirements that are applicable to other Exchange Act reporting companies that are not emerging growth companies, including but not limited to:

- not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act;
- being permitted to comply with reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements; and
- being exempt from the requirement to hold a non-binding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved.

In addition, Section 107 of the JOBS Act also provides that an emerging growth company can take advantage of the extended transition period provided in Section 7(a)(2)(B) of the Securities Act for complying with new or revised accounting standards. In other words, an emerging growth company can delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We have elected to take advantage of the benefits of this extended transition period. Our financial statements may therefore not be comparable to those of companies that comply with such new or revised accounting standards.

We expect to take advantage of these reporting exemptions until we are no longer an emerging growth company. We will remain an emerging growth company until the earliest of (i) the last day of the fiscal year following the fifth anniversary of an initial public offering, (ii) the last day of the first fiscal year in which our total annual gross revenues are \$1.235 billion or more, (iii) the date that we become a “large accelerated filer” as defined in Rule 12b-2 under the Exchange Act, which would occur if the market value of our common stock that is held by non-affiliates exceeds \$700 million as of the last business day of our most recently completed second fiscal quarter or (iv) the date on which we have issued more than \$1 billion in non-convertible debt during the preceding three year period.

If we decide to apply for the quotation of our common stock on the OTC market, we will be subject to the OTC Market’s Reporting Standards, which can be satisfied in a number of ways, including by remaining in compliance with (i) SEC reporting requirements, if we elect to become a public reporting company under the Exchange Act, or (ii) Regulation A reporting requirements, if we elect not to become a reporting company under the Exchange Act.

In either case, we will be subject to ongoing public reporting requirements that are less rigorous than Exchange Act rules for companies that are not emerging growth companies, and our stockholders could receive less information than they might expect to receive from more mature public companies.

**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

<b>Minimum Amount of the Securities Offered</b>	\$10,000
<b>Total Amount of the Securities Outstanding After Offering (if Target Offering Amount Met)</b>	N/A
<b>Maximum Amount of the Securities Offered</b>	\$350,000
<b>Total Amount of the Securities Outstanding after Offering (if Maximum Offering Amount is Met)</b>	N/A
<b>Price Per Security</b>	N/A
<b>Minimum Individual Purchase Amount</b>	\$500
<b>Offering Deadline</b>	November 30, 2025
<b>Use of Proceeds</b>	See Question 8
<b>Voting Power</b>	See Question 13

\*The Company reserves the right to amend the Minimum Individual Purchase Amount, in its sole discretion. In particular, the Company may elect to participate in one of the Intermediary's special investment programs and may offer alternative Minimum Individual Purchase Amounts to Investors participating in such programs without notice.

This Company is offering securities under Regulation CF through PicMii. PicMii is a FINRA/SEC registered funding portal and will receive cash compensation equal to 4.9% of the value of the securities sold through Regulation CF. Investments made under Regulation CF involve a high degree of risk and those investors who cannot afford to lose their entire investment should not invest.

The Company plans to raise between \$10,000 and \$350,000 through an offering under Regulation CF. Specifically, if we reach the Minimum Raise Amount of \$10,000, we may conduct the first of multiple or rolling closings of the Offering early if we provide 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). Oversubscriptions will be allocated on a first-come, first-served basis. Changes to the Offering, material or otherwise, occurring after a closing, will only impact investments which have not yet to be closed.

In the event the Company fails to reach the Minimum Raise Amount of \$10,000, any investments made under the Offering will be cancelled and the investment funds will be returned to the investor.

### **7. What is the purpose of this Offering?**

If the maximum offering amount is raised, our anticipated use of proceeds is as follows in Question 8.



## 8. How does the Company intend to use the proceeds of this Offering?

	% of Capital if Target Offering Amount Raised	Amount if Target Offering Amount Raised	% of Capital if Maximum Offering Amount Raised	Amount if Maximum Offering Amount Raised
<b>PicMii Portal Fee</b>	4.90%	\$490	4.9%	\$17,150.00
<b>Sales &amp; Marketing</b>	95.10%	\$9,510	45.10%	\$157,850.00
<b>Research &amp; Development</b>	0.00%	\$0	30.00%	\$105,000.00
<b>Operational and Administrative Staffing</b>	0.00%	\$0	20.00%	\$70,000.00
<b>Total</b>	100%	\$10,000	100%	\$350,000

\*We reserve the right to change the above use of proceeds if management believes it is in the best interest of the Company.

## 9. How will the Company complete the transaction and deliver securities to the investors?

Upon each closing, the Company will issue the Notes and will maintain the investment records. Upon conversion of the Notes, the shares will be issued by VStock Transfer LLC, the Company's transfer agent.

## 10. How can an investor cancel an investment commitment?

You may cancel an investment commitment for any reason until 48 hours prior to the deadline identified in the Offering. PicMii will notify investors when the Target Offering Amount has been met. If the Company 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). PicMii Crowdfunding will notify investors when the Target Offering Amount has been met. 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 Company 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.

## 11. Can the Company perform multiple closings or rolling closings for the Offering?

If we reach the Target Offering Amount prior to the Offering Deadline, we may conduct the first of multiple closings of the Offering early, if we provide notice about the new offering deadline at least five business days prior (absent a material change that would require an extension of the offering and reconfirmation of the investment commitment). Thereafter, we may conduct additional closings until the Offering Deadline. We will issue securities in connection with each

closing. Oversubscriptions will be allocated on a first come, first served basis. Changes to the Offering, material or otherwise, occurring after a closing, will only impact investments which have yet to be closed.

# Ownership and Capital Structure

## The Offering

### 12. Describe the terms of the securities being offered.

*The Company is offering securities in the form of convertible notes. A convertible note is a debt instrument used by emerging growth companies and startups that converts into equity during a future funding round or upon a merger, acquisition, or public listing, typically offering investors a discount and/or valuation cap to determine their share allocation. Below are the terms of the Notes.*

**Type of Security:** Convertible Promissory Notes

**Minimum Raise Amount:** \$10,000

**Maximum Raise Amount:** \$350,000

**Maturity Date:** 24 months from the Loan Date

**Discount:** 20%

**Interest Rate:** 15.0%

**Repayment.** Unless otherwise converted, all unpaid principal, together with all unpaid and accrued interest, shall be due and payable within ten (10) days after the Maturity Date.

**Interest Rate.** Interest shall accrue on the outstanding principal amount of the Notes from the Loan Date until payment in full, which interest shall be payable at the rate of fifteen percent (15%) per annum or the maximum rate permissible by Maryland law, whichever is less. Such interest shall be calculated based on a 365-day year for the actual number of days elapsed.

**Maturity Date.** Unless the Notes have been pre-paid or previously converted, the entire outstanding principal balance and all unpaid accrued interest shall be repaid within ninety (90) days of written demand from the holder; provided, however, that such written demand may not occur prior to the Maturity Date, which is twenty-four (24) months from Loan Date.

**Prepayment.** The obligations under the Notes may not be pre-paid by Company without the prior written consent of the Majority Holders.

**Application of Payments.** Any payments shall be applied first to accrued interest, and thereafter to the outstanding principal balance.

