Risk Factors Comparison 2024-02-29 to 2023-03-02 Form: 10-K

Legend: **New Text** ~~Removed Text~~ Unchanged Text Moved Text Section

The Company is in a market environment that cannot be predicted and that involves significant risks, many of which are beyond our control. Before making a decision to invest in, hold or sell our common stock, stockholders and potential stockholders should carefully consider the risks and uncertainties described below, in addition to the other information contained in this report, as well as the other information we file with the SEC. If any of the following risks are realized, our business, financial condition, results of operations and prospects could be materially and adversely affected. In that case, the value of our common stock could decline and stockholders may lose all or part of their investment. Furthermore, additional risks and uncertainties of which we are currently unaware, or which we currently consider to be immaterial, could have a material adverse effect on our business, financial condition or results of operations. Summary Risk Factors Our business is subject to numerous risks and uncertainties, including those highlighted in the section entitled " Risk Factors, " that represent challenges that we face in connection with the successful implementation of our strategy and growth of our business. The occurrence of one or more of the events or circumstances described in the section entitled " Risk Factors, " alone or in combination with other events or circumstances, may have an adverse effect on our business, financial condition, results of operations, and prospects. Such risks include, but are not limited to: Risks Relating to Our Financial Condition and Capital Requirements • We ~~have~~ **are a company with** a history of net losses; we expect to incur net losses in the future and may never achieve profitability. • We have a limited operating history and we expect a number of factors to cause our operating results to fluctuate on a quarterly and annual basis, which may make our future performance difficult to predict ~~. • Our financial condition, commercialization efforts and results of operations could be adversely affected by outbreaks of contagious diseases, including the COVID- 19 pandemic~~ . • Our commercial success could be compromised if customers do not pay our invoices or if commercial payors, including managed care organizations and Medicare, do not provide coverage and reimbursement, breach, rescind, or modify their contracts or reimbursement policies, reimburse at a low rate, or delay payments for the DMT and our planned tests. • ~~We will need~~ **There is substantial doubt about our ability to continue as a going concern. If we are unable** to raise additional capital ~~to fund~~ **when needed** ~~our~~ **or on acceptable terms, we may be forced to delay, reduce and / or eliminate one or more of our business initiatives or liquidate (which could result in our stockholders not receiving full value, or receiving no value, for their investment) or, if we are successful in raising additional capital, it may be on terms that are highly dilutive to** existing **stockholders** ~~operations, commercialize our products, and expand our operations~~ . • If clinicians, including dermatologists, decide not to order the DMT or our future tests, we may be unable to generate sufficient revenue to sustain our business. • We expect to continue to incur significant expenses to develop and market our existing and planned tests, which could make it difficult for us to achieve and sustain profitability. • We may not be able to generate sufficient revenue from the commercialization of the DMT ~~, or successfully develop and commercialize other tests~~ to achieve or sustain profitability. • If we are unable to successfully execute our marketing strategy for the DMT and are unable to gain acceptance in the market, we may be unable to generate sufficient revenue to sustain our business. • The telemedicine market is immature and unpredictable, and if it does not develop, if it develops more slowly than we expect, if it encounters negative publicity or if limitations on reimbursement or difficulties in obtaining regulatory approvals impede our ability to adopt telemedicine, the growth of our business will be harmed. • If we cannot ~~develop~~ **enhance our** tests to keep pace with rapid advances in technology, medicine and science, our operating results and competitive position could be harmed ~~. • Our future success will depend in part upon our ability to enhance the DMT, and to develop, introduce, and commercialize other novel innovative and non- invasive diagnostics tests and services; new test development involves a lengthy and complex process and we may be unable to commercialize new or improved tests or any other products we may develop on a timely basis, or at all~~ . • We rely on a limited number of suppliers and, in some cases, a single supplier, for certain of our laboratory substances, equipment and other materials, and any delays or difficulties securing these materials could disrupt our laboratory operations and materially harm our business. • The DMT employs a novel diagnostic platform and may never be **widely** accepted by its intended markets. • If the DMT **does** ~~and our planned tests do~~ not ~~to~~ perform as expected, as a result of human error or otherwise, it could have a material adverse effect on our operating results, reputation, and business. • If our sole laboratory facility becomes damaged or inoperable, or we are required to vacate the facility, our ability to sell and provide molecular tests and pursue our research and development (" R & D ") efforts may be jeopardized. • If we cannot compete successfully with our competitors, we may be unable to increase or sustain our revenues or achieve and sustain profitability. • ~~We may encounter manufacturing problems or delays that could result in lost revenue. •~~ If we cannot support demand for the DMT ~~and our planned future tests~~ , including successfully managing the evolution of our technology and manufacturing platforms, our business could suffer. • If we were to be sued for product or professional liability, we could face substantial liabilities that exceed our resources. • We may acquire other businesses, form joint ventures, or make investments in other companies or technologies that could harm our operating results, dilute our stockholders' ownership, increase our debt, or cause us to incur significant expense. • International expansion of our business would expose us to business, regulatory, political, operational, financial, and economic risks associated with doing business outside of the United States ~~. • Declining general economic and business conditions as a result of the COVID - 19 pandemic have had a negative impact on our business, and the extent and duration of the effects of the COVID - 19 pandemic and economic downturn are difficult to predict, which makes our future performance more difficult to predict~~ . • Intrusions into our computer systems could compromise confidential information and our ability to continue operations. • We rely on FedEx Corporation (" FedEx ") and United Parcel Service, Inc. (" UPS ") to distribute our Smart Sticker to customers and transport

specimens back to our laboratory facility, and any damage to their facilities **, labor strike** or inability to deliver our products could have **a material** ~~an~~ **and** adverse effect on our results of operations and business. Regulatory Risks Related to Our Business • Changes in health care law and policy may have **a material** ~~an~~ **and** adverse effect on our financial condition, results of operations, and cash flows ~~. • Our business could be adversely impacted by our failure or clinicians' failure to comply with the International Classification of Diseases, Tenth Revision, Clinical Modification (" ICD- 10- CM ") Code Set~~ . • Billing for the DMT is complex, and we must dedicate substantial time and resources to the billing process to be paid for the DMT; long payment cycles **and changes in claims processing practices** of Medicare, Medicaid, and / or other commercial payors, or other payment delays, could hurt our cash flows and increase our need for working capital. • Our business could be harmed by the loss, suspension, or other restriction on a license, certification, or accreditation **(including the termination of our CAP accreditation scheduled for April 6, 2024)** , or by the imposition of a fine or penalties, under CLIA, its implementing regulations, or other state, federal, and foreign laws and regulations affecting licensure or certification, or by future changes in these laws or regulations. • If the FDA were to begin requiring approval or clearance of the DMT and our planned future tests, or our proprietary Smart Sticker, we could incur substantial costs and time delays associated with meeting the requirements. • If we were to be required by the FDA to conduct additional clinical studies or trials before continuing to offer tests that we have developed or may develop as LDTs those studies or trials could lead to delays or failure to obtain necessary regulatory clearance or approval, which could cause significant delays in commercializing any future products and harm our ability to achieve profitability. • We are subject to numerous federal, local and foreign laws and regulations; complying with laws pertaining to our business is an expensive and time- consuming process, and any failure to comply could result in substantial penalties and a material adverse effect to our business and operations. Intellectual Property Risks Related to Our Business • If we are unable to maintain intellectual property protection, our competitive position could be harmed. Risks Related to Our Securities • Future issuances of equity securities may dilute the interests of our security holders and reduce the price of our securities ~~. We are a company with a history of net losses; we expect to incur net losses in the future and may never achieve profitability~~ . We have historically incurred substantial net losses in each year since our inception, including net losses of $ ~~116~~ **100** . ~~7~~ **9** million for the twelve months ended December 31, ~~2022~~ **2023** . As of December 31, ~~2022~~ **2023** , we had an accumulated deficit of $ ~~323~~ **423** . ~~0~~ **9** million. We expect our losses to continue as a result of costs relating to ongoing R & D and for increased sales and marketing costs for existing ~~and planned~~ products. These losses have had, and will continue to have, an adverse effect on our working capital, total assets, and stockholders' equity. Because of the numerous risks and uncertainties associated with our commercialization efforts, we are unable to predict when we will become profitable, and we may never become profitable. Even if we achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our inability to achieve and then maintain profitability would negatively affect our business, financial condition, results of operations, and cash flows. We are an emerging molecular diagnostics company with a limited operating history. Our operations to date have been primarily focused on developing and ~~market~~ **marketing** ~~testing~~ our technology. We have not obtained regulatory approvals from the FDA for any of our existing and planned tests as we operate a clinical laboratory under the CLIA guidelines and believe the DMT is an LDT that is not currently being regulated by the FDA. Consequently, if regulatory approval is determined to be necessary or if Congress enacts legislation that alters the regulatory framework for LDTs, any predictions made about our future success or viability may not be as accurate as they could be if we had a longer operating history or more commercialized products. Our financial condition and operating results have varied significantly in the past and will continue to fluctuate from quarter- to- quarter or year- to- year due to a variety of factors, many of which are beyond our control. Factors relating to our business that may contribute to these fluctuations include other factors described elsewhere in this report and also include: • our ability to obtain additional funding to **further** develop and market our existing ~~and planned~~ products and tests; • the market adoption and demand for our existing and ~~planned~~ **potential future** tests **; • inflationary pressures, such as those the global market is currently experiencing, which have and may increase costs for materials, supplies, and services; • natural disasters; political and economic instability, including wars, terrorism and political unrest, such as conflicts in the Ukraine and the Middle East; outbreak of disease; boycotts; and other business restrictions** ; • the existence of favorable or unfavorable clinical guidelines for our existing and planned tests; • the reimbursement of our existing or planned tests by Medicare and commercial payors; • our ability to obtain and maintain any necessary regulatory approval for any of our existing and planned tests in the United States and foreign jurisdictions, if required; • potential side effects of our existing and planned tests that could delay or prevent commercialization, limit the use of our existing and planned tests, or cause any of our commercialized tests to be taken off the market; • our dependence on third- party suppliers and manufacturers, to supply or manufacture our specimen collection products; • our ability to establish or maintain collaboration, licensing, or other arrangements; • our ability to maintain and grow an effective sales and marketing infrastructure, either through the expansion of our commercial infrastructure or through strategic collaborations; • competition from existing and planned tests or new tests that may emerge; • the ability of patients or healthcare providers to obtain coverage of or sufficient reimbursement for our existing and planned tests; • our ability to leverage our proprietary technology platform to discover and develop additional test candidates; • our ability to successfully obtain, maintain, defend, and enforce intellectual property rights important to our business; • our ability to attract and retain key personnel to manage our business effectively; • our ability to build our finance infrastructure and improve our accounting systems and controls; • potential product liability claims; • potential liabilities associated with hazardous materials; and • our ability to obtain and maintain adequate insurance policies. Accordingly, the results of any quarterly or annual periods should not be relied upon as indications of future operating performance. ~~Any outbreak of a contagious disease, such as the COVID - 19 pandemic, or other adverse public health developments, could have a material and adverse effect on our business operations. Such adverse effects could include disruptions or restrictions on the ability of our, our collaborators', or our suppliers' personnel to travel, and could result in temporary closures of our facilities or the facilities of our collaborators or suppliers, including our sole laboratory. The extent to~~