### **Conversion.**

**(a) Automatic Conversion Upon Stock Exchange Listing.** If, prior to repayment or conversion of the Notes, the Company's (or a successor to the Company's) shares are listed on a national securities exchange, including, without limitation, through a firm underwritten initial public offering, merger, reverse merger, or direct-listing (the "Public Company Stock"), all of the principal and accrued interest then outstanding under the Notes shall be automatically

converted, without any action by the holders, into a number of shares of Public Company Stock equal to the number that results from the following equation: dividing (i) all of the principal and accrued interest then outstanding under the Notes by (ii) a conversion price equal to (A) eighty percent (80%) of the price per share of the Public Company Stock sold to the public by the underwriters at the closing of the initial public offering, or (B) in the event of a merger, reverse merger, or direct-listing, the volume weighted average price of the Public Company Stock during the five (5) trading days following such merger, reverse merger, or direct-listing.

**(b) Conversion Upon Qualified Financing.** If, prior to repayment or conversion of the Notes, the Company consummates a financing transaction whereby any equity or equity-linked securities of the Company are sold to investors in exchange for cash in which the Company receives gross proceeds of at least four million dollars (\$4,000,000) (including the conversion of the Notes) (a “Qualified Financing”), then effective upon the closing of the Qualified Financing, all of the principal and accrued interest then outstanding under the Notes shall be automatically converted, without any action by the holders, into a number of shares or units, as applicable, that were sold in such Qualified Financing at a conversion price equal to eighty percent (80%) of the price per share or unit, as applicable, sold in such Qualified Financing.

**(c) Optional Conversion at non-Qualified Financing.** If, prior to repayment or conversion of the Notes, the Company consummates a financing transaction whereby any equity or equity-linked securities of the Company are sold to investors in exchange for cash in a transaction that does not constitute a Qualified Financing, then the Majority Holders shall have the option to treat such equity financing as a Qualified Financing on the same terms set forth herein.

The Minimum Individual Purchase Amount accepted under this Offering is \$500.00. The Company must reach its Target Offering Amount of \$10,000.00 by November 30, 2025, the Offering Deadline. Unless the Company raises at least the Target Offering Amount of \$10,000.00 by the Offering Deadline, no securities will be sold in this Offering, investment commitments will be cancelled, and committed funds will be returned.

### **13. Do the securities offered have voting rights? Voting Rights and Proxy:**

The securities being offered are convertible notes, which do not carry voting rights. Upon conversion into equity under the terms of the Notes, the resulting shares may have voting rights as determined by the Company’s governing documents and the terms of the conversion at that time.

### **14. Are there any limitations on any voting or other rights identified above?**

See Question 13.

### **15. How may the terms of the securities being offered be modified?**

We may choose to modify the terms of the securities before the Offering is completed. However, if the terms are modified, and we deem it to be a material change, we need to contact you and

you will be given the opportunity to reconfirm your investment. Your reconfirmation must be completed within five business days of receipt of the notice of a material change, and if you do not reconfirm, your investment will be cancelled and your money will be returned to you.

## **Restrictions on Transfer of the Securities Offered**

### *Issuer Specific Transfer Restrictions:*

A holder may not transfer a Note to a third party without the prior written consent of the Company, except with respect to estate planning transfers. In addition, the securities issuable upon conversion of the Notes have not been registered under the Securities Act or any state securities laws. As a result, they may not be offered, sold, pledged, or otherwise transferred except pursuant to an effective registration statement or an exemption from the registration requirements of the Securities Act and applicable state securities laws. Any proposed transfer of the securities must also comply with the terms and conditions set forth in the Company's governing documents.

### *Regulation Crowdfunding Transfer Restrictions:*

The securities being offered may not be transferred by any purchaser of such securities during the one-year period beginning when the securities were issued, unless such securities are transferred:

- to the issuer;
- to an accredited investor;
- as part of an offering registered with the U.S. Securities and Exchange Commission; or 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.
- 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. The term "member of the family of the purchaser or the equivalent" includes a child, stepchild, grandchild, parent, stepparent, grandparent, spouse or spousal equivalent, sibling, mother-in-law, father-in-law, son-in-law, daughter-in-law, brother-in-law, or sister-in-law of the purchaser, and includes adoptive relationships. The term "spousal equivalent" means a cohabitant occupying a relationship generally equivalent to that of a spouse.

## Description of Company's Securities

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

Class of Security	Amount Authorized	Amount Outstanding	Reserved Options	Convertible Note/SAFEs	Voting Rights
<b>Common Stock</b>	50,000,000	4,917,249 <sup>(1)</sup>	2,979,860	(2)(3)	Yes
<b>Series A Preferred Stock</b>	1,303,000	846,368	N/A	N/A	Yes
<b>Series A-1 Preferred Stock</b>	978,000	651,465	N/A	N/A	Yes
<b>Series A-2 Preferred Stock</b>	800,000	442,402	N/A	N/A	Yes
<b>Series B Preferred Stock</b>	3,569,405	1,471,487	N/A	N/A	Yes
<b>Series C Preferred Stock</b>	3,340,909	1,204,040	N/A	N/A	Yes
<b>Series D Preferred Stock</b>	936,329	101,565	N/A	N/A	Yes

- (1) The Company also has 619,332 shares of common stock available for issuance under its 2022 Stock Incentive Plan and has warrants outstanding for the purchase of 15,096 shares of common stock.
- (2) The Company previously issued convertible promissory notes in the principal amount of \$70,000. These notes are convertible into common stock as follows:
  - a. If the Company's common stock is listed on a national securities exchange, then the unpaid principal and interest shall automatically convert into shares of common stock at conversion price equal to 80% of the per share price of the common stock sold by the underwriters of the initial public offering; provided that in no event shall the number of shares issuable upon such conversion be less than the number of shares issuable pursuant to a conversion pursuant to (b) below (i.e., based upon the lower conversion price).
  - b. In the event that the Company consummates a financing transaction in which it sells equity or equity-linked securities to investors for cash resulting in gross proceeds of at least \$10 million, then the unpaid principal and interest shall automatically convert into shares of common stock at conversion price equal to 80% of the per share price paid by

the investors in such financing; provided that the conversion price shall not exceed the quotient of \$70,000,000 divided by the aggregate number of outstanding shares of common stock on a fully-diluted basis (assuming full conversion or exercise of all convertible and exercisable securities then outstanding other than these notes).

- c. In the event that the Company consummates an equity financing pursuant to which it sells shares of equity or equity-linked securities in a transaction that does not meet the requirements in (b) above, then the holders of at least a majority in principal amount of the notes then outstanding shall have the option to treat such equity financing as a financing that does meet such requirements.
- (3) The Company also previously issued convertible promissory notes in the principal amount of \$493,000. These notes are convertible into common stock as follows:
- a. If the Company's (or a successor to the Company's) shares are listed on a national securities exchange, including, without limitation, through a firm underwritten initial public offering, merger, reverse merger, or direct listing, all of the principal and accrued interest then outstanding under the notes shall be automatically converted, without any action by the holders, into a number of shares equal to the number that results from the following equation: dividing (i) all of the principal and accrued interest then outstanding under the notes by (ii) a conversion price equal to (A) eighty percent (80%) of the price per share sold to the public by the underwriters at the closing of the initial public offering, or (B) in the event of a merger, reverse merger, or direct listing, the volume weighted average price of our common stock during the five (5) trading days following such merger, reverse merger, or direct listing.
  - b. If we consummate a financing transaction whereby any equity or equity-linked securities are sold to investors in exchange for cash in which we receive gross proceeds of at least four million dollars (\$4,000,000) (including the conversion of the notes), then effective upon the closing of such financing, all of the principal and accrued interest then outstanding under the notes shall be automatically converted, without any action by the holders, into a number of shares or units, as applicable, that were sold in such financing at a conversion price equal to eighty percent (80%) of the price per share or unit, as applicable, sold in such financing.
  - c. If we consummate a financing transaction whereby any equity or equity-linked securities are sold to investors in exchange for cash in a transaction that does not meet the requirements in (b) above, then the holders of a majority of the then outstanding principal amount of the notes shall have the option to treat such equity financing as a financing that does meet such requirements.