~~which COVID - 19 affects our operations will depend on future developments, which are highly uncertain and cannot be predicted with confidence, additional information that may emerge concerning the severity of COVID - 19 and ongoing actions to contain COVID - 19 or mitigate its impact, among others, which could have a further adverse effect on our business, financial condition, results of operations, and cash flows.~~ We expect to continue to incur increased costs as a result of operating as a public company and our management will be required to devote substantial time to compliance initiatives and corporate governance practices. As a public company, we incur and expect to continue to incur additional significant legal, accounting and other expenses in relation to our status as a public reporting company. ~~We expect that these expenses will further increase as a result of our recent transition to no longer being an " emerging growth company. "~~ We may need to hire additional accounting, finance and other personnel in connection with our continuing efforts to comply with the requirements of being a public company, and our management and other personnel will need to continue to devote a substantial amount of time towards maintaining compliance with these requirements. In addition, the Sarbanes- Oxley Act of 2002 and rules subsequently implemented by the SEC and The Nasdaq Stock Market LLC have imposed various requirements on public companies, including establishment and maintenance of effective disclosure and financial controls and corporate governance practices. Our management and other personnel will need to devote a substantial amount of time to these compliance initiatives. Moreover, these rules and regulations will increase our legal and financial compliance costs and will make some activities more time-consuming and costly. Pursuant to Section 404 of the Sarbanes- Oxley Act of 2002 (" Section 404 "), we ~~are~~ **will be** required to furnish a report by our management on our internal controls over financial reporting **. However , while we remain a " smaller reporting company " and a non- accelerated filer, we will not be required to** ~~including~~ **include** an attestation report on internal control over financial reporting issued by our independent registered public accounting firm. To achieve compliance with Section 404 within the prescribed period, we have been and will be engaged in a process to document and evaluate our internal control over financial reporting, which is both costly and challenging. In this regard, we will need to continue to dedicate internal resources, potentially engage outside consultants and adopt a detailed work plan to assess and document the adequacy of internal control over financial reporting, continue steps to improve control processes as appropriate, validate through testing that controls are functioning as documented and implement a continuous reporting and improvement process for internal control over financial reporting. ~~We have identified material weaknesses in our internal control over financial reporting as more fully described in Item 9A — Controls and Procedures, which could result in an adverse reaction in the financial markets due to any loss of confidence in the reliability of our consolidated financial statements. We plan to implement or improve documentation of alternative control procedures to remediate these material weaknesses. These remediation measures may be time consuming and costly and there is no assurance that these measures will ultimately have the intended effects.~~ Our commercial success could be compromised if customers do not pay our invoices or if commercial payors, including managed care organizations and Medicare, do not provide coverage and reimbursement, breach, rescind, or modify their contracts or reimbursement policies, reimburse at a low rate, or delay payments for the DMT and our planned future tests. Clinicians, including dermatologists, may not order the DMT or our planned tests unless commercial payors, such as managed care organizations and ~~federal~~ government health care programs (e. g., Medicare and Medicaid), pay a substantial portion of the test price. Coverage and reimbursement by a commercial payor may depend on a number of factors, including a payor' s determination that tests using our technologies are: • not experimental or investigational; • medically necessary; • appropriate for the specific patient; • cost- effective; • deemed to require prior authorization; • supported by peer- reviewed publications; and • included in clinical practice guidelines. Uncertainty surrounds commercial payor reimbursement of any test incorporating new technology, including tests developed using our technologies. Technology assessments of new medical tests conducted by research centers and other entities may be disseminated to interested parties for informational purposes. Commercial payors may use such technology assessments as grounds to deny coverage for a test or procedure. Technology assessments can include evaluation of clinical utility studies, which define how a test is used in a particular clinical setting or situation. Because each payor generally determines for its own enrollees or insured patients whether to cover or otherwise establish a policy to reimburse the DMT, seeking payor approvals is a time- consuming and costly process. We cannot be certain that coverage for the DMT and our planned future tests will be provided in the future by additional commercial payors or that existing policy decisions or reimbursement levels will remain in place or be fulfilled under existing terms and provisions. In addition, the coding procedure used by all commercial payors with respect to establishing payment rates for various procedures, including the DMT, is complex, does not currently adapt well to the genetic tests we perform and may not enable coverage or adequate reimbursement rates for the DMT. If we cannot obtain or maintain coverage and reimbursement from commercial payors and federal health care programs such as Medicare and Medicaid for the DMT, or **for** new tests or test enhancements that we may develop in the future, our ability to generate revenues could be limited, which may have a material adverse effect on our financial condition, results of operations, and cash flows. Measures have been undertaken to reduce payment rates for and decrease utilization of the clinical laboratory testing generally, including PAMA, which has resulted in reduced rates on the CLFS. These reductions may also impact the DMT and tests we develop in the future. Because of the cost- trimming trends, commercial payors that cover and provide reimbursement for the DMT and our planned tests may suspend, revoke, or discontinue coverage at any time, or may reduce the reimbursement rates payable to us. Any such action could have a negative impact on our revenues, which may have a material adverse effect on our financial condition, results of operations, and cash flows. Additionally, if we are not able to obtain sufficient clinical information in support of the DMT, commercial payors could designate the DMT as experimental or investigational and decline to cover and reimburse the DMT because of this designation. As a result of these factors, obtaining approvals from commercial payors to cover the DMT and establishing adequate reimbursement levels is an unpredictable, challenging, time- consuming, and costly process, and we may never be successful. Further, we have experienced in the past, and will likely experience in the future, delays and interruptions in the receipt of payments from commercial payors due to missing documentation **, changes in practices** and / or other issues, which **has in the**

past delayed and could **again** cause delay in recognizing our revenue. Additionally, we are currently considered a " non-contracted provider " or " out of network " by most commercial payors because we have not entered into a specific contract to provide tests to their insured patients at specified rates of reimbursement. We also may be considered now or later to be designated as an " out of network " lab by private commercial payors, who may deny our claims in whole or in part as a result. If we were to become a contracted provider with one or more payors in the future, the amount of overall reimbursement we receive would likely decrease because we could be reimbursed less money per test performed at a contracted rate than at a non-contracted rate, which could have a negative impact on our revenues. Further, we pursue payment of patient co- payments, co-insurance and deductibles, but we typically do not collect substantial payments from patients and therefore experience overall loss to revenue as a result. **There is substantial doubt about our ability to continue as a going concern. We will need to raise additional capital, which may not be available on acceptable terms, if at all, to fund our existing operations, commercialize our products, and expand our operations. If we are unable to raise additional capital when and as needed, we may be required to further curtail our operations, liquidate or otherwise dispose of assets, wind- down or cease operations entirely. In these circumstances, investors may not receive full value, or any value, for their investment. There is substantial doubt regarding our ability to continue as a going concern.** As of December 31, ~~2022~~ **2023**, our cash and cash equivalents totaled approximately $ ~~77~~ **36**. ~~8~~ **7** million and short- term marketable securities totaled $ ~~48~~ **19**. ~~4~~ **1** million ~~. On February 28, 2020, we entered into a securities purchase agreement with certain institutional investors for a private placement, which closed on March 4, 2020, of our equity securities for aggregate gross proceeds of approximately $ 65. 0 million, and net proceeds to the Company of approximately $ 59. 9 million, after deducting estimated offering expenses payable by the Company. On November 10, 2020, we entered into a sales agreement to sell shares of our common stock having aggregate sales proceeds of up to $ 50. 0 million from time to time. In connection with this sales agreement, we raised aggregate gross proceeds of approximately $ 44. 5 million, and net proceeds to the Company of approximately $ 42. 9 million during 2020 and 2021. On January 11, 2021, the Company completed an underwritten public offering of our common stock for aggregate gross proceeds of approximately $ 143. 7 million, and net proceeds to the Company of approximately $ 134. 6 million, after deducting offering expenses payable by the Company. On August 8, 2022, we entered into a sales agreement to sell shares of our common stock having aggregate sales proceeds of up to $ 75. 0 million from time to time~~. Based on our current business operations ~~and the additional financing completed in January 2021~~, we believe our current cash and cash equivalents will **not** be sufficient to meet our anticipated cash requirements for at least the next twelve months **after the date the financial statements are issued. Based on the foregoing, we have concluded that substantial doubt exists about our ability to continue as a going concern. Based on our current operating plan, we believe that our existing cash and cash equivalents will be sufficient to fund our operating expenses and capital expenditure requirements only into the first quarter of 2025 but not to exceed 12 months from the date of issuance of the financial statements included in this Annual Report on Form 10- K. Our financial statements have been prepared on a going concern basis, which contemplates the realization of assets and satisfaction of liabilities in the ordinary course of business. The financial statements do not include any adjustments relating to the recoverability and classification of recorded asset amounts or the amounts and classification of liabilities that might result from the outcome of the uncertainties described above. If we are unable to obtain additional funding on acceptable terms when and as needed, we may be forced to delay or reduce the scope of our commercial and sales activities, extend payment terms with suppliers, liquidate assets where possible at a potentially lower amount than as recorded in our financial statements, further curtail planned operations or cease operations entirely and wind down our business. Any of these could materially and adversely affect the Company' s liquidity, financial condition and business prospects and, as a result, our stockholders may not receive full value, or may receive no value, for their investment. In light of our existing cash and cash equivalents and our current obligations, such a liquidation or disposition process may occur subject to bankruptcy protections, which may further reduce the value that we may receive for our assets. During the year ended December 31, 2023, we raised aggregate gross proceeds of approximately $ 0. 3 million, and net proceeds to the Company of approximately $ 0. 1 million, in connection with our existing at the market offering. Our ability to utilize the $ 74. 7 million of capacity remaining under our at the market offering sales agreement is limited by our compliance with the baby shelf rules (as defined below). As of the filing of this Annual Report on Form 10- K, our public float is less than $ 75 million, and under SEC regulations, for so long as our public float remains less than $ 75 million, the amount we can raise through primary public offerings of securities in any twelve- month period using shelf registration statements subject to Instruction I. B. 6. to Form S- 3 is limited to an aggregate of one- third of our public float, which is referred to as the " baby shelf rules. " As of February 23, 2024, our public float was approximately $ 43. 2 million, based on 34, 008, 061 shares of outstanding common stock held by non- affiliates and at a price of $ 1. 27 per share, which was the last reported sale price of our common stock on the Nasdaq Capital Market on February 23, 2024**. We anticipate that we will need to raise additional capital through equity offerings, debt financings, collaborations, or licensing arrangements in the future in order to satisfy our anticipated liquidity requirements. We may also consider raising additional capital in the future to expand our business, to pursue strategic investments, to take advantage of financing opportunities, or for other reasons, including to: • increase our efforts to drive market adoption of the DMT and address competitive developments; • fund research and development activities and efforts of commercializing future products; • acquire, license, or invest in technologies; • acquire or invest in complementary businesses or assets; and • finance capital expenditures and general and administrative expenses. Our present and future funding requirements will depend on many factors, including: • our revenue growth rate and ability to generate cash flows from operating activities; • our sales and marketing and R & D activities; • effects of competing technological and market developments; • costs of and potential delays in product development; • changes in regulatory oversight applicable to the DMT; and • timing of and costs related to future international expansion. ~~The~~ **There can be no assurances that we will be able to secure such additional financing, if at all, or on terms that are satisfactory to us, and**

that it will be sufficient to meet our needs. In the event that we are able to secure additional financing, the various ways we could raise additional capital carry potential risks. If we raise funds by issuing equity securities, **convertible debt or securities convertible into equity our stockholders may experience substantial** dilution **and the terms of these new** ~~to our stockholders could result. Any equity~~ securities ~~issued also~~ could provide for rights, preferences, or privileges senior to those of holders of our common stock. If we raise funds by issuing debt securities, those debt securities would have rights, preferences, and privileges senior to those of holders of our common stock. The terms of debt securities issued or borrowings pursuant to a credit agreement could impose significant restrictions on our operations. If we raise funds through collaborations and licensing arrangements, we might be required to relinquish significant rights to our platform technologies or products, or grant licenses on terms that are not favorable to us. Additional equity or debt financing might not be available on reasonable terms, if at all. ~~If we cannot secure additional funding when needed, we may have to delay, reduce the scope of, or eliminate one or more R & D programs or sales and marketing initiatives. In addition, we may have to work with a partner on one or more of our development programs, which could lower the economic value of those programs to us.~~ We will also need to raise additional capital to expand our business to meet our long- term business objectives. Additional financing may be from the sale of equity or convertible or other debt securities in a public or private offering, from a credit facility or strategic partnership coupled with an investment in us, or a combination of both **. If we are unable to raise additional funds when and as needed or on acceptable terms, our business, prospects, results of operations and potentially the price of our common stock will be adversely affected** . For further discussion of our liquidity requirements as they relate to our long- term plans, see the section entitled " Management' s Discussion and Analysis of Financial Condition and Results of Operations ~~—~~ - Liquidity and Capital Resources. " Our cash, cash equivalents and short- term marketable securities are subject to economic risk. The Company invests its cash, cash equivalents and short- term marketable securities in domestic bank deposits, money market funds, U. S. Government debt securities, corporate debt, and certificates of deposit. Certain types of these investments are subject to general credit, liquidity, market and interest rate risks. In the event these risks caused a decline in value of any of the Company' s investments, it could adversely affect the Company' s financial condition. **We maintain cash deposits in excess of federally insured limits. Adverse developments affecting financial institutions, including bank failures, could adversely affect our liquidity and financial performance. We maintain our cash, cash equivalents, and marketable securities with high quality, accredited financial institutions. However, some of these accounts exceed the Federal Deposit Insurance Corporation, or FDIC, insurance limit of $ 250, 000 and, while we believe the Company is not exposed to significant credit risk due to the financial strength of these depository institutions or investments, if any such depositary institution fails to return our deposits, or if a depository institution is subject to other adverse conditions in the financial or credit markets, this could further impact access to our invested cash or cash equivalents and could adversely impact our operating liquidity and financial performance. Further, the failure or collapse of one or more of these depository institutions or default on these investments could materially adversely affect our ability to recover these assets and / or materially harm our financial condition.** If clinicians, including dermatologists, decide not to order the DermTech Melanoma Test, or our future tests, we may be unable to generate sufficient revenue to sustain our business **to achieve or sustain profitability** . To generate demand for the DMT and our planned tests, we will need to educate dermatologists and other health care professionals on the clinical utility, benefits, and value of the tests we provide through published papers, presentations at scientific conferences, educational programs, and one- on- one education sessions by members of our sales force. In addition, we need to assure dermatologists of their ability to obtain and maintain adequate reimbursement coverage from commercial payors for office visits during which the specimens for the DMT are collected. Medical professionals are influenced by standard- setting bodies that influence and / or dictate the standard of care. If we are not successful in changing current guidelines from legacy standards to new molecular- based approaches our market adoption will suffer. If we cannot convince medical practitioners to order the DMT and our planned tests, we will likely be unable to create demand in sufficient volume for us to achieve profitability or meet our anticipated revenue projections. In recent years, we have incurred significant costs in connection with the development of our existing and planned tests. For the twelve months ended December 31, **2023, our R & D expenses were $ 15. 2 million, our sales and marketing expenses were $ 45. 0 million and our general and administrative expenses were $ 43. 8 million. For the twelve months ended December 31,** 2022, our R & D expenses were $ 24. 1 million, our sales and marketing expenses were $ 58. 7 million and our general and administrative expenses were $ 36. 1 million. ~~For the twelve months ended December 31, 2021, our R & D expenses~~ **Expenses may** ~~were $ 16. 3 million, our sales and marketing expenses were $ 37. 6 million and our general and administrative expenses were $ 24. 8 million. We expect our expenses to continue to~~ increase for the foreseeable future as we conduct studies of our existing ~~test and planned~~ tests, grow our sales and marketing organization, **and** drive adoption of and reimbursement for the DMT ~~, and develops new tests~~ . As a result, we need to generate significant revenues in order to achieve profitability. We may not be able to generate sufficient revenue from the commercialization of the DermTech Melanoma Test ~~, or successfully develop and commercialize other tests to achieve or sustain profitability~~ . We launched the DMT, without the add- on test for TERT, during the first half of 2016 and the DMT with the add- on test for TERT in the second quarter of 2021. ~~We are~~ **The optional TERT add- on assay will be discontinued** in **March** ~~varying stages~~ of **2024** ~~R & D for other tests that we may offer in the future~~ . We believe that our commercialization success is dependent upon our ability to significantly increase the number of customers who are using the DMT. In addition, demand for the DMT may not increase as quickly as planned and we may be unable to increase our revenue levels as expected. We are currently not profitable. Even if we succeed in increasing adoption of the **DMT** ~~DermTech Melanoma Test~~ by dermatologists, in maintaining and creating relationships with our existing and new customers ~~, and developing and commercializing additional molecular diagnostic testing products~~ , we may not be able to generate sufficient revenue to achieve or sustain profitability. If we are unable to successfully execute our marketing strategy for the DermTech Melanoma Test and are unable to gain acceptance in the market, we may be unable to generate sufficient revenue to sustain our business. Although we believe that the DMT ~~and planned future tests~~

~~represent~~ **represents** a promising commercial opportunity, the DMT may never gain significant acceptance in the marketplace and therefore may never generate substantial revenue or profits for us. We will need to establish a market for the DMT and build that market through clinician education, awareness programs, and the publication of clinical trial results. Gaining acceptance in medical communities requires publication in leading peer- reviewed journals of results from studies using the DMT and / or our planned future tests. The process of publication in leading medical journals is subject to a peer- review process and peer- reviewers may not consider the results of our studies sufficiently novel or worthy of publication. Failure to have our studies published in peer- reviewed journals would limit the adoption of the DMT and our planned tests. Our ability to successfully market ~~the~~ **our** tests ~~that we develop~~ will depend on numerous factors, including: • conducting clinical utility studies of such tests in collaboration with key thought leaders to demonstrate their use and value in important medical decisions such as treatment selection; • the success of our sales force; • whether health care providers believe such tests provide clinical utility; • whether the medical community accepts that such tests are sufficiently sensitive and specific to be meaningful in patient care and treatment decisions; and • whether health insurers, government health care programs, and other commercial payors will cover and pay for such tests and, if so, whether they will adequately reimburse us. Failure to achieve widespread market acceptance of the DMT and our planned future tests would materially harm our business, financial condition, and results of operations. The telemedicine market is immature and unpredictable, and if it does not develop, if it develops more slowly than we expect, if it encounters negative publicity or if limitations on reimbursement or difficulties in obtaining regulatory approvals impede our ability to utilize a telemedicine channel, the growth of our business will be harmed. The DMT, can be ordered via telemedicine channels given the sample collection can be achieved at- home using the Smart Sticker Collection Kit. The telemedicine ~~channels~~ **channel** ~~consist~~ **consists** of clinicians ~~(i)~~ use of third- party telemedicine technologies ~~to assess their patients and (ii) subscribing to our DermTech Connect platform~~ to assess their patients. However, it is uncertain whether these solutions, or telemedicine generally, will achieve and sustain high levels of demand, consumer acceptance and market adoption. Our success will depend to a substantial extent on the willingness of clinicians and their patients to use a telemedicine solution, as well as on our ability to demonstrate the value of a telemedicine solution to commercial payors and other purchasers of healthcare for beneficiaries. To the extent the COVID- 19 pandemic ~~continue~~ **continues** to subside, and patient access to clinician offices for in- person testing improves, the demand for a telemedicine channel could be adversely affected. Negative publicity concerning use of a telemedicine solution or the telemedicine market as a whole could limit market acceptance. If clinicians or their patients do not believe that a telemedicine channel can provide accurate evaluation of suspicious lesions and testing using the DMT, as our clinical studies have already demonstrated, or if clinicians or their patients are not willing to utilize the clinician- supervised remote collection process due to technological limitations or otherwise then an adoption of a telemedicine solution to access the DMT may be slow to develop, or may not develop at all. Changes by state professional licensing boards to the standards of care or other requirements governing the practice of telemedicine, including any such requirements from federal regulatory bodies, could impact the growth or even adoption of a telemedicine solution. Additionally, reimbursement from governmental and commercial payors may not be available or may be too limited for physician services or laboratory testing ordered through a telemedicine channel. Similarly, individual and healthcare industry concerns or negative publicity regarding patient confidentiality and privacy in the context of telemedicine could limit market acceptance for telemedicine. If any of these events occur, it could have a material adverse effect on our business, financial condition or results of operations. ~~The DermTech Connect telemedicine platform is dependent on relationships with subscribing health professionals and provider organizations, which we do not own, to provide patient services, and the DermTech Connect business would be harmed if those relationships were disrupted. There is a risk that U. S. state authorities in some jurisdictions may find that our contractual relationships with health providers providing telemedicine services utilizing DermTech Connect violates laws prohibiting the corporate practice of medicine. These laws generally prohibit the practice of medicine by lay persons or entities and are intended to prevent unlicensed persons or entities from interfering with or inappropriately influencing a physician' s professional judgment. The extent to which each state considers particular actions or contractual relationships to constitute improper influence of professional judgment varies across the states and is subject to change and to evolving interpretations by state boards of medicine and state attorneys general, among others. As such, we must monitor our compliance with laws in every jurisdiction in which we operate on an ongoing basis and we cannot guarantee that subsequent interpretation of the corporate practice of medicine laws will not circumscribe our business operations. State corporate practice of medicine doctrines also often impose penalties on physicians themselves for aiding the corporate practice of medicine, which could discourage health professionals from subscribing to utilize the DermTech Connect telemedicine platform with their patients.~~ In recent years, there have been numerous advances in technologies relating to the molecular diagnosis for cancer and other medical conditions. Several new cancer drugs have been approved, including several for melanoma, and a number of new drugs in clinical development may increase patient survival time. There have also been advances in methods used to identify patients likely to benefit from these drugs based on analysis of biomarkers. We must continuously ~~develop new~~ **enhance our existing** tests ~~and enhance any existing test~~ to keep pace with evolving standards of care. The DMT ~~and our planned tests~~ could become obsolete unless we continually innovate and expand them to demonstrate benefit in the diagnosis, monitoring, or prognosis of patients with cancer and other dermatologic conditions. If we cannot adequately demonstrate the applicability of the DMT ~~and our planned future tests~~ to new diagnostic and treatment developments, sales of the DMT could decline, which would have a material adverse effect on our business, financial condition, results of operations and cash flows ~~. Our future success will depend in part upon our ability to enhance the DermTech Melanoma Test, and to develop, introduce, and commercialize other novel innovative and non- invasive diagnostics tests and services; new test development involves a lengthy and complex process and we may be unable to commercialize new or improved tests or any other products we may develop on a timely basis, or at all. Our future success will depend in part upon our ability to enhance the DermTech Melanoma Test, and to develop new innovative products. Our failure to successfully develop new products on a timely basis could have a material adverse effect on~~

~~our revenue, results of operations, and business. The development of new or enhanced tests is a complex and uncertain process requiring precise technological execution. In addition, the successful development of new products may depend on the development of new technologies. We may be required to undertake time- consuming and costly development activities. We may experience difficulties that could delay or prevent the successful development, commercialization, and marketing of these new products. Before we can commercialize any new products, we will need to expend significant funds in order to conduct substantial R & D, including validation studies. Our product development process involves a high degree of risk, and product development efforts may fail for many reasons, including a failure to demonstrate the performance of the product or an inability to obtain any required certification or regulatory approval, if required. As we develop new tests and other products, we will have to make significant investments in product development, as well as sales and marketing resources. In addition, competitors may develop and commercialize competing products faster than we are able to do so, which could have a material adverse effect on our revenue, results of operations and business~~ . We rely on a limited number of suppliers for certain of our laboratory substances, including reagents, as well as for the sequencers and various other equipment and materials we use in our laboratory operations. In particular, we rely on Thermo Fisher and VWR for supplies and Adhesive Research for our adhesive tape material. We do not have long- term supply agreements with any of our suppliers and, as a result, they could cease supplying these materials and equipment to us at any time due to an inability to reach agreement with us on supply terms, disruptions in their operations (including as a result of **infectious disease outbreaks** ~~the COVID- 19 pandemic~~), a determination to pursue other activities or lines of business, or for other reasons, or they could fail to provide us with sufficient quantities of materials that meet our specifications. Transitioning to a new supplier or locating a temporary substitute, if any are available, would be time- consuming and expensive, could result in interruptions in or otherwise affect the performance specifications of our laboratory operations, or could require that we revalidate the DMT. In addition, the use of equipment or materials provided by a replacement supplier could require us to alter our laboratory operations and procedures as well as our research and development activities. Moreover, we believe there are currently only a few manufacturers that are capable of supplying and servicing some of the equipment and other materials necessary for our laboratory operations, including sequencers and various associated reagents. As a result, replacement equipment and materials that meet our quality control and performance requirements may not be available on reasonable terms, in a timely manner or at all. If we encounter delays or difficulties securing, reconfiguring or revalidating the equipment, reagents and other materials we require for the DMT, our operations could be materially disrupted and our business, financial condition, results of operations, and reputation could be adversely affected. As we introduce any new test, we may experience supply issues as we ramp test volume. ~~Moreover, the COVID- 19 pandemic has disrupted supply chains globally, and could adversely affect our ability to source essential reagents, equipment and other materials in a timely manner or at all.~~ Our future success depends on our ability to successfully commercialize the DermTech Melanoma Test ~~, as well as our ability to develop and market other tests that use our proprietary technology platform~~ . The scientific discoveries that form the basis of our proprietary technology platform and the DMT ~~is~~ **are** relatively new. We are not aware of any other genomic tests such as ours and there can be no assurance that clinicians will be willing to use them. If we do not successfully develop and commercialize the DMT based upon our technological approach, we may not become profitable and the value of our common stock may decline. The novel nature of our existing and planned tests also means that fewer people are trained in or experienced with products of this type, which may make it difficult to find, hire, and retain capable personnel for research, development, and clinical laboratory positions. Further, our focus solely on genomic tests, as opposed to multiple, more proven technologies for patient diagnosis, increases the risks associated with the ownership of our common stock. If we do not achieve market acceptance for the DMT, we may be required to change the scope and direction of our product development activities. In that case, we may not be able to identify and implement successfully an alternative product development strategy. Our success depends on the market' s confidence that we can provide reliable, high- quality diagnostic results. There is no guarantee that any accuracy we have demonstrated to date will continue, particularly as the number of tests using our assays increases and ~~as~~ **if** the number of different tests that we develop and commercialize expands. We believe that our customers are likely to be particularly sensitive to test defects and errors. As a result, the failure **or perceived failure** of our current ~~or planned~~ tests to perform as expected could significantly impair our reputation and the public image of our tests ~~. As a result, the failure or perceived failure of our~~ **or** ~~products to perform as expected~~ could have a material adverse effect on our business, financial condition, results of operations and cash flows. We may be unable to manage our future growth effectively, which could make it difficult to execute our business strategy. As part of our strategy, we expect to increase our number of employees as our business grows. This future growth could create strain on our organizational, administrative, and operational infrastructure, including laboratory operations, quality control, customer service, and sales and marketing. Our ability to manage our growth properly will require us to continue to improve our operational, financial, and management controls, as well as our reporting systems and procedures. If our current infrastructure is unable to handle our growth, we may need to further expand our infrastructure and staff and implement new reporting systems. The time and resources required to implement such expansion and systems could adversely affect our operations. ~~Our expected future~~ **Future** growth ~~will~~ **would** impose significant added responsibilities on members of management, including the need to identify, recruit, maintain, and integrate additional employees. Our future financial performance and our ability to commercialize our products and to compete effectively will depend, in part, on our ability to manage this potential future growth effectively, without compromising quality. If our sole laboratory facility becomes damaged or inoperable, or we are required to vacate the facility, our ability to sell and provide molecular tests and pursue our R & D efforts may be jeopardized. We do not have any clinical reference laboratory facilities outside of our **new** facility in ~~La Jolla~~ **San Diego** , California. Our facilities and equipment could be harmed or rendered inoperable by natural or man- made disasters, including fire, earthquake, flooding, pandemics or other disease outbreaks and power outages, which may render it difficult or impossible for us to perform our diagnostic test for some period of time. The inability to perform the DMT ~~, our planned tests,~~ or the backlog of tests that could develop if our facility is inoperable for even a short period of time **,** may result in the loss of