## Options, Warrants and Other Rights

### **17. How may the rights of the securities being offered be materially limited, diluted or qualified by the rights of any other class of securities?**

Investors should understand the potential for dilution. The investor's stake in a company could be diluted due to the company issuing additional shares. In other words, when the company issues more shares, the percentage of the company that you own will go down, even though the value of the company may go up. You will own a smaller piece of a larger company. This increase in number of shares outstanding could result from a stock offering (such as an initial public offering, another crowdfunding round, a venture capital round, angel investment), employees exercising stock options, or by conversion of certain instruments (e.g., convertible bonds, preferred shares or warrants) into stock. If the Company decides to issue more shares, an investor could experience value dilution, with each share being worth less than before, and control dilution, with the total percentage an investor owns being less than before. There may also be earnings dilution, with a reduction in the amount earned per share (though this typically occurs only if the company offers dividends, and most early-stage companies are unlikely to offer dividends, preferring to invest any earnings into the company).

### **18. Are there any differences not reflected above between the securities being offered and each other class of security of the Company?**

As noted above, the Company has issued multiple series of preferred stock, which have the rights described below.

The following is a summary of the terms of the series A preferred stock, series A-1 preferred stock, series A-2 preferred stock, series B preferred stock and series C preferred stock (collectively, the “Designated Preferred Stock”):

**Ranking.** With respect to dividend rights and rights on liquidation, winding up and dissolution, shares of Designated Preferred Stock rank *pari passu* to each other and senior to all shares of common stock.

**Voting Rights.** Shares of Designated Preferred Stock vote together with the holders of common stock on an as-converted basis on all matters for which the holders of common stock vote at an annual or special meeting of stockholders or act by written consent, except as required by law. For so long as shares of Designated Preferred Stock are outstanding, the holders of such shares vote together, as a separate class, to elect one director to the Company’s board, and for so long as shares of series A-1 preferred stock are outstanding, the holders of series A-1 preferred stock vote together, as a separate class, to elect one director to the Company’s board.

**Conversion Rights.** Each share of Designated Preferred Stock is convertible at any time at the option of the holder at the then current conversion rate. The conversion rate for the Designated Preferred Stock is currently one share of common stock for each share of Designated Preferred Stock, calculated by dividing the liquidation preference of such share by the conversion price then in effect. In addition, all outstanding shares of Designated Preferred Stock, plus accrued but



unpaid dividends thereon, shall automatically be converted into shares of common stock, at the then effective conversion rate, upon the earlier to occur of (a) the closing of the sale of shares of common stock to the public at a price of at least \$8.15 per share (subject to appropriate adjustment in the event of any stock dividend, stock split, combination or other similar recapitalization with respect to the common stock), in a public offering pursuant to an effective registration statement or offering statement under the Securities Act resulting in at least \$5,000,000 of gross proceeds to the Company, (b) the date on which the shares of common stock are listed on a national stock exchange, including without limitation the New York Stock Exchange or the Nasdaq Stock Market, or (c) the date and time, or the occurrence of an event, specified by vote or written consent of the holders of at least 67% of the then outstanding shares of Designated Preferred Stock, voting together on an as-converted to common stock basis (which vote or consent shall include the holders of at least 67% of the shares of series A-1 preferred stock outstanding voting as a separate class).

*Liquidation Rights.* In the event of any voluntary or involuntary liquidation, dissolution or winding up of the Company or a deemed liquidation event, each holder of Designated Preferred Stock then outstanding shall be entitled to be paid out of the cash and other assets of the Company available for distribution to its stockholders, prior and in preference to all shares of common stock, an amount in cash equal to the aggregate liquidation preference of all shares held by such holder. The shares of series A preferred stock, series A-1 preferred stock, series A-2 preferred stock, series B preferred stock and series C preferred stock have a liquidation preference of \$3.07, \$3.07, \$3.26, \$3.53 and \$4.40, respectively (subject to appropriate adjustment in the event of any stock dividend, stock split, combination or other similar recapitalization) plus any accrued and unpaid dividends. If upon any liquidation or deemed liquidation event the remaining assets available for distribution are insufficient to pay the holders of Designated Preferred Stock the full preferential amount to which they are entitled, the holders of Designated Preferred Stock shall share ratably in any distribution of the remaining assets and funds in proportion to the respective full preferential amounts which would otherwise be payable, and the Company shall not make or agree to make any payments to the holders of common stock. A “deemed liquidation event” means, unless otherwise determined by the holders of at least a majority of the Designated Preferred Stock then outstanding (voting together as a single class on an as-converted basis), (a) a sale of all or substantially all of the Company’s assets to a non-affiliate of the Company, (b) a merger, acquisition, change of control, consolidation or other transactions or series of transactions in which stockholders prior to such transaction or series of transactions do not retain a majority of the voting power of the surviving entity immediately following such transaction or series of transactions, or (c) the grant of an exclusive license to all or substantially all of the Company’s technology or intellectual property rights except where such exclusive license is made to one or more wholly-owned subsidiaries of the Company.

*Dividends.* The Designated Preferred Stock will not be entitled to dividends or distributions unless and until the board declares a dividend or distribution in cash or other property to holders of outstanding shares of common stock, in which event, the aggregate amount of such each distribution shall be distributed as follows: (a) first, seventy percent (70%) of the distribution amount to the holders of shares of Designated Preferred Stock, on a pro rata basis, until such time as such holders have received an aggregate amount in distributions or other payments in respect of such holder’s shares that is equal to the number of shares owned by such holders

multiplied by the liquidation preference stated above, and (b) second, thirty percent (30%) of the distribution amount to the holders of shares of common stock, on a pro rata basis.

Notwithstanding the foregoing, at such time as the holders of Designated Preferred Stock and common stock have received the amounts described above, the holders of the Designated Preferred Stock shall receive Distributions *pari passu* with the holders of the common stock on an as-converted basis, using the then-current conversion rate of such shares of Designated Preferred Stock.

*Preemptive Rights.* Until the Company's initial public offering of common stock occurs and unless otherwise waived by the prior express written consent of the holders of the majority of the voting power of all then outstanding Designated Preferred Stock, voting together on an as-converted to common stock basis, in the event that the Company proposes to issue any common stock or shares convertible or exercisable for common stock, except for excluded issuances, the Company must first offer those additional equity securities to holders of Designated Preferred Stock for a period of no less than thirty (30) days prior to selling or issuing any such additional equity securities to any person, in accordance with the procedures set forth in the Company's certificate of incorporation, as amended. For purposes hereof, "excluded securities" means the issuance of shares of common stock or securities convertible into shares of common stock (a) granted pursuant to or issued upon the exercise of stock options granted under an equity incentive plan to employees, officers, directors, consultants or strategic partners, (b) granted to employees, officers, directors, consultants or strategic partners for services, including in connection with an incentive plan, or other fair value received or committed, (c) in consideration for a transaction approved by the board which does not result in the issuance for cash of more than five percent (5%) of the outstanding shares of common stock, (d) in connection with an acquisition transaction approved by the board, (e) to vendors, commercial partners, financial institutions or lessors in connection with commercial credit transactions, equipment financings or similar transaction approved by the board (provided that such securities do not exceed 10% of the consideration in such transaction), (f) pursuant to conversion or exchange rights included in securities previously issued by the Company or (g) in connection with a stock split, stock division, reclassification, stock dividend or other recapitalization.