customers or harm to our reputation or relationships with scientific or clinical collaborators, and we may be unable to regain those customers or repair our reputation in the future. Furthermore, our facilities and the equipment we use to perform our R & D work could be costly and time- consuming to repair or replace. The San Diego area has recently experienced serious fires **, floods** and power outages, and is considered to lie in an area with earthquake **and fire** risk. If our sole laboratory facility is destroyed or otherwise rendered inoperable, we may have difficulty replacing or rebuilding this facility and there can be no assurance we could do so in a timely manner, on terms favorable to us or at all. Additionally, a key component of our **operations and** R & D process involves using biological samples as the basis for the development of our diagnostic tests. In some cases, these samples are difficult to obtain. If the parts of our laboratory facility where we store these biological samples were damaged or compromised, our ability to pursue our R & D projects, as well as our reputation, could be jeopardized. We carry insurance for damage to our property and the disruption of our business, but this insurance may not be sufficient to cover all of our potential losses and may not continue to be available to us on acceptable terms, if at all. Further, if our CLIA- certified laboratory became inoperable or was destroyed, we may not be able to license or transfer our technology to another facility with the necessary state licensure and CLIA certification under which the DMT ~~and our planned future tests~~ could be performed. **For more information refer to the risk factor below under the heading " Our business could be harmed by the loss, suspension, or other restriction on a license, certification, or accreditation, or by the imposition of a fine or penalties, under CLIA, its implementing regulations, or other state, federal, and foreign laws and regulations affecting licensure or certification, or by future changes in these laws or regulations. "** Even if we find a facility with such qualifications to perform the DMT, it may not be available to us on commercially reasonable terms. In addition, the use of a third- party laboratory to perform the DMT could affect their classification as LDTs and require us to seek FDA market authorization for the test prior to the completion of such a transfer ~~. On July 1, 2021, we entered into a lease with respect to a building also located in San Diego, California, which will serve as the Company' s new principal office and laboratory facility (the " New Lab "). We are in the process of building out the New Lab and expect to move our operations and equipment to the New Lab in the first half of 2023. Our current or new facilities and equipment could be harmed or rendered inoperable during the move and we may experience delays or difficulties in transitioning to our New Lab which could adversely affect our ability to perform our tests. We are required to notify our applicable regulatory and accrediting entities, CAP, CMS and applicable state agencies, of the move of our laboratory facility. We do not anticipate any impact to our certification or any licensing status as a result of these notifications. However, validation of our facility move will be subject to evaluation at the time of our next on- site inspection for the purposes of both our certification under CLIA and our California state laboratory licensure. All regulatory and accrediting entities will continue to have the right to inspect our laboratory facilities at any time~~ . Our principal competition comes from mainstream clinical diagnostic methods, used by dermatologists for many years, which focus on visual tumor tissue analysis. It may be difficult to change the methods or behavior of dermatologists to incorporate the DMT and Smart Sticker into their practices in conjunction with, or instead of, tissue biopsies and analysis. In addition, companies offering capital equipment and kits or reagents to local dermatologists represent another source of potential competition. These tests are used directly by ~~the~~ dermatologists, which can facilitate adoption. We plan to focus our marketing and sales efforts on medical dermatologists rather than pathologists. We also face competition from companies that offer device products or are conducting research to develop device products for analysis of pigmented lesions. In particular, MELA Sciences, Inc., used to market its MelaFind ® device to dermatologists, but we believe they no longer actively market this product. Scibase AB and Verisante Technology, Inc. have devices under development and may market their medical products directly to dermatologists if and when they obtain FDA approval. In addition to these companies, our competitors also include other device companies selling photographic technologies, whole body photography services, dermatoscopes, or confocal microscopy, such as Fotofinder, Molemate, Canfield Scientific, MedX, and Caliber I. D. Many of these groups, in addition to operating R & D laboratories, are selling equipment and devices **. DermaSensor, Inc. has an FDA- approved point- and- click handheld device that is marketed solely to primary care physicians for evaluation of suspicious lesions** . In addition to these device companies, Castle Biosciences, Inc. offers an expression test for melanoma that is used on surgical biopsy specimens. Castle Biosciences, Inc. could also try and market their test as a biopsy aid at the point- of- care. Genomic testing is a relatively new area of science, especially in dermatology and we cannot predict what tests others will develop that may compete with or provide results similar or superior to the results we are able to achieve with the tests we develop. There are a number of companies that are focused on the oncology diagnostic market and expression tests including Exact Sciences Corporation, Veracyte, Inc., Guardant Health and others. Additionally, projects related to cancer diagnostics and particularly genomics have received increased government funding, both in the United States and internationally. As more information regarding cancer genomics becomes available to the public, we anticipate that more products aimed at analyzing pigmented lesions and identifying melanoma may be developed and that these products may compete with ours. In addition, competitors may develop their own versions of our current or planned tests in countries where we did not apply for patents or where our patents have not issued or have expired and may compete with us in those countries, including encouraging the use of their test by clinicians or patients in other countries. In addition, one or more competitors may seek to invalidate or render unenforceable any of our patents in a court of competent jurisdiction or at the United States Patent and Trademark Office (" USPTO "). If any such proceeding were to be successful and result in the invalidation or unenforceability of one or more patents in our intellectual property portfolio, we may be unable to prevent unlicensed third- party competition in the marketplace with respect to our current and planned future tests. Some of our present and potential competitors have widespread brand recognition and substantially greater financial and technical resources and development, production, and marketing capabilities than we do. Others may develop lower- priced, less complex tests that payors and dermatologists could view as functionally equivalent to our current or planned tests, which could force us to lower the list price of our tests and impact our operating margins and ability to achieve and maintain profitability. In addition, technological innovations that result in the creation of enhanced diagnostic tools that are more sensitive or specific than ours

may enable other clinical laboratories, hospitals, clinicians, or medical providers to provide specialized diagnostic tests similar to ours in a more patient- friendly, efficient, or cost- effective manner than is currently possible. If we cannot compete successfully against current or future competitors, we may be unable to increase or create market acceptance and sales of our current or planned tests, which could prevent us from increasing or sustaining our revenues or achieving or sustaining profitability. Our competitors may be able to respond more quickly and effectively than we can to new or changing opportunities, technologies, standards, or customer requirements. We anticipate that we will face increased competition in the future as existing companies and competitors develop new or improved products and distribution strategies and as new companies enter the market with new technologies and distribution strategies. We may not be able to compete effectively against these organizations. Our ability to compete successfully and to increase our market share is dependent upon our reputation for providing responsive, professional, and high- quality products and services and achieving strong customer satisfaction. Increased competition in the future could adversely affect our revenue, revenue growth rate, if any, margins and market share. If we are unable to identify collaborators willing to work with us to conduct clinical utility studies, or the results of those studies do not demonstrate that a test provides clinically meaningful information and value, commercial adoption of the DMT may be slow, which would negatively impact our business. We believe clinical utility studies will show how the DermTech Melanoma Test changes the decision- making of the dermatologist when making a surgical biopsy decision, particularly to avoid performing a surgical biopsy when the test is negative. Clinical utility studies also show the impact of the test results on patient care and management. Clinical utility studies are typically performed with collaborating dermatologists at medical centers and hospitals, analogous to a clinical trial, and generally result in peer- reviewed publications. We are currently conducting a variety of clinical trials for the DermTech Melanoma Test and other non- melanoma tests with investigators at multiple sites in the U. S. We will need to conduct additional studies for these tests, as well as other tests we may offer in the future, to drive test adoption in the marketplace and reimbursement. Should we not be able to perform these studies, or should their results not provide clinically meaningful data and value for clinicians, including dermatologists and oncologists, adoption of our existing and planned tests could be impaired and we may not be able to obtain reimbursement for them. We are undergoing a management transition. **We** ~~Since the beginning of 2019, we~~ have ~~added a number~~ **recently experienced turnover in our executive team, with the addition** of **a** new ~~executives. Our management reporting structure may continue to change~~ **CEO and CCO, and the departure of our COO** . Such a management transition subjects us to a number of risks, including risks pertaining to coordination of responsibilities and tasks, creation of new management systems and processes, differences in management style, effects on corporate culture, and the need for transfer of historical knowledge. In addition, our operations will be adversely affected if our management does not work together harmoniously, efficiently allocate responsibilities between themselves, or implement and abide by effective controls. The loss of key members of our executive management team could adversely affect our business. Our success in implementing our business strategy depends largely on the skills, experience, and performance of key members of our executive management team and others in key management positions, including **Bret Christensen** ~~John Dobak, M. D.~~ , the Company' s Chief Executive Officer ~~. The~~ **, as well as their** collective efforts ~~of our executive management team are critical to us as we continue to develop our technologies, tests, and R & D and sales programs~~ . As a result of the difficulty in locating qualified new management, the loss or incapacity of existing members of our executive management team could adversely affect our operations. If we were to lose one or more of these key employees, we could experience difficulties in finding qualified successors, competing effectively, developing our technologies, and implementing our business strategy. Each member of our executive management team has an employment agreement; however, the existence of an employment agreement does not guarantee retention of the members of our executive management team and we may not be able to retain those individuals for the duration of or beyond the end of their respective terms. We do not maintain " key person " life insurance on any of our employees. In addition, we rely on collaborators, consultants, and advisors, including scientific, clinical and payor advisors, to assist us in formulating our commercialization strategy. Our collaborators, consultants, and advisors are generally employed by employers other than us and may have commitments under agreements with other entities that may limit their availability to us. The loss of a key employee, the failure of a key employee to perform in his or her current position, or our inability to attract and retain skilled employees could result in our inability to continue to grow our business or to implement our business strategy. Most of our management has limited experience in operating a public company. Most of our management team has limited experience in the management of a publicly traded company. Our management team may not successfully or effectively manage ~~our transition to~~ operating as a public company that is subject to significant regulatory oversight and reporting obligations under federal securities laws. Our limited experience in dealing with the increasingly complex laws pertaining to public companies could be a significant disadvantage in that it is likely that an increasing amount of our time may be devoted to these activities which will result in less time being devoted to the management and growth of the Company. It is possible that we will be required to expand our employee base and hire additional employees to support our operations as a public company **,** which will increase our operating costs in future periods. There is a scarcity of experienced professionals in our industry. If we are not able to retain and recruit personnel with the requisite technical skills, we may be unable to successfully execute our business strategy. The specialized nature of our industry results in an inherent scarcity of experienced personnel in the field. Our future success depends upon our ability to attract and retain highly skilled personnel, including scientific, technical, laboratory, sales, marketing, business, regulatory, and administrative personnel necessary to support our anticipated growth, develop our business, and perform certain contractual obligations. Given the scarcity of professionals with the scientific knowledge that we require and the competition for qualified personnel among life science businesses, we may not succeed in attracting or retaining the personnel we require to continue and grow our operations. Our inability to attract, hire, and retain a sufficient number of qualified sales professionals would hamper our ability to launch and increase demand for the DMT ~~, to expand geographically, and to successfully commercialize any other tests or products we may develop~~ . To succeed in selling the DMT ~~, and any other tests or products that we are able to develop~~ , we must expand our sales force in the United