*Redemption.* Shares of each series of Designated Preferred Stock are not redeemable without the prior express written consent of the holders of the majority of the voting power of all then outstanding shares of such applicable series of Designated Preferred Stock, voting as a separate class.

*Protective Rights.* So long as at least twenty-five percent (25%) of the Designated Preferred Stock collectively remains outstanding, in addition to any other vote or consent of stockholders required by law, the vote or consent of the holders of at least a majority of all shares of Designated Preferred Stock then outstanding and entitled to vote thereon, voting together and on an as-converted to common stock basis, given in person or by proxy, either in writing without a meeting or by vote at any meeting called for the purpose, including the consent of the holders of series A-1 preferred stock, shall be necessary for effecting or validating, either directly or indirectly by amendment, merger, consolidation or otherwise:

(a) the authorization, creation and/or issuance of any equity security, other than shares of common stock or options to purchase common stock issued to investors, employees, managers,

officers or directors of, or consultants or advisors to, the Company or any of its subsidiaries pursuant to a plan, agreement or arrangement approved by the board;

(b) the amendment, alteration or repeal of any provision of the certificate of incorporation or bylaws or otherwise alter or change any right, preference or privilege of any Designated Preferred Stock in a manner adverse to the holders thereof (c) any increase or decrease in the size of the board;

(d) the purchase, redemption, or acquisition of any shares other than from a selling holder pursuant to the provisions of the certificate of incorporation or any other restriction provisions applicable to any shares in agreements approved by the board or in the operating agreement of any limited liability company utilized for the purpose of facilitating investment in the Company;

(e) the liquidation or dissolution of the Company or the sale, lease, pledge, mortgage, or other disposal of all or substantially all of its assets;

(f) any election to engage in any business that deviates in any material respect from the Company's business as contemplated under any operating plan approved by the board;

(g) the waiver of any adjustment to the conversion price applicable to the Designated Preferred Stock; or

(h) any declaration or payment of any cash dividend or other cash distribution to any holders of capital stock.

The following is a summary of the terms of the series D preferred stock:

**Ranking.** With respect to dividend rights and rights on liquidation, winding up and dissolution, shares of series D preferred stock rank *pari passu* to the Designated Preferred Stock and senior to the common stock.

**Voting Rights.** The series D preferred stock shall not have any voting rights or powers of any type, and the consent of the holders thereof shall not be required for the taking of any corporate action, except as otherwise provided by applicable law. Notwithstanding the foregoing, so long as at least twenty-five percent (25%) of the series D preferred stock remains outstanding, in addition to any other vote or consent of stockholders required by law or the Certificate of Designation, the vote or consent of the holders of at least a majority of all shares of the series D preferred stock then outstanding and entitled to vote thereon, given in person or by proxy, either in writing without a meeting or by vote at any meeting called for the purpose, shall be necessary for effecting or validating, either directly or indirectly by amendment, merger, consolidation or otherwise, (i) any amendment, alteration or repeal of any provision of the Certificate of Designation, the Company's Certificate of Incorporation or its Bylaws or otherwise alter or change any right, preference or privilege of the series D preferred stock in a manner adverse to the series D preferred stock, or (ii) the liquidation or dissolution of the Company or the sale, lease, pledge, mortgage, or other disposal of all or substantially all of the Company's assets.

**Conversion Rights.** Each share of series D preferred stock is convertible at any time at the option of the holder at the then current conversion rate. The conversion rate for the series D preferred

stock is currently one share of common stock for each share of series D preferred stock, calculated by dividing the liquidation preference of such share by the conversion price then in effect. In addition, all outstanding shares of series D preferred stock, plus accrued but unpaid dividends thereon, shall automatically be converted into shares of common stock, at the then effective conversion rate, upon the earlier to occur of (a) the closing of the sale of shares of common stock to the public at a price of at least \$8.15 per share (subject to appropriate adjustment in the event of any stock dividend, stock split, combination or other similar recapitalization with respect to the common stock), in a public offering pursuant to an effective registration statement or offering statement under the Securities Act resulting in at least \$5,000,000 of gross proceeds to the Company, (b) the date on which the shares of common stock are listed on a national stock exchange, including without limitation the New York Stock Exchange or the Nasdaq Stock Market, or (c) the date and time, or the occurrence of an event, specified by vote or written consent of the holders of at least 67% of the then outstanding shares of series D preferred stock and Designated Preferred Stock, voting together on an as-converted to common stock basis (which vote or consent shall include the holders of at least 67% of the shares of series A-1 preferred stock outstanding voting as a separate class).

**Liquidation Rights.** In the event of any voluntary or involuntary liquidation, dissolution or winding up of the Company or a deemed liquidation event, each holder of series D preferred stock then outstanding shall be entitled to be paid out of the cash and other assets of the Company available for distribution to its stockholders, prior and in preference to all shares of common stock and *pari passu* with the Designated Preferred Stock, an amount in cash equal to the aggregate liquidation preference of all shares held by such holder. The shares of series D preferred stock have a liquidation preference of \$5.34 (subject to appropriate adjustment in the event of any stock dividend, stock split, combination or other similar recapitalization) plus any accrued and unpaid dividends. If upon any liquidation or deemed liquidation event the remaining assets available for distribution are insufficient to pay the holders of series D preferred stock and Designated Preferred Stock the full preferential amount to which they are entitled, the holders of series D preferred stock and Designated Preferred Stock shall share ratably in any distribution of the remaining assets and funds in proportion to the respective full preferential amounts which would otherwise be payable, and the Company shall not make or agree to make any payments to the holders of common stock. A “deemed liquidation event” means, unless otherwise determined by the holders of at least a majority of the series D preferred stock and Designated Preferred Stock then outstanding (voting together as a single class on an as-converted basis), (a) a sale of all or substantially all of the Company’s assets to a non-affiliate of the Company, (b) a merger, acquisition, change of control, consolidation or other transactions or series of transactions in which stockholders prior to such transaction or series of transactions do not retain a majority of the voting power of the surviving entity immediately following such transaction or series of transactions, or (c) the grant of an exclusive license to all or substantially all of the Company’s technology or intellectual property rights except where such exclusive license is made to one or more wholly-owned subsidiaries of the Company.

**Dividends.** The series D preferred stock will not be entitled to dividends or distributions unless and until the board declares a dividend or distribution in cash or other property to holders of outstanding shares of common stock, in which event, the aggregate amount of such each distribution shall be distributed as follows: (a) first, seventy percent (70%) of the distribution amount to the holders of shares of series D preferred stock and Designated Preferred Stock, on a

pro rata basis, until such time as such holders have received an aggregate amount in distributions or other payments in respect of such holder's shares that is equal to the number of shares owned by such holders multiplied by the liquidation preference stated above, and (b) second, thirty percent (30%) of the distribution amount to the holders of shares of common stock, on a pro rata basis. Notwithstanding the foregoing, at such time as the holders of series D preferred stock, Designated Preferred Stock and common stock have received the amounts described above, the holders of the series D preferred stock shall receive Distributions *pari passu* with the holders of Designated Preferred Stock and the common stock on an as-converted basis, using the then-current conversion rate of such shares of series D preferred stock and Designated Preferred Stock.

**Redemption.** Shares of each series of series D preferred stock are not redeemable without the prior express written consent of the holders of the majority of the voting power of all then outstanding shares of such applicable series of series D preferred stock, voting as a separate class.

**19. How could the exercise of rights held by the principal owners identified in Question 5 above affect the purchasers of securities being offered?**

The holders of a majority of the voting rights in the Company may make decisions with which you disagree, or that negatively affect the value of your investment in the Company, and you will have no recourse to change those decisions. Your interests may conflict with the interests of other investors, and there is no guarantee that the Company will develop in a way that is advantageous to you. For example, the majority stockholders may decide to issue additional shares to new investors, sell convertible debt instruments with beneficial conversion features, or make decisions that affect the tax treatment of the Company in ways that may be unfavorable to you. Based on the risks described above, you may lose all or part of your investment in the securities that you purchase, and you may never see positive returns.

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

The securities being offered are valued at the Company's discretion. An early-stage company typically sells its shares (or grants options over its shares) to its founders and early employees at a very low cash cost, because they are, in effect, putting their "sweat equity" into the company. When the company seeks cash investments from outside investors, like you, the new investors typically pay a much larger sum for their shares than the founders or earlier investors, which means that the cash value of your stake is immediately diluted because each share of the same type is worth the same amount, and you paid more for your shares than earlier investors did for theirs.

There are several ways to value a company, and none of them is perfect and all of them involve a certain degree of guesswork. Any of these methods, plus others, may be used to determine valuation in the future:

**Liquidation Value** - The amount for which the assets of the company can be sold, minus the liabilities owed, e.g., the assets of a bakery include the cake mixers, ingredients, baking tins, etc. The liabilities of a bakery include the cost of rent or mortgage on the bakery. However, this value does not reflect the potential value of a business, e.g., the value of the secret recipe. The value for most startups lies in their potential, as many early-stage companies do not have many assets.

**Book Value** - This is based on analysis of the company's financial statements, usually looking at the company's balance sheet as prepared by its accountants. However, the balance sheet only looks at costs (i.e., what was paid for the asset), and does not consider whether the asset has increased in value over time. In addition, some intangible assets, such as patents, trademarks or trade names, are very valuable but are not usually represented at their market value on the balance sheet.

**Earnings Approach** - This is based on what the investor will pay (the present value) for what the investor expects to obtain in the future (the future return), taking into account inflation, the lost opportunity to participate in other investments, the risk of not receiving the return. However, predictions of the future are uncertain and valuation of future returns is a best guess.

Different methods of valuation produce a different answer as to what your investment is worth. Typically, liquidation value and book value will produce a lower valuation than the earnings approach. However, the earnings approach is also most likely to be risky as it is based on many assumptions about the future, while liquidation value and book value are much more conservative.

Future investors (including people seeking to acquire the company) may value the company differently. They may use a different valuation method, or different assumptions about the company's business and its market. Different valuations may mean that the value assigned to your investment changes. It frequently happens that when a large institutional investor such as a venture capitalist makes an investment in a company, it values the company at a lower price than the initial investors did. If this happens, the value of the investment would go down.

## **21. What are the risks to purchasers of the securities relating to minority ownership in the Company?**

The Company's Certificate of Incorporation can be amended by the holders of a majority of the issued and outstanding shares of the Company. As minority owners, the crowdfunding investors are subject to the decisions made by the majority owners. As a minority owner, you may be outvoted on issues that impact your investment, such as, among other things: (a) the liquidation, dissolution or winding up of the Company, or effecting any merger or consolidation; (b) amendment of any provision of the Certificate of Incorporation; (c) creation and issuance of other securities having rights, preferences or privileges senior to the common stock sold to the crowdfunding investors, or increasing the authorized number of shares of stock of the Company; or (d) creation of any debt security.

**22. What are the risks to purchasers associated with corporate actions including:**

- 1. Additional issuances of securities**
- 2. Company repurchases of securities**
- 3. A sale of the Company or of assets of the Company**
- 4. Transactions with related parties**

The authorization and issuance of additional shares of the Company's common stock will dilute the ownership of the crowdfunding investors. As a result, if the Company achieves profitable operations in the future, its net income per share will be reduced because of dilution, and the market price of the Company's common stock, if there is a market price, could decline as a result of the additional issuances of securities. If the Company repurchases securities, so that the above risk is mitigated, and there are fewer shares of common stock outstanding, the Company may not have enough cash available for marketing expenses, growth, or operating expenses to reach our goals. If we do not have enough cash to operate and grow, we anticipate the market price of our securities would decline. A sale of the Company or of all of the assets of the Company may result in an entire loss of your investment. We cannot predict the market value of the Company or its assets, and the proceeds of a sale may not be cash, but instead, unmarketable securities, or an assumption of liabilities. It is unlikely that in the near term, a sale would result in a premium that is significant enough over book value to generate a return to our investors. We may need to negotiate with a related party for additional capital. No assurance can be given that such funds will be available or, if available, will be on commercially reasonable terms satisfactory to us. Even if such financing is available, it may be on terms that are materially adverse to your interests with respect to dilution of book value, dividend preferences, liquidation preferences, or other terms.

**23. Describe the material terms of any indebtedness of the Company:**

Creditor(s)	Amount Outstanding	Interest Rate	Maturity Date
See Question 27	See Question 27	See Question 27	See Question 27

**24. What other exempt offerings has the Company conducted within the past three years?**

**Type of security sold:** Preferred Stock

**Final amount sold:** \$5,275,485

**Use of proceeds:** General Operations

**Date:** 6/2021

**Offering exemption relied upon:** Regulation A+

**Type of security sold:** Convertible Note

**Final amount sold:** \$220,495

**Use of proceeds:** General Operations

**Date:** 12/2022

**Offering exemption relied upon:** Regulation Crowdfunding

**Type of security sold:** Preferred Stock

**Final amount sold:** \$555,661

**Use of proceeds:** General Operations

**Date:** 2/2025

**Offering exemption relied upon:** Regulation Crowdfunding

**Type of security sold:** Preferred Stock

**Final amount sold:** \$70,000

**Use of proceeds:** General Operations

**Date:** 2/2025

**Offering exemption relied upon:** 506(b)

**Type of security sold:** Convertible Promissory Note

**Final amount sold:** \$544,705

**Use of proceeds:** General Operations

**Date:** 8/2025

**Offering exemption relied upon:** Regulation Crowdfunding

**25. Was or is the Company or any entities controlled by or under common control with the Company a party to any transaction since the beginning of the Company'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 Company in reliance on Section 4(a)(6) of the Securities Act during the preceding 12-month period, including the amount the Company 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 Company;**
- 2. Any person who is, as of the most recent practicable date, the beneficial owner of 20 percent or more of the Company's outstanding voting equity securities, calculated on the basis of voting power;**
- 3. If the Company was incorporated or organized within the past three years, any promoter of the Company; or**
- 4. Any immediate family members of any of the foregoing persons.**

During the year ended December 31, 2024, four board members invested a total amount of \$50,000 in the series D preferred stock offering.