States and / or internationally by recruiting sales representatives with extensive experience in dermatology and close relationships with medical dermatologists, dermatopathologists, and other hospital personnel. To achieve our marketing and sales goals, we will need to substantially build our sales and commercial infrastructure, with which to date we have had little experience. Sales professionals with the necessary technical and business qualifications are in high demand, and there is a risk that we may be unable to attract, hire, and retain the number of sales professionals with the right qualifications, scientific backgrounds, and relationships with decision- makers and potential customers needed to achieve our sales goals. We expect to face competition from other companies in our industry, some of whom are much larger than us and who can pay greater compensation and benefits than we can, in seeking to attract and retain qualified sales and marketing employees. If we are unable to hire and retain qualified sales and marketing personnel, our business will suffer. **We may encounter manufacturing problems or delays that could result in lost revenue.** The Smart Stickers specimen collection kits we distribute are produced by a third- party supplier. This contractor assembles several components, including the key adhesive patch trifold, into a finished product, then labels, stores, and ships this finished product **to us** . The adhesive tape subcomponent of the Smart Sticker is provided by a single- source third party. This tape is assembled into the individual Smart Stickers by another third- party supplier. We believe we have arranged for adequate manufacturing capacity for the Smart Sticker through our third- party manufacturer. If demand for the DMT and our planned future tests increases significantly, we will need to either expand manufacturing capabilities through our existing third- party manufacturers or outsource to other manufacturers. If our third-party or other manufacturers engaged by us fail to manufacture and deliver the Smart Sticker or certain reagents in a timely manner for any reason, including as a result of ~~the COVID- 19 pandemic or~~ supply chain failures, or they are unable to fulfil our orders due to regulatory non- compliance or other quality- related issues, our relationships with our customers could be seriously harmed. We cannot assure you that manufacturing or quality control problems will not arise as we attempt to increase the production of the Smart Sticker or that we can increase our manufacturing capabilities and maintain quality control in a timely manner or at commercially reasonable costs. If we cannot have the Smart Sticker manufactured consistently on a timely basis because of these or other factors, it could have a significant negative impact on our ability to perform tests and generate revenues. **If we cannot support demand for the DMT and our planned future tests, including successfully managing the evolution of our technology and manufacturing platforms, our business could suffer.** As the DMT volume grows, we will need to increase the DMT testing capacity, implement automation, increase our scale and related processing, customer service, billing, collection, and systems process improvements, and expand our internal quality assurance program and technology to support testing on a larger scale. We will also need additional technicians, certified laboratory scientists, and other scientific and technical personnel to process these additional tests. Any increases in scale, related improvements and quality assurance may not be successfully implemented and appropriate personnel may not be available. ~~As additional tests are commercialized, we may need to implement new equipment, systems, technology, controls and procedures, and hire personnel with different qualifications.~~ Failure to implement necessary procedures or to hire the necessary personnel could result in a higher cost of processing or an inability to meet market demand. We cannot assure you that we will be able to perform tests on a timely basis at a level consistent with demand, that our efforts to scale our commercial operations will not negatively affect the quality of the DMT results or that we will respond successfully to the growing complexity of the DMT testing operations. If we encounter difficulty meeting market demand or quality standards for the DMT ~~and our planned future tests~~ , our reputation could be harmed and our future prospects and business could suffer, which may have a material adverse effect on our financial condition, results of operations, and cash flows. If we were to be sued for product liability or professional liability, we could face substantial liabilities that exceed our resources. The marketing, sale, and use of the DMT ~~and our planned future diagnostic tests~~ could lead to the filing of product liability claims against us if someone alleges that our tests failed to perform as designed. We may also be subject to liability for errors in the test results we provide to clinicians or for a misunderstanding of, or inappropriate reliance upon, the information we provide. A product liability or professional liability claim could result in substantial damages and be costly and time- consuming for us to defend. Although we believe that our existing product and professional liability insurance is adequate, our insurance may not fully protect us from the financial impact of defending against product liability or professional liability claims. Any product liability or professional liability claim brought against us, with or without merit, could increase our insurance rates or prevent us from securing insurance coverage in the future. Additionally, any product liability lawsuit could damage our reputation, result in the recall of tests, or cause current partners to terminate existing agreements and potential partners to seek other partners, any of which could impact our results of operations. If we use biological and hazardous materials in a manner that causes injury or violates laws or regulations, we could be liable for damages or subject to enforcement actions. Our activities currently require the controlled use of potentially harmful biological and hazardous materials and chemicals. We cannot eliminate the risk of accidental contamination or injury to employees or third parties from the use, storage, handling or disposal of these materials. In the event of contamination or injury, we could be held liable for any resulting damages, and any liability could exceed our resources or any applicable insurance coverage we may have. Additionally, we are subject to, on an ongoing basis, federal, state, and local laws and regulations governing the use, storage, handling, and disposal of these materials and specified waste products. The cost of compliance with these laws and regulations may become significant and could have a material adverse effect on our financial condition, results of operations and cash flows. In the event of an accident or if we otherwise fail to comply with applicable regulations, we could lose our permits or approvals or be held liable for damages or penalized with fines. As part of our business strategy, we may pursue acquisitions of businesses and assets. We also may pursue strategic alliances and joint ventures that leverage our core technology and industry experience to expand our offerings or distribution. We have no experience with acquiring other companies and limited experience with forming strategic alliances and joint ventures. We may not be able to find suitable partners or acquisition candidates, and we may not be able to complete such transactions on favorable terms, if at all. If we make any acquisitions, we may not be able to integrate these acquisitions successfully into our existing business, and we could assume unknown or

contingent liabilities. Any future acquisitions also could result in significant write- offs or the incurrence of debt and contingent liabilities, any of which could have a material adverse effect on our financial condition, results of operations and cash flows. Integration of an acquired company also may disrupt ongoing operations and require management resources that would otherwise focus on developing our existing business. We may experience losses related to investments in other companies, which could have a material negative effect on our results of operations. We may not identify or complete these transactions in a timely manner, on a cost- effective basis, or at all, and we may not realize the anticipated benefits of any acquisition, technology license, strategic alliance, or joint venture. To finance any acquisitions or joint ventures, we may choose to issue shares of our common stock as consideration, which would dilute the ownership of our stockholders. If the price of our common stock is low or volatile, we may not be able to acquire other companies or fund a joint venture project using our stock as consideration. Alternatively, it may be necessary for us to raise additional funds for acquisitions through public or private financings. Additional funds may not be available on terms that are favorable to us, or at all. Our business strategy contemplates possible international expansion, including partnering with academic and commercial testing laboratories, and introducing the DermTech Melanoma Test ~~or other future products~~ outside the United States and exporting the Smart Sticker ~~. We are currently testing samples through a distributor in Canada~~. Doing business internationally involves a number of risks, including: • multiple, conflicting, and changing laws and regulations such as tax laws, export and import restrictions, privacy, data security and data transfer laws, employment laws, intellectual property laws, regulatory requirements, and other governmental approvals, permits and licenses; • failure by us or our distributors to obtain regulatory approvals for the sale or use of the DMT and our planned future tests in various countries, if required; • difficulties in managing foreign operations; • complexities associated with managing government payor systems, multiple payor- reimbursement regimes, or self- pay systems; • logistics and regulations associated with shipping blood samples, including infrastructure conditions and transportation delays; • limits on our ability to penetrate international markets if the DMT and our planned future diagnostic tests cannot be processed by an appropriately qualified local laboratory; • financial risks, such as longer payment cycles, difficulty enforcing contracts and collecting accounts receivable and exposure to foreign currency exchange rate fluctuations; • reduced protection for intellectual property rights, or lack of them in certain jurisdictions, forcing more reliance on any trade secrets we may have, if such protection is available; • natural or man- made disasters, political and economic instability, including wars, terrorism and political unrest, outbreak of disease ~~(such as the COVID - 19 pandemic)~~, boycotts, curtailment of trade, and other business restrictions; and • failure to comply with the Foreign Corrupt Practices Act, including its books and records provisions and its anti- bribery provisions, by maintaining accurate information and control over sales activities and distributors' activities, as well as similar foreign anti-bribery and anti- corruption laws that may become applicable to our business. Any of these risks, if encountered, could significantly harm our future international expansion and operations and, consequently, have a material adverse effect on our financial condition, results of operations, and cash flows. ~~Intrusions into~~ **Cybersecurity incidents, cyberattacks and** ~~the~~ **other information technology failures** ~~computer systems that we use~~ could result in **loss of data,** compromise of confidential information and **adverse effects to our business, financial results and** our ability to continue operations ~~(in event of a cyber-attack)~~. Despite the implementation of security measures, our **information** technology ~~or~~ **and** systems ~~that we interface with~~, including the Internet and related systems, may be **damaged** ~~vulnerable to physical break- ins~~, **disrupted or shut down due to cybersecurity attacks that are material and adverse to our business and operations, which are often carried out by experienced programmers or** hackers, **which** ~~improper employee or contractor access, computer viruses, programming errors, or similar problems. Any of these might result in confidential medical, business, or payment information, including as~~ may be ~~disclosed~~ **able to penetrate our security. Cyberattacks include deployment of harmful malware and key loggers, ransomware, a denial- of- service attack, a malicious website and the use of other means to affect the confidentiality, integrity and availability of our technology systems and data. Cyberattacks may also be due to employee error or malfeasance, power outages, hardware failures, telecommunication or utility failures, catastrophes or other unforeseen events, and our system redundancy and other disaster recovery planning may be ineffective or inadequate in preventing or responding to any of these circumstances. Techniques used in cybersecurity attacks to obtain unauthorized access, disable or sabotage information technology systems are evolving rapidly and cybersecurity events are becoming more prevalent. Any compromise of our information technology systems could result in the unauthorized access to, or acquisition or publication of our confidential business or proprietary information, patient, supplier or employee data, or other personal data or trade secrets information that are material and adverse to our business and operations and could expose us to legal claims or proceedings, liability under privacy or other laws, disruption of our operations and damage to our reputation, which could divert our management' s attention from the operation of our business and materially and adversely affect our business, revenues, and competitive position. In addition, our liability insurance may not be sufficient in type or amount to cover us against claims related to security incidents, cyberattacks, and other related cybersecurity incidents. The cost and operational consequences of implementing further data protection measures, either** as ~~part of~~ a ~~credit card transaction~~ **response to specific cybersecurity incidents or as a result of evolving risks** , **could be material. In addition,** ~~or~~ **our** ~~other~~ **inability to use or access our** information ~~of~~ **systems at critical points in time could adversely affect** ~~other~~ -- **the** ~~persons~~ **timely and efficient operation of** ~~or~~ **our business** ~~of us, including employees, being revealed to unauthorized persons. Additional use of remote working technology as a result of the COVID - 19 pandemic may increase these vulnerabilities~~. If the security measures with respect to our telemedicine solution or the telemedicine platforms of third- party vendors that offer one or more of our tests fail or are breached, it could result in unauthorized persons accessing sensitive customer or patient data (including PHI), a loss of or damage to our data, an inability to access data sources, or process data or provide our services to our customers **in a manner material to our business. In addition to risks affecting our own systems, we could also be negatively impacted by a security incident impacting a third party' s network and affecting us, such as our third- party vendors and service providers. In the event that these third parties do not adequately safeguard**