The Company utilizes the services of the brother of the Chief Executive Officer, who is trained as a computer engineer and has over seven years' experience with clinical lab operations, to oversee the Company's laboratory information systems and patient/physician portals. During the years ended December 31, 2024 and 2023, the Company paid \$62,070 and \$101,978, respectively, to this related party.



The Chief Executive Officer founded an organization in January 2021 to create an alliance of clinical labs, entrepreneurs, scientists, healthcare providers, and concerned citizens who oppose Congressional legislation to require FDA pre-approval for new laboratory tests, known as the VALID Act. The Company contributed \$40,650 and \$31,050 in 2024 and 2023 to this organization, respectively.

# Financial Condition of the Company

## 26. Does the Company have an operating history?

Yes.

## 27. Describe the financial condition of the Company, including, to the extent material, liquidity, capital resources and historical results of operations.

### *Overview*

We develop and commercialize AI-powered, laboratory-based blood tests for the early detection and prevention of cancers and chronic diseases.

We offer two families of lab tests, both under our OneTest brand: (i) OneTest for Cancer, a MCED blood test which has been our primary commercial focus and source of revenues since we wound down our COVID-19 testing business, and (ii) OneTest for Longevity, which measures inflammatory biomarkers, that we expect to launch in the first half of 2025. Both tests are run in our CAP accredited, CLIA licensed laboratory in Gaithersburg, MD. That laboratory also hosts our CLIAx, which we believe is the country's first shared CLIA laboratory for overseas diagnostics start-ups seeking to launch novel lab tests in the U.S. without the expense of establishing and operating their own, independent lab.

As noted above, during the COVID-19 pandemic, we also provided COVID-19 viral testing using PCR analytical equipment in our clinical laboratory. Our legacy business also includes a pioneering field test kit for screening suspicious powders for bioterror agents known as BioCheck.

### *Recent Developments*

#### *Private Placement of Convertible Notes*

In January 2025, we commenced a private placement of convertible promissory notes. To date, we have issued notes in the aggregate principal amount of \$70,000 for gross proceeds of \$70,000. The notes bear interest at a rate of five percent (5%) per annum and are due and payable within thirty (30) days of written demand from the holder; provided that such written demand may not occur prior to the date that is thirty-six (36) months from the date of issuance. The notes are unsecured and contain customary events of default. The notes are convertible into our common stock as follows:

- If our common stock is listed on a national stock exchange, including, without limitation, through a firm underwritten initial public offering, all of the principal and accrued interest then outstanding under the notes shall be automatically converted, without any action by the holder, into shares of common stock at a conversion price equal to eighty percent (80%) of the price per share sold to the public by the underwriters at the closing of the initial public offering; provided, however, that in no event shall the number of shares be less than the number of shares issuable pursuant to a conversion upon a

Qualified Financing (as defined below).

- If we consummate a financing transaction whereby any equity or equity-linked securities are sold to investors in exchange for cash for gross proceeds of at least ten million dollars (\$10,000,000) (which we refer to as a Qualified Financing), then effective upon the closing of the Qualified Financing, all of the principal and accrued interest then outstanding under the notes shall be automatically converted, without any action by the holder, into a number of shares or units, as applicable, that were sold in such Qualified Financing at a conversion price equal to eighty percent (80%) of the price per share or unit, as applicable, sold in such Qualified Financing; provided, however, that the conversion price per share or unit, as applicable, shall not exceed the quotient obtained by dividing \$70,000,000 by the total number shares of common stock outstanding on a fully diluted basis (assuming conversion of all securities convertible into common stock and exercise of all outstanding options and warrants, but excluding the shares of equity securities issuable upon the conversion of the notes or other convertible securities issued for capital raising purposes (e.g., Simple Agreements for Future Equity)).
- If we consummate an equity financing pursuant to which we sell shares of equity or equity-linked securities in a transaction that does not constitute a Qualified Financing, then the holders of at least a majority in principal amount of the notes then outstanding shall have the option to treat such equity financing as a Qualified Financing.

#### Crowdfunding Offering of Convertible Notes

In May 2025, we launched an equity crowdfunding offering under Section 4(a)(6) of the Securities Act and Regulation Crowdfunding promulgated thereunder, pursuant to which we offered convertible promissory notes. The initial closing of this offering was completed in July 2025 and the offering terminated on August 14, 2025. We issued notes in the aggregate principal amount of \$493,000 for gross proceeds of \$493,000 and net proceeds of approximately \$438,000. The notes bear interest at a rate of fifteen percent (15%) per annum and are due and payable within ninety (90) days of written demand from the holder; provided that such written demand may not occur prior to the date that is twenty-four (24) months from the date of issuance. The notes may not be pre-paid by us without the prior written consent of the holders of a majority of the then outstanding principal amount of the notes. The notes are unsecured and contain customary events of default. The notes are convertible into common stock as follows:

- If the Company's (or a successor to the Company's) shares are listed on a national securities exchange, including, without limitation, through a firm underwritten initial public offering, merger, reverse merger, or direct listing, all of the principal and accrued interest then outstanding under the notes shall be automatically converted, without any action by the holders, into a number of shares equal to the number that results from the following equation: dividing (i) all of the principal and accrued interest then outstanding under the notes by (ii) a conversion price equal to (A) eighty percent (80%) of the price per share sold to the public by the underwriters at the closing of the initial public offering, or (B) in the event of a merger, reverse merger, or direct listing, the volume weighted average price of our common stock during the five (5) trading days following such merger, reverse merger, or direct listing.

- If we consummate a financing transaction whereby any equity or equity-linked securities are sold to investors in exchange for cash in which we receive gross proceeds of at least four million dollars (\$4,000,000) (including the conversion of the notes) (which is referred to as a Qualified Financing), then effective upon the closing of the Qualified Financing, all of the principal and accrued interest then outstanding under the notes shall be automatically converted, without any action by the holders, into a number of shares or units, as applicable, that were sold in such Qualified Financing at a conversion price equal to eighty percent (80%) of the price per share or unit, as applicable, sold in such Qualified Financing.
- If we consummate a financing transaction whereby any equity or equity-linked securities are sold to investors in exchange for cash in a transaction that does not constitute a Qualified Financing, then the holders of a majority of the then outstanding principal amount of the notes shall have the option to treat such equity financing as a Qualified Financing.

### ***Principal Factors Affecting Our Financial Performance***

Our operating results are primarily affected by the following factors:

- our ability to access additional capital and the size and timing of subsequent financings;
- the costs of acquiring additional data, technology, and/or intellectual property to successfully reach our goals and to remain competitive;
- personnel and facilities costs in any region in which we seek to introduce and market our products;
- the costs of sales, marketing, and customer acquisition;
- the average price per test paid by consumers;
- the number of tests ordered per quarter;
- the costs of third-party laboratories to run our tests;
- the costs of compliance with any unforeseen regulatory obstacles or governmental mandates in any states or countries in which we seek to operate; and
- the costs of any additional clinical studies which are deemed necessary for us to remain viable and competitive in any region of the world.

### ***Results of Operations***

The following table sets forth key components of our results of operations during the years ended December 31, 2024 and 2023, both in dollars and as a percentage of our revenues.