our data, cybersecurity incidents could result and negatively impact our business, operations and financial results . Such failures or breaches of our or our third- party vendors' security measures, or our or our third- party vendors' inability to effectively resolve such failures or breaches in a timely manner, could ~~severely~~ damage our reputation **in a manner material to our business** , adversely affect customer or investor confidence in us, and reduce the demand for our services from existing and potential customers. In addition, we could face litigation, damages for contract breach, monetary penalties, or regulatory actions for violation of applicable laws or regulations, and incur significant costs for remedial measures to prevent future occurrences and mitigate past violations **that materially and adversely affect our business** . We may have to comply with laws governing the use and disclosure of genetic testing information. Many states have adopted laws governing genetic testing and the use and disclosure of genetic test results. These laws impose specific testing consent requirements and patient authorization requirements for the use and disclosure of test results, and some impose limits on the retention and secondary use of patient samples. Many of these laws are vaguely written and some are overly broad. We must analyze and ensure compliance with the genetic testing laws in the jurisdictions from which we obtain samples and may be required to expend significant capital and other resources to ensure ongoing compliance. Our failure to comply could interfere with our ability to operate and / or lead to sanctions, fines, or other regulatory actions as well as civil claims. We depend on our information technology and telecommunications systems, and any failure of these systems could harm our business. We depend on information technology and telecommunications systems for significant aspects of our operations ~~, including technology and telecommunications systems for the operation of our telehealth platforms~~ . In addition, our third- party billing and collections provider depends upon telecommunications and data systems provided by outside vendors and information we provide on a regular basis. These information technology and telecommunications systems support a variety of functions, including test processing, sample tracking, quality control, customer service and support, billing and reimbursement, R & D activities, and our general and administrative activities. Information technology and telecommunications systems are vulnerable to damage from a variety of sources, including telecommunications or network failures, malicious human acts, and natural disasters. Moreover, despite network security and back- up measures, some of our servers are potentially vulnerable to physical or electronic break- ins, computer viruses, and similar disruptive problems. Despite the precautionary measures we have taken to prevent unanticipated problems that could affect our information technology and telecommunications systems, failures or significant downtime of our information technology or telecommunications systems, or those used by our third- party service providers could prevent us from processing tests, providing test results to oncologists, pathologists, billing payors, processing reimbursement appeals, handling patient or clinician inquiries, conducting R & D activities, and managing the administrative aspects of our business **such that our business is materially and adversely harmed** . Any disruption or loss of information technology or telecommunications systems on which critical aspects of our operations depend could have a material effect on our business, financial condition, results of operations and cash flows. We rely on FedEx and UPS for the distribution of our Smart Stickers to customers and to transport specimens back to our laboratory facility and, if FedEx or UPS incurs any damage to their facilities **, labor strike** or **inability** ~~is unable~~ to deliver our products as needed, it could have a material **and** adverse effect on our results of operations and business. We rely on FedEx and UPS for the distribution of our Smart Stickers to customers, as well as to transport patient specimens back to our laboratory facility for processing. The FedEx or UPS facilities involved in such distribution may be harmed or rendered inoperable by natural or man- made disasters, including earthquakes, power outages, communications failure, infectious disease outbreaks, severe weather, or terrorism. Any material destruction to their facilities could adversely affect the ability of FedEx or UPS to meet the needs of our customers. In addition, a disruption or slowdown in the operations of FedEx or UPS, including as a result of ~~the COVID - 19 pandemic and restrictions on business activity,~~ damage to the facilities of FedEx or UPS or a strike by FedEx or UPS employees, could cause delays in our ability to fulfill customer orders and may cause orders to be cancelled, lost, or delivered late, our shipments to be returned, or receipt of shipments to be refused, any of which could adversely affect our business and our results of operations. If our shipping costs were to increase as a result of an increase by FedEx or UPS or as a result of obtaining a new third- party logistics company and if we are unable to pass on these higher costs to our customers, it could have a material adverse effect on our results of operations and business, financial condition, results of operations and cash flows. ~~Changes~~ **We may fail to achieve the expected cost savings and related benefits from our Restructuring Plans. On June 26, 2023, our board of directors approved certain restructuring actions (the" 2023 Restructuring Plan ") intended to prioritize the significant growth opportunities for the DMT, streamline operations, suspend pipeline programs and significantly reduce overall operating expenses. The 2023 Restructuring Plan primarily relates to sales, marketing and G & A functions and resulted** in ~~health~~ **a workforce reduction of approximately 15 % of the Company' s workforce. As part of the 2023 Restructuring Plan, the Company incurred one- time charges of $ 2. 1 million in the second quarter of 2023. The one- time charges consist primarily of severance payments, employee benefits, and stock- based compensation for the acceleration of share- based awards. On January 29, 2024, our board of directors approved certain restructuring actions (the " 2024 Restructuring Plan " and, together with the 2023 Restructuring Plan, the " Restructuring Plans ") to continue to align the Company' s resources with its previously announced strategic prioritization for the DMT. The restructuring includes operating expense reductions and a reduction in force. The 2024 Restructuring Plan primarily affected operations, but impacted the entire organization, and resulted in a workforce reduction of approximately 30 employees, or approximately 15 % of the Company' s workforce. The Company expects to achieve approximately $ 40 million in total operating expense reductions compared to fiscal 2022, from the aggregate of the Restructuring Plans. The Company estimates that it will incur aggregate pre- tax charges of approximately $ 1. 3 million in connection with the 2024 Restructuring Plan, primarily consisting of severance payments, employee benefits, outplacement services and related costs. The Company expects that the 2024 Restructuring Plan will be complete by the end of March 2024 and that these one- time charges will be incurred in the first quarter of 2024. There is no guarantee that the Restructuring Plans will achieve their intended benefits. For example, the**

Company' s cost restructuring efforts may not result in the anticipated savings or other economic benefits, or could result in total costs and expenses that ~~care~~ **are** ~~law~~ **greater than expected. In addition, the Company may not be able to effectively realize all the cost savings anticipated by the Restructuring Plans and may incur termination and other costs not previously contemplated, which could be material. The Restructuring Plans may cause disruption to the Company' s business operations. For example, the Restructuring Plans resulted in the loss of a number of long- term employees, which could result in the loss of institutional knowledge and expertise and the reallocation and combination of certain roles and responsibilities across the organization, all of which could adversely affect the Company' s operations. In addition, the Restructuring Plans could negatively impact the Company' s ability to attract, integrate, retain, and motivate key employees. Inflation may adversely affect us by materially increasing our costs. Recently, inflation has increased throughout the U. S. economy. Inflation can adversely affect us by materially increasing the costs of our suppliers, manufacturers, and other costs of doing business. We may experience material increases in the prices of labor. In** ~~and~~ **an** ~~policy~~ **inflationary environment, cost increases may materially outpace our expectations, causing us to use our cash and other liquid assets faster than forecasted. If this happens, we may need to raise additional capital to fund our operations, which may not be available in sufficient amounts or on reasonable terms, if at all, sooner than expected. Political uncertainty** may have **an** ~~a material~~ adverse ~~effect~~ **impact** on our **operating performance and results of operations. General political uncertainty may have an adverse impact on our operating performance and results of operations. In particular, the United States continues to experience significant political events that cast uncertainty on global** financial **and economic markets, especially in light of the upcoming presidential election. It is presently unclear exactly what actions the new administration in the United States will implement, and if implemented, how these actions may impact the pharmaceutical and diagnostics industries in the United States. Any actions taken by a new U. S. administration may have a negative impact on the United States economies and on our business, financial** ~~condition~~ **conditions** , **and** results of operations ~~, and cash flows~~ . In March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act (collectively, the " ACA "), became law. This law substantially changed the way health care is financed by both governmental and commercial payors, and continues to significantly impact our industry. ~~Since its enactment, there have been judicial and Congressional challenges to certain aspects of the ACA, and as a result, certain sections of the ACA have not been fully implemented or were effectively repealed. However, following several years of litigation in the federal courts, in June 2021, the United States Supreme Court upheld the ACA when it dismissed a legal challenge to the Act' s constitutionality. Further legislative and regulatory changes under the ACA remain possible it is unknown what form any such changes or any law would take, and how or whether it may affect the medical device industry as a whole or our business in the future.~~ Future changes or additions to the ACA, the Medicare and Medicaid programs, and changes stemming from other health care reform measures, especially with regard to health care access, financing or other legislation in individual states, could have a material adverse effect on the health care industry in the U. S. The uncertainty around the future of the ACA, and in particular the impact to reimbursement levels and the number of insured individuals, may lead to delay in the purchasing decisions of our customers, which may in turn negatively impact our product sales. Further, if reimbursement levels are inadequate, our business and results of operations could be adversely affected. In ~~addition~~ **April 2014, Congress passed PAMA, which included substantial changes** to **the way in which clinical laboratory services are be paid under Medicare Clinical Laboratory Fee Schedule. Under PAMA, certain clinical laboratories are required to periodically report to CMS private payor payment rates and volumes for** ~~the~~ **their** ~~ACA~~ **tests** , **and laboratories that fail to report the required payment information may be subject to substantial civil monetary penalties. Medicare reimbursement for clinical laboratory diagnostic tests is based on the weighted- median of the payments made by private payors for these tests, rendering private payor payment levels even more significant than in the past. As a result, future Medicare payments may fluctuate more often and become subject to the willingness of private payors to recognize the value of diagnostic tests generally and any given test individually. The impact of this payment system on rates for our tests, including any current or future tests we may develop, is uncertain. Additionally, state legislatures have increasingly passed legislation and implemented regulations designed to control the cost of health care services, including clinical laboratory and pathology services. States may pursue a variety of strategies to control spending growth, including but not limited to promoting competition, reducing prices through regulation, imposing spending targets and promoting payment reform. These cost containment strategies may result in less favorable reimbursement rates and in some cases could negatively impact our ability to change or expand our operations in certain states. Further, the impact on our business of the expansion of the federal and state governments' role in the U. S. health care industry generally, including the social, governmental and other pressures to reduce health care costs while expanding individual benefits, is uncertain. We expect that** there will continue to be proposals by legislators and regulators at both the federal and state levels, as well as by commercial payors to reduce costs while expanding individual health care benefits. Certain of these changes could impose additional limitations on the prices we will be able to charge for the DMT or the amounts of reimbursement available for the DMT from governmental or commercial payors. Any future changes to legal or regulatory requirements or new cost containment initiatives could have a materially adverse effect on our business, financial condition, results of operation, and cash flows. Our business could be adversely impacted by our failure or the failure of clinicians to comply with the ICD- 10- CM Code Set. Compliance with ICD- 10- CM is required for all claims with dates of service on or after October 1, 2015. We believe we have fully implemented ICD- 10- CM. However, our failure to effectively implement and apply the new code set could adversely impact our business. In addition, if clinicians fail to provide appropriate codes for desired tests, we may not be reimbursed for tests we perform. Billing for clinical laboratory testing services is complex, time- consuming, and expensive. Depending on the billing arrangement and applicable law, we will bill various payors, including Medicare, Medicaid, and commercial payors, all of which have different billing requirements. As required by law or contract, we routinely bill patients

for co- payments, co- insurance, and deductible amounts owed. We may also face increased risks in our collection efforts, including potential write- offs of doubtful accounts, long collection cycles, and failure by third parties to properly process payment of claims in a timely manner that could adversely affect our business, results of operations, and financial condition. Several factors make the billing practice complex, including: • differences between the list price for the DMT and the reimbursement rates of payors; • compliance with complex federal regulations related to Medicare billing; • disputes among payors as to which party is responsible for payment and resistance by patients to cover any substantial amount of the payment; • differences in coverage among payors and effect of patient co- payments, co- insurance, or deductibles; • differences in information and billing requirements among payors; • incorrect or missing billing information; and • the resources required to manage the billing and claims appeals process. Additionally, our billing activities require us to implement compliance procedures and oversight, train and monitor our employees, challenge coverage and payment denials, assist patients in appealing claims, and undertake internal audits to evaluate compliance with applicable laws and regulations as well as internal compliance policies and procedures. Payors also conduct external audits to evaluate payments and may seek refunds depending on the audit results, which adds further complexity to the billing process. Failure to comply with these billing requirements may result in non- payment, refunds, exclusion from government healthcare programs, and civil or criminal liabilities, any of which may have a material adverse effect on our revenues and earnings. These billing complexities and the related uncertainties in obtaining reimbursement could negatively affect our cash flow and our ability to achieve profitability. The diagnostic testing industry is subject to extensive laws and regulations, many of which have not been interpreted by the courts. CLIA requires virtually all laboratories to be certified by the federal government and mandates compliance with various operational, personnel, facilities administration, quality, and proficiency testing requirements intended to ensure that testing services are accurate, reliable, and timely. Our clinical laboratory must be certified under CLIA in order for us to perform testing on human specimens **for diagnostic purposes** . CLIA certification is also a prerequisite to be eligible to bill state and federal health care programs as well as commercial payors. Further, many commercial payors require ~~CAP~~ **CLIA certification as well as** accreditation **from specific accrediting organizations** as a condition to contracting with clinical laboratories to cover their tests ~~. In addition, some countries outside the United States require CLIA certification and / or CAP accreditation as a condition to permitting clinical laboratories to test samples taken from their citizens~~ . We have a current CLIA certificate of accreditation from the CMS to perform high- complexity testing and a state license issued by California **' s Department of Public Health,** Laboratory Field Services ~~(" CA LFS ")~~ . To renew our CLIA certificate, we are subject to survey and inspection every two years. We hold ~~a certificate~~ **certificates** of accreditation **from** ~~because we are accredited by~~ CAP **and JCO** , which ~~has~~ **have each** been granted deeming authority by CMS. CAP ~~is an~~ **and JCO are** independent, non- governmental organization ~~of board- certified pathologists~~ that ~~accredits~~ - **accredit** laboratories nationwide on a voluntary basis. ~~Because~~ **Our laboratory must comply with all CLIA requirements as well as with any additional requirements imposed by an accrediting organization. As a condition of CLIA certification, we are subject to surveys and inspections by our designated accrediting organization every other year, in addition to being subject to unannounced inspections. In mid- February 2024, we received a notification from** CAP ~~has deemed status~~ **that our accreditation** with ~~CLIA, our biennial inspections are performed by~~ CAP **would not be renewed on its renewal date, and thus would terminate as of April 6, 2024. The notice did not provide a specific reason for this decision. We designated JCO as our primary accrediting organization, effective February 29, 2024** . Sanctions for failure to comply with ~~CAP~~ **accreditation organization** or CLIA requirements may include suspension, revocation, or limitation of a laboratory' s CLIA certificate, which is necessary to conduct business, as well as the imposition of significant fines or criminal penalties. In addition, we are subject to regulation under state laws and regulations governing laboratory licensure. Two states, one of which is New York, have enacted state licensure laws that are more stringent than CLIA. Failure to maintain CLIA certification, ~~CAP~~ accreditation **organization certification** , or required state licenses could have a material adverse effect on the sales of the DMT and the results of our operations. **As noted above, CAP elected to not renew and thus terminate our accreditation status effective April 6, 2024.** If ~~we~~ **JCO** were to ~~lose~~ **terminate its accreditation with us for any reason, we may not again be able to attain CAP accreditation or accreditation from any other organization or obtain CAP accreditation or accreditation from another organization on a timely basis. To retain** our CLIA certification, ~~CAP~~ **we must have at least one certificate of** accreditation **from an accrediting organization or, in the absence of a certificate of accreditation, obtain a CLIA certificate of compliance from the California Department of Public Health. If we were to lose our CLIA certification** or California laboratory license, whether as a result of a revocation, suspension, or limitation, we would no longer be able to offer the DMT or any other testing, which would limit our revenues and harm our business **or cause us to cease operations entirely** . If we were to lose our license in any other state where we are required to hold a license, we would not be able to test specimens from those states. In addition, state and foreign requirements for laboratory certification may be costly or difficult to meet and could affect our ability to receive specimens from certain states or foreign countries. We receive specimens from all 50 U. S. states and certain provinces in Canada. Some states maintain independent licensure, registration, or certification procedures that apply to out- of- state laboratories with which we must maintain compliance in order to receive and test samples from those states. Maintaining compliance with the myriad state and foreign requirements is time consuming and resource intensive and failure to maintain compliance could result in sanctions. Any sanction imposed under CLIA, its implementing regulations, or state or foreign laws or regulations governing licensure, or our failure to renew a CLIA **certificate, accreditation organization** certificate, a state or foreign license, or accreditation, could have a material adverse effect on our business, financial condition, results of operations and cash flows. If the CLIA certificate of our laboratory is revoked, that could also impact our licensure or certification in the states or in foreign jurisdictions. If the FDA were to begin requiring approval or clearance of the DMT and our planned future tests, or our proprietary specimen collection kit, we could incur substantial costs and time delays associated with meeting requirements for premarket clearance or approval. The laws and regulations governing the marketing of diagnostic products are evolving, extremely complex and in

many instances, there are no significant regulatory or judicial interpretations of these laws and regulations. Pursuant to its authority under the federal Food, Drug, and Cosmetic Act (“ FDCA ”), the FDA has jurisdiction over medical devices, including in vitro diagnostics and, therefore, our clinical laboratory tests; however, we believe our laboratory tests qualify as LDTs, which are currently subject to the FDA’ s enforcement discretion. Among other things, pursuant to the FDCA and its implementing regulations, the FDA regulates the research, testing, manufacturing, safety, labeling, storage, recordkeeping, premarket clearance or approval, marketing and promotion, and sales and distribution of medical devices in the United States to ensure that medical products distributed domestically are safe and effective for their intended uses. Although the FDA has asserted that it has authority to regulate the development and use of LDTs, such as our and many other laboratories’ tests, as medical devices, it has generally exercised enforcement discretion and has not otherwise enforced device regulatory requirements for most LDTs, which are designed, manufactured and performed within a single high **-** complexity CLIA- certified laboratory. We believe that our tests, as utilized in our clinical laboratory **.** meet the requirements for classification as LDTs **at this time** . As a result, we believe that we are not required to obtain regulatory clearances or approvals from the FDA for our LDTs **. However, in October 2023, the FDA issued a proposed rule aimed at regulating LDTs under the current medical device framework and proposing to phase out its existing enforcement discretion policy for this category of diagnostic tests. The agency’ s proposal envisions that the LDT enforcement policy phase- out process would occur in gradual stages over a total period of four years, with premarket approval applications for high- risk tests to be submitted by the 3. 5- year mark, although more details are expected to be provided with the upcoming final rule. The likelihood of the FDA finalizing the proposed rule in April 2024 (as currently projected), as well as potential litigation challenging the agency’ s authority to take such action, is uncertain at this time. Affected stakeholders continue to press for a comprehensive legislative solution to create a harmonized paradigm for oversight of LDTs by both the FDA and CMS, instead of implementation of the proposed FDA administrative action, which may be disruptive to the industry and to patient access to certain diagnostic tests** . In addition, we believe the Smart Sticker we provide for collection and transport of skin samples from a health care provider (or in our **available** ~~recently launched~~ telemedicine option, from the patient directly) to our clinical laboratory is considered a Class I medical device subject to the FDA’ s general device controls but exempt from premarket review. However, the FDA could assert the Smart Sticker is non- exempt or is a Class II or III device, which would subject it to premarket clearance or approval requirements, which could be time- consuming and expensive. While we believe that we are currently in material compliance with applicable laws and regulations, we cannot assure you that the FDA, or other regulatory agencies, would agree with our determinations. Any determination by the government that we have violated the FDCA or any FDA regulations, or a public announcement that we are being investigated for possible violations of these laws or regulations, could adversely affect our business, prospects, results of operations, or financial condition. Even though we **presently** commercialize the DMT as an LDT, the DMT may in the future become subject to more onerous regulation by the FDA. For example, **the FDA may disagree with our assessment that our test falls within the definition of an LDT and seek to regulate it as a medical device, or the proposed rule to regulate LDTs as medical devices may be finalized and implemented by the agency. Separately, members of** Congress ~~has~~ **have** been working for the past several years on legislation to create an LDT and IVD regulatory framework that would be separate and distinct from the existing medical device regulatory framework. ~~Most recently~~ **For example** , ~~legislation called~~ **as drafted and re- introduced for consideration by the current Congress,** the Verifying Accurate, Leading- edge IVCT Development Act, or VALID Act, ~~has been garnering bipartisan and bicameral support.. The VALID Act~~ would codify into law the term “ in vitro clinical test, ” or IVCT, to create a new medical product category separate from medical device that includes all products currently regulated as IVDs as well as LDTs ~~, and bring all such products within the scope of FDA’ s oversight~~ . The VALID Act would also create a new system for labs and hospitals to use to submit their tests electronically to the FDA for approval, which is aimed at reducing the amount of time it takes for the agency to approve such tests, and establish a new program to expedite the development of diagnostic tests that can be used to address a current unmet need for patients. **It is unclear whether the VALID Act would be passed by Congress in its current form or signed into law by President Biden. Until the FDA finalizes LDT regulations through the ongoing notice- and- comment rulemaking process, or the VALID Act or other legislation is passed reforming the federal government’ s regulation of LDTs, it is unknown how the FDA may regulate our tests in the future and what testing and data may be required to support any required clearance or approval.** Whether as a result of new legislative authority or following formal notice- and- comment rulemaking, if the FDA begins to enforce ~~its~~ **new** regulatory requirements for LDTs, or if the FDA disagrees with our assessment that the DMT is an LDT, the DMT could for the first time be subject to a variety of regulatory requirements, including registration and listing, medical device reporting, and quality control ~~, and we~~ **. We also** could be required to obtain premarket clearance or approval for our existing test and any new tests we are developing or may develop, which may force us to cease marketing the DMT until we obtain the required clearance or approval. The premarket review process for diagnostic products can be lengthy, expensive, time- consuming, and unpredictable. Further, obtaining premarket clearance or approval may involve, among other things, successfully completing clinical trials. Clinical trials require significant time and cash resources and are subject to a high degree of risk, including risks of experiencing delays, failing to complete the trial or obtaining unexpected or negative results. If we are required to obtain premarket clearance or approval and / or conduct premarket clinical trials, our development costs could significantly increase, our introduction of any new tests we may develop may be delayed, and sales of our existing test could be interrupted or stopped. Any of these outcomes could reduce our revenue or increase our costs and materially adversely affect our business, prospects, results of operations, or financial condition. Moreover, any cleared or approved labeling claims may not be consistent with our current claims or adequate to support continued adoption of and reimbursement for the DMT. For instance, if we are required by the FDA to label the DMT as investigational, or if labeling claims the FDA allows us to make are limited, order levels may decline and reimbursement may be adversely affected. As a result, we could experience significantly increased development costs and a delay in generating

additional revenue from our existing test or from tests we may develop. Until the FDA finalizes its regulatory position regarding LDTs, or federal legislation is passed concerning regulation of LDTs, it is unknown how the FDA may regulate the DMT in the future and what testing and data may be required to support any required clearance or approval as a medical device or an " in vitro clinical test " (as that category is being defined in the as - introduced VALID Act). The requirement of premarket review could negatively affect our business until such review is completed and regulatory clearance or approval is obtained. The FDA could require that we stop selling the DMT pending premarket clearance or approval. The regulatory authorization process may involve, among other things, successfully completing additional clinical trials and making a premarket submission, such as a 510 (k) notification, a premarket approval **application** (" PMA "), ~~application~~ or a de novo device classification request to the FDA. If the FDA requires any form of premarket review, the DMT may not be cleared or approved on a timely basis, if at all. We may also decide voluntarily to pursue FDA premarket review and authorization of the DMT if we determine that doing so would be appropriate. Additionally, should future regulatory actions affect any of the reagents we obtain from suppliers and use in conducting the DMT, our business could be adversely affected in the form of increased costs of testing or delays, limits, or prohibitions on the purchase of reagents necessary to perform DMT testing. While we qualify all materials used in our products in accordance with the regulations and guidelines of CLIA, the FDA could promulgate regulations or **issue** guidance ~~documents~~ **for industry that may** ~~impacting~~ --- **impact** our ability to purchase materials necessary for the performance of the DMT. If any of the reagents we obtain from suppliers and use in the DMT are affected by future regulatory actions, our business could be adversely affected, including by increasing the cost of testing or delaying, limiting, or prohibiting the purchase of reagents necessary to perform testing with our products ~~. The COVID- 19 pandemic and high demand for laboratory testing services may also have an impact on the supply chain for such reagents and other supplies and cause an adverse effect on our business~~. Failure to comply with any applicable FDA requirements could trigger a range of enforcement actions by the FDA, including **but not limited to** warning letters, civil monetary penalties, injunctions, criminal prosecution, recall or seizure, operating restrictions, partial suspension or total shutdown of operations and denial of or challenges to applications for clearance or approval, as well as significant adverse publicity. If we were to be required by the FDA to conduct additional clinical studies ~~or trials~~ before continuing to offer tests that we have developed or may develop as LDTs, those studies ~~or trials~~ could lead to delays or failure to obtain necessary regulatory clearance or approval, which could cause significant delays in commercializing any future products and harm our ability to achieve profitability. If the FDA decides to require that we obtain 510 (k) clearance, premarket approvals pursuant to a PMA, or any other type of premarket authorization in order for us to commercialize our current **DMT** ~~Melanoma Test~~ or our planned future tests, whether as a result of new legislative authority or following **finalization** ~~formal notice~~ and ~~- comment rulemaking~~ **implementation of the October 2023 proposed rule** or based on its determination that any of those tests does not meet the definition of an LDT, we may be required to conduct additional clinical testing before submitting a regulatory submission for commercial marketing authorization. In addition, as part of our long- term strategy we may plan to seek FDA clearance or approval for certain genomic tests in order to permit them to be offered by other clinical laboratories in addition to our own; however, we would need to conduct additional clinical validation activities on the DMT before we could submit an application for FDA approval or clearance. Clinical trials to support marketing authorization from the FDA must be conducted in compliance with **various** ~~regulations~~ - **regulatory requirements**, including investigational device exemption regulations and good clinical ~~practice~~ **practices** ~~regulations~~, or else the FDA may take certain enforcement actions or reject the data. We believe it would likely take two years or more to conduct the clinical studies ~~and trials~~ necessary to obtain approval from the FDA to commercially launch the DMT and our planned future tests outside of our clinical laboratory. Even if clinical trials are completed as planned, we cannot be certain that their results would be able to support the DMT claims or that the FDA or foreign authorities will agree with our conclusions regarding the results of our clinical trials. 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 clinical trials to support a premarket submission to the FDA, whether using prospectively acquired samples or archival samples, delays in the commencement or completion of clinical testing could significantly increase the development costs for the DMT or our planned future tests 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 commencement of clinical trials may be delayed due to insufficient patient enrollment, which is a function of many factors, including the size of the patient population, the nature of the protocol, the proximity of patients to clinical sites and the eligibility criteria for the clinical trial. Moreover, the clinical trial process may fail to demonstrate that the DMT and our planned future tests are effective for the proposed indications for use, which could cause us to abandon a test candidate and may delay development of other tests. We may find it necessary to engage contract research organizations to perform data collection and analysis and other aspects of our clinical trials, which would increase the cost and complexity of our trials. We would also depend on clinical investigators, medical institutions, and contract research organizations to perform the trials properly. If these **third** parties do not successfully carry out their contractual duties or obligations or meet expected deadlines, or if the quality, completeness, or accuracy of the ~~clinical~~ data **or results** they obtain is compromised due to the failure to adhere to our clinical protocols or applicable regulations or for other reasons, our clinical trials may have to be extended, delayed or terminated. Many of these factors would be beyond our control. We may not be able to enter into replacement arrangements without undue delays or considerable expenditures. If there are delays in **clinical** testing or **human research** approvals as a result of the failure to perform by third parties, our R & D costs would increase, and we may not be able to obtain regulatory clearance or approval for the DMT or our planned future tests, if needed. In addition, we may not be able to establish or maintain relationships with these **third** parties on favorable terms, if at all. Each of these outcomes would harm our ability to market the DMT outside of the LDT context or to achieve profitability. Our operations are subject to extensive federal, state, local and foreign laws and regulations, all of which are subject to change. These laws and regulations currently include, among other things: • CLIA, which requires that laboratories obtain certification