	December 31, 2024		December 31, 2023	
	Amount	% of Revenues	Amount	% of Revenues
Revenues	\$ 1,752,343	100.00%	\$ 1,424,304	100.00%
Cost of revenues	1,373,432	78.38%	1,315,166	92.34%
Gross profit	378,911	21.62%	109,138	7.66%
Operating expenses:				
Sales, general and administrative	4,454,787	254.22%	5,061,450	355.36%
Research and development	1,160,181	66.21%	1,409,150	98.94%
Loss on impairment of fixed assets	16,356	0.93%	209,073	14.68%
Total operating expenses	5,631,324	321.36%	6,679,673	468.98%
Operating loss	(5,252,413)	(299.74)%	(6,570,535)	(461.32)%
Other income (expense):				
Interest expense	(12,646)	(0.72)%	(27,915)	(1.96)%
Interest income	79,467	4.53%	209,150	14.68%
Other income (expense)	58,925	3.36%	(2,009)	(0.14)%
Total other (income) expense	125,746	7.17%	179,226	12.58%
Net loss	<u>\$ (5,126,667)</u>	<u>(292.56)%</u>	<u>\$ (6,391,309)</u>	<u>(448.74)%</u>

**Revenues.** We generated revenues from sales of OneTest, BioCheck and from the CLIAx during the year ended December 31, 2024, and also generated revenues from COVID-19 tests in the year ended December 31, 2023. Our total revenues increased by \$328,039, or 23.03%, to \$1,752,343 for year ended December 31, 2024 from \$1,424,304 for the year ended December 31, 2023. Such an increase was due to a significant increase in revenues from sales of OneTest and an increase in revenues from the CLIAx, offset by decreased revenues from BioCheck and COVID-19 testing. The following table summarizes our revenues by product:

	December 31, 2024		December 31, 2023	
	Amount	% of Revenues	Amount	% of Revenues
COVID-19 PCR Tests	\$ -	-	\$ 250,145	17.56%
COVID-19 Antibody/Antigen Tests	-	-	2,375	0.17%
OneTest	1,490,881	85.08%	921,502	64.70%
BioCheck	177,283	10.12%	187,926	13.19%
CLIAx	84,179	4.80%	62,356	4.38%
Total revenues	<u>\$ 1,752,343</u>		<u>\$ 1,424,304</u>	

Revenues from COVID-19 tests were derived from two classes of tests: (i) rapid point-of-care tests (antibody and antigen) that were distributed after validating and (ii) lab-based PCR testing of nasal swabs sent to our CLIA lab from area nursing homes, numerous county school systems in the State of Maryland and the Montgomery County Health Department. We did not generate any revenues from COVID-19 testing for the year ended December 31, 2024, as compared to revenues of \$252,520 for the year ended December 31, 2023. We do not anticipate additional COVID-19 testing absent a new variant resulting in a significant increase in cases.

Revenues from sales of OneTest increased by \$569,379, or 61.79%, to \$1,490,881 for the year ended December 31, 2024 from \$921,502 for the year ended December 31, 2023. The launch of OneTest Premium in October 2023 contributed to the increase in revenue as the OneTest Premium pricing is approximately 73% higher than OneTest Standard and approximately 30% of total revenues were derived from OneTest Premium in 2024. We also added additional sales

personnel to drive sales growth for commercial businesses, primarily fire departments, and on-line advertising was directed to OneTest for direct-to-consumer sales over the last year.

Revenues from sales of BioCheck decreased by \$10,643, or 5.66%, to \$177,283 for the year ended December 31, 2024 from \$187,926 for the year ended December 31, 2023. The BioCheck product is no longer under patent protection and as such, sales are generated mainly by existing customers. There are no dedicated sales personnel or marketing dollars directed to the generation of BioCheck sales.

Revenues from our CLIAx increased by \$21,823, or 35.00%, to \$84,179 for the year ended December 31, 2024 from \$62,356 for the year ended December 31, 2023. Such an increase was the result of increased lab services to process the increase in sales by the CLIAx customer of their specific test in the U.S. The agreement with the CLIAx customer includes future revenue sharing and co-marketing of their test into the U.S. market if we are involved in the selling of these tests. We are not currently selling their product.

*Cost of revenues.* Our cost of revenues includes materials, labor, and laboratory expenses. Our cost of revenues increased by \$58,266, or 4.43%, to \$1,373,432 for the year ended December 31, 2024 from \$1,315,166 for the year ended December 31, 2023. As a percentage of revenues, cost of revenues was 78.38% and 92.34% for the years ended December 31, 2024 and 2023, respectively. This decrease was primarily driven by the lack of sales of COVID-19 tests, which had very low gross margins in 2023, and the increase in revenue from sales of OneTest Premium, which have higher sales prices than OneTest Standard, while our fixed costs related to laboratory operations remained stable, as illustrated by the following table:

	December 31, 2024				December 31, 2023			
	Revenues	Cost of Revenues	Gross Profit	Gross Margin	Revenues	Cost of Revenues	Gross Profit	Gross Margin
COVID Tests	\$ -	\$ -	\$ -	-	\$ 252,520	\$ 260,556	\$ (8,036)	(3.18%)
OneTest	1,490,881	1,263,523	227,358	15.25%	921,502	939,924	(18,422)	(2.00%)
BioCheck	177,283	86,445	90,838	51.24%	187,926	100,335	87,591	46.61%
CLIAx	84,179	23,464	60,715	72.13%	62,356	14,351	48,005	76.99%
	<u>\$1,752,343</u>	<u>\$ 1,373,432</u>	<u>\$ 378,911</u>	<u>21.62%</u>	<u>\$ 1,424,304</u>	<u>\$ 1,315,166</u>	<u>\$ 109,138</u>	<u>7.66%</u>

*Gross profit and gross margin.* As a result of the foregoing, our gross profit increased by \$269,773, or 247.19%, to \$378,911 for the year ended December 31, 2024 from \$109,138 for the year ended December 31, 2023. Gross profit as a percentage of revenues (gross margin) was 21.62% and 7.66% for the years ended December 31, 2024 and 2023, respectively.

*Sales, general and administrative expenses.* Our sales, general and administrative expenses include sales, marketing, office leases, overhead, executive compensation, legal, regulatory, government relations, and similar expenses. Our sales, general and administrative expenses decreased by \$606,663, or 11.99%, to \$4,454,787 for the year ended December 31, 2024 from \$5,061,450 for the year ended December 31, 2023. As a percentage of revenues, sales, general and administrative expenses were 254.22% and 355.36% for the years ended December 31, 2024 and 2023, respectively. Contributors to the decrease include an overall decrease in salary and related costs of \$366,215, which was primarily related to administrative and support staff as COVID-19 related activities diminished, a reduction in advertising and related activities of \$127,229, a decrease in office related costs of \$191,027, as well as professional fees for

accounting, legal, regulatory and business development activities reduced by \$127,229 related to decreased regulatory filings and negotiation of license agreements for technology to enhance our product offerings. An offset to the decrease was primarily due to the recognition of \$1,245,963 in non-cash stock compensation expense recorded upon the granting of stock options in 2024 as compared to \$892,332 in 2023.