from the federal government, and state licensure laws; • FDA laws and regulations **, including but not limited to requirements for offering LDTs** ; • HIPAA, which imposes comprehensive federal standards with respect to the privacy and security of ~~protected health information (“~~ PHI ~~”)~~, and requirements for the use of certain standardized electronic transactions; amendments to HIPAA under HITECH, which strengthened and expanded HIPAA privacy and security compliance requirements, increased penalties for violators, extended enforcement authority to state attorneys general and imposed requirements for breach notification; • state laws regulating genetic testing and protecting the privacy of genetic test results, as well as state laws protecting the privacy and security of health information and personal data and mandating reporting of breaches to affected individuals and state regulators; • the federal Anti- Kickback Statute, which prohibits knowingly and willfully offering, paying, soliciting, or receiving remuneration, directly or indirectly, in exchange for or to induce either the referral of an individual, or the furnishing, arranging for, or recommending of an item or service that is reimbursable, in whole or in part, by a federal health care program; • the Eliminating Kickbacks in Recovery Act, which is an all- payor anti- kickback law that makes it a criminal offense to pay any remuneration to induce referrals to, or in exchange for, patients using the services of a recovery home, a substance use clinical treatment facility, or laboratory; • the federal False Claims Act, which imposes liability on any person or entity that, among other things, knowingly presents, or causes to be presented, a false or fraudulent claim for payment to the federal government; • the CMP Law, which prohibits, among other things, the offering or transfer of remuneration to a Medicare or Medicaid beneficiary if the person knows or should know it is likely to influence the beneficiary’ s selection of a particular provider, practitioner, or supplier of services reimbursable by Medicare or Medicaid, unless an exception applies; • other federal and state fraud and abuse laws, such as anti- kickback laws, prohibitions on self- referral, and false claims acts, which may extend to services reimbursable by any commercial payor, including private insurers; • PAMA, which requires applicable laboratories to report commercial payor data in a timely and accurate manner every three years (and in some cases annually); • state laws that impose reporting and other compliance- related requirements; and • similar foreign laws and regulations that apply to us in the countries in which we operate. As a clinical laboratory, our business practices may face heightened scrutiny from government enforcement agencies such as the Department of Justice, the OIG and CMS. The OIG has issued fraud alerts in recent years that identify certain arrangements between clinical laboratories and referring physicians as implicating the Anti-Kickback Statute. The OIG has stated that it is particularly concerned about these types of arrangements because the choice of laboratory, as well as the decision to order laboratory tests, typically are made or strongly influenced by the physician, with little or no input from the patient. Moreover, the provision of payments or other items of value by a clinical laboratory to a referral source could be prohibited under the federal self- referral prohibition, commonly known as the Stark Law or the Physician Self-Referral Law, unless the arrangement meets all criteria of an applicable exception. The government has actively enforced these laws against clinical laboratories in recent years. These laws and regulations are complex and are subject to interpretation by the courts and by government agencies. Our failure to comply could lead to significant civil or criminal penalties, exclusion from participation in state and federal health care programs, individual imprisonment, disgorgement of profits, 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, curtailment or restructuring of our operations, or prohibitions or restrictions on our laboratories’ ability to provide or receive payment for our services, any of which could adversely affect our ability to operate our business and pursue our strategy. We believe that we are in material compliance with all statutory and regulatory requirements, but there is a risk that one or more government agencies could take a contrary position, or that a private party could file suit under the qui tam provisions of the federal False Claims Act or a similar state law. Such occurrences, regardless of their outcome, could damage our reputation and adversely affect important business relationships with third parties, including managed care organizations, and other private commercial payors. The growth of our business and our **future** expansion outside of the United States may increase the potential of violating similar foreign laws or our internal policies and procedures. The risk of us being found in violation of these or other laws and regulations is further increased by the fact that many have not been fully interpreted by the regulatory authorities or the courts, and their provisions are open to a variety of interpretations. Any action brought against us for violation of these or other laws or regulations, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management’ s attention from the operation of our business. Any of the foregoing consequences could seriously harm our business and our financial results. We must comply with complex and overlapping laws protecting the privacy and security of health information and personal data. ~~There are a number of state, federal and international laws protecting the privacy and security of health information and personal data. Under the administrative simplification provisions of HIPAA, the HHS has issued regulations which establish uniform standards governing the conduct of certain electronic health care transactions and protecting the privacy and security of PHI used or disclosed by health care providers and other covered entities.~~ The privacy regulations regulate the use and disclosure of PHI by health **plans, health care clearing houses, and health** care providers engaging in certain electronic transactions ~~or (~~ ~~“~~ **Covered Entities** ~~standard transactions.~~ ~~”~~ **).** They also set forth certain rights that an individual has with respect to his or her PHI maintained by ~~a covered~~ **Covered Entities** ~~health care provider~~, including the right to access or amend certain records containing PHI, request an accounting of PHI disclosures, or to request restrictions on the use or disclosure of PHI. The HIPAA security regulations establish administrative, physical, and technical standards for maintaining the **confidentiality,** integrity and availability of PHI in electronic form. These standards apply to ~~covered~~ **Covered Entities** ~~health care providers~~ and also to “ business associates ” or third parties providing services involving the use or disclosure of PHI. The HIPAA privacy and security regulations establish a uniform federal “ floor ” and do not supersede state laws that are more stringent or provide individuals with greater rights with respect to the privacy or security of, and access to, their records containing PHI and other personal information ~~. For~~ **, for** example, the California Consumer Privacy Act (“ CCPA ”), which became effective January 1, 2020. **The** ~~In addition, the~~ California Privacy Rights Act (“ CPRA ”) **, which amends the CCPA,** went into effect in January of 2023 ~~. The CPRA amends the CCPA significantly~~ and creates new regulatory authority in

California with enforcement powers, resulting in additional **compliance** costs and expenses ~~in an effort to comply~~, and additional potential harm and liability for failure to comply. Other states are enacting similar comprehensive privacy laws, for example Virginia, Colorado, Connecticut, and Utah all enacted new data privacy laws that **took** ~~will take~~ effect throughout 2023 that have similarities to the CCPA and CPRA, but also have significant differences, creating compliance challenges across different jurisdictions. **While there is an exception for protected health information that is subject to HIPAA in the state consumer privacy laws, these laws may impact some business operations if we are covered under such laws. We are a " business " for purposes of the CCPA, and unlike other state privacy laws, the CCPA regulates personal information collected in a business to business and in human resources contexts related to our California employees.** As a result, we **are** ~~will be~~ required to comply with both HIPAA privacy regulations and varying state privacy and security laws. Moreover, **HIPAA as amended by** HITECH ~~, among other things~~, established certain health information security breach notification requirements. In the event of a breach of unsecured PHI, a ~~covered~~ **Covered** ~~entity~~ **Entity** must notify each individual whose PHI is breached, federal regulators and in some cases, must publicize the breach in local or national media. Breaches affecting 500 individuals or more are publicized by federal regulators who publicly identify **via website posting** the breaching entity, the circumstances of the breach and the number of individuals affected. These laws contain significant fines and other penalties for wrongful use or disclosure of PHI. 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. Moreover, these laws and their interpretations may become more stringent or inclusive over time. For example, increasing concerns about health information privacy have recently prompted the federal government to issue guidance taking a newly expansive view of the scope of the laws and regulations that they enforce. Further adding to the complexity is that our operations are evolving and the requirements of these laws will apply differently depending on such things as whether or not we bill electronically for our services, or provide services involving the use or disclosure of PHI and incur compliance obligations as a business associate. The costs of complying with any changes to ~~the~~ HIPAA, HITECH and state privacy **and security** 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 consumer initiated litigation and reputational damage. We also are required to collect and maintain personal information about our employees, and we collect information about customers as part of some of our marketing programs, as well as receive and transfer certain payment information **using a third- party billing vendor** , to accept payments from our customers, including credit card information. Most states have adopted laws requiring notification of affected individuals and state regulators in the event of a breach of personal information, which is a broader class of information than the health information protected by HIPAA. Many state laws impose significant data security requirements, such as encryption or mandatory contractual terms to ensure ongoing protection of personal information **. In addition, many U. S. states are enacting consumer privacy statutes to enhance protections for personal data and to provide residents with more choices concerning their data collected by businesses, increasing compliance complexity and increasing risks of failures to comply** . Activities outside of the United States implicate local and national data protection standards, impose additional compliance requirements, and generate additional risks of enforcement for non-compliance. The collection and use of such information may be subject to contractual obligations as well. If the security and information systems that we or our outsourced third- party providers use to store or process such information are compromised or if we, or such third parties, otherwise fail to comply with these laws, regulations, and contractual obligations, we could face litigation and the imposition of penalties that could adversely affect our financial performance. We must comply with all applicable privacy and data security laws in order to operate our business and may be required to expend significant capital and other resources to ensure ongoing compliance, to protect against security breaches and hackers or to alleviate problems caused by such breaches. Breaches of health information and / or personal data may be extremely expensive to remediate, may prompt federal or state investigation, fines, civil and / or criminal sanctions and significant reputational damage. Our services present the potential for embezzlement, identity theft or other similar illegal behavior by our employees, consultants, service providers or commercial partners. Our operations involve the use and disclosure of personal and business information that could be used to impersonate third parties or otherwise gain access to their data or funds. If any of our employees, consultants, service providers or commercial partners takes, converts or misuses these funds or data, we could be liable for any resulting damages, which could harm our financial condition and damage our business reputation. Clinical research is heavily regulated and failure to comply with human subject protection regulations may disrupt our research program leading to significant expense, regulatory enforcement, private lawsuits, and reputational damage. Clinical research is subject to federal, state, and, for studies conducted outside of the United States, international regulation. At the federal level, HHS imposes regulations for the protection of human subjects and requirements such as initial and ongoing institutional review board review, informed consent requirements, adverse event reporting and other protections to minimize the risk and maximize the benefit to research participants. Clinical studies done under an investigational device exemption for purposes of an anticipated FDA premarket submission are subject to ~~an additional~~ **a separate** layer of human subject protection regulations. Many states also impose human subject protection laws that mirror or in some cases exceed federal requirements **and, in some states, the violation of federal human subject protection regulations constitutes a violation of state law** . HIPAA and other privacy laws also regulate the use and disclosure of PHI in connection with research activities. Research conducted overseas is subject to a variety of national protections such as ethics committee review, informed consent and adverse event reporting, as well as laws regulating the use, disclosure and cross-border transfer of personal data. The costs of compliance with these laws may be significant and compliance with regulatory requirements may result in delay. Noncompliance may disrupt our research and result in data that is unacceptable to regulatory authorities, data lock, or other sanctions that may significantly disrupt our operations. We could be adversely affected by alleged violations of the Federal Trade Commission Act or other truth- in- advertising and consumer protection laws. Our advertising

for laboratory services and tests is subject to federal truth- in- advertising laws enforced by the FTC as well as comparable state consumer protection laws. Under the Federal Trade Commission Act, the FTC is empowered, among other things, to (a) prevent unfair methods of competition and unfair or deceptive acts or practices in or affecting commerce; (b) seek monetary redress and other relief for conduct injurious to consumers; and (c) gather and compile information and conduct investigations relating to the organization, business, practices, and management of entities engaged in commerce. The FTC has very broad enforcement authority, and failure to abide by the substantive requirements of the FTC Act and other consumer protection laws can result in administrative or judicial penalties, including civil penalties, injunctions affecting the manner in which we would be able to market services or products in the future, or criminal prosecution. Our direct- to- consumer advertising and social media presence, as well as our physician- directed advertising, are subject to these federal and state truth- in- advertising laws. Any actual or perceived non- compliance with those laws could lead to an investigation by the FTC or a comparable state agency, or could lead to allegations of misleading advertising by private plaintiffs. Any such action against us would disrupt our business operations, cause damage to our reputation, and result in ~~a~~ material adverse effects on our business, financial condition, results of operation, and cash flows. Medical product manufacturers' use of social media platforms presents new risks. We believe that our customer base and potential patient populations are active on social media and we have begun engaging through those platforms to elevate our national marketing presence. Social media practices in the **diagnostic,** pharmaceutical, biotechnology and medical device industries are evolving, which creates uncertainty and risk of noncompliance with regulations