Research and development expenses. Our research and development expenses include clinical data acquisitions, laboratory validation and bridging studies, data analysis algorithms, and non-capitalizable machine learning software development. It also includes laboratory test validation and technical consultation. Our research and development expenses decreased by \$248,969, or 17.67%, to \$1,160,181 for the year ended December 31, 2024 from \$1,409,150 for the year ended December 31, 2023. As a percentage of revenues, research and development expenses were 66.21% and 98.94% for the years ended December 31, 2024 and 2023, respectively. Approximately 90%, or \$1,044,163, of the expenses in 2024 were incurred on the clinical and LDT validations of OneTest Standard and Premium (BioInfra I-Finder) capillary collection methodology, with the remaining \$116,018 on activities supporting preliminary studies for the OneTest Longevity. The decrease in research and development costs was due to higher expenses in 2023 related to the development of OneTest Premium. We anticipate continued costs for research and development for our OneTest for Longevity, which is expected to launch in 2025.

Loss on impairment of fixed assets. In the year ended December 31, 2024, the Company recorded an impairment charge of \$16,356 for certain lab equipment. In the year ended December 31, 2023, we performed an impairment analysis of laboratory equipment utilized in COVID-19 testing due to the significant material decrease in revenue and cash flow related to the COVID-19 testing and recorded an impairment charge of \$209,073. It was determined after discussion with lab personnel that certain PCR laboratory equipment could be repurposed for potential future products and would be retained for research and development. As of December 31, 2023, we had no PCR testing inventory since the supplies were expensed to for research and development.

Total other income (expense). We had total other income net, of \$125,746 for the year ended December 31, 2024, as compared to other income, net, of \$179,226 for the year ended December 31, 2023. Total other income, net, for the year ended December 31, 2024 consisted of interest income of \$79,467 and other income of \$58,925 due to a refund of sales and use taxes from the State of Maryland, offset by interest expense of \$12,646, while total other income, net, for the year ended December 31, 2023 consisted of interest income of \$209,150, offset by interest expense of \$27,915 and other expenses of \$2,009.

Net loss. As a result of the cumulative effect of the factors described above, we generated a net loss of \$5,126,667 for the year ended December 31, 2024, as compared to \$6,391,309 for the year ended December 31, 2023, a decrease of \$1,264,642, or 19.79%.

## **Liquidity and Capital Resources**

As of December 31, 2024, we had cash and cash equivalents of \$1,784,009. Historically, our sources of cash have included private placements of equity securities and cash generated from revenues.

Management has prepared estimates of operations and believes that sufficient funds will be generated from operations to fund our operations and to service our debt obligations for at least the next twelve months. We may, however, in the future require additional cash resources due to changing business conditions, implementation of our strategy to expand our business, or investments or acquisitions we may decide to pursue. If our own financial resources are insufficient to satisfy our capital requirements, we may seek to sell additional equity or debt securities or obtain additional credit facilities. The sale of additional equity securities could result in dilution to our stockholders. The incurrence of indebtedness would result in increased debt service obligations and could require us to agree to operating and financial covenants that would restrict our operations. Financing may not be available in amounts or on terms acceptable to us, if at all. Any failure by us to raise additional funds on terms favorable to us, or at all, could limit our ability to expand our business operations and could harm our overall business prospects.

### ***Summary of Cash Flows***

The following table provides detailed information about our net cash flow for the period indicated:

	<b>Years Ended December 31,</b>	
	<b>2024</b>	<b>2023</b>
Net cash used in operating activities	\$ (2,598,785)	\$ (4,479,971)
Net cash used in investing activities	-	(43,764)
Net cash provided by (used in) financing activities	293,333	(194,379)
Net decrease in cash and cash equivalents	(2,305,452)	(4,718,114)
Cash and cash equivalents at beginning of period	4,089,461	8,807,575
Cash and cash equivalent at end of period	<u>\$ 1,784,009</u>	<u>\$ 4,089,461</u>

Net cash used in operating activities was \$2,598,785 for the year ended December 31, 2024, as compared to \$4,479,971 for the year ended December 31, 2023. Cash used in operating activities for the year ended December 31, 2024 was mainly attributed to the net loss of \$5,126,667 and the addition of non-cash adjustments that positively impact operating cashflows, which includes \$1,751,098 of stock-based compensation and a loss on impairment of fixed assets of \$16,356. The remaining change was primarily attributed to net positive cash from changes in operating assets and liabilities of \$619,693. Cash used in operating activities for the year ended December 31, 2023 was mainly attributed to the net loss of \$6,391,309 and the addition of non-cash adjustments that positively impact operating cashflows, which includes \$1,303,952 of stock-based compensation and \$209,073 of impairment of fixed assets. The remaining net decrease was primarily attributed to net positive cash from accounts receivable of \$696,090 offset by a reduction to accounts payable and accrued expenses of \$521,113.

Net cash used in investing activities was \$0 for the year ended December 31, 2024, as compared to \$43,764 for the year ended December 31, 2023. The net cash used in investing activities for the year ended December 31, 2023 consisted of the acquisition of technology under a license agreement of \$34,381 and purchases of capital equipment of \$9,383.

Net cash provided by financing activities was \$293,333 for the year ended December 31, 2024, as compared to net cash used in financing activities of \$194,379 for the year ended December 31, 2023. The net cash provided by financing activities for the year ended December 31, 2024



consisted of proceeds from preferred stock offerings of \$293,333, while the net cash used in financing activities for the year ended December 31, 2023 consisted of deferred offering costs of \$148,387 and principal payments on financing lease payments of \$46,575, offset by net of proceeds from the exercise of warrants of \$583.

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

See Exhibit A

**29. With respect to the Company, any predecessor of the Company, any affiliated Company, any director, officer, general partner or managing member of the Company, any beneficial owner of 20 percent or more of the Company'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 Company 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 the Company, its predecessors and affiliated companies) before the filing of this offering statement, of any felony or misdemeanor:**
  - i. In connection with the purchase or sale of securities?**
  - ii. Involving the making of any false filing with the commission?**
  - iii. Arising out of the conduct of the business of an underwriter, broker, dealer, municipal securities dealer, investment advisor, funding portal or paid solicitor of purchasers of securities?**
- 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?**
  - ii. Involving the making of any false filing with the Commission?**
  - iii. Arising out of the conduct of the business of an underwriter, broker, dealer, municipal securities dealer, investment advisor, funding portal or paid solicitor of purchasers of securities?**
- 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 this offering statement bars the person from:**
    - 1. Association with an entity regulated by such commission, authority, agency or officer?**
    - 2. Engaging in business of securities, insurance, or banking?**

3. Engaging in savings association or credit union activities?
- 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?
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 advisor or funding portal?
  - ii. Places limitations on the activities, functions or operations of such person?
  - iii. Bars such person from being associated with any entity or from participating in the offering of any penny stock?
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?
  - ii. Section 5 of the Securities Act?
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?
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?
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?

The Company answers 'NO' to all of the above questions



# Other Material Information

30. In addition to the information expressly required to be included in this Form, include: any other material information presented to investors; and 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. The following documents are being submitted as part of this offering:

**Audited Financials:** See Exhibit A

**Offering Page:** See Exhibit B

**Subscription Agreement:** See Exhibit C

**Certificate of Incorporation:** Exhibit D

**Bylaws:** Exhibit E

## **Exhibit A**

*Audited Financial Statements (attached to filings)*

## **Exhibit B**

*Offering Page (attached to filings)*

## **Exhibit C**

*Subscription Agreement (attached to filings)*

## **Exhibit D**

*Certificate of Incorporation (attached to filings)*



## **Exhibit E**

*Bylaws (attached to filings)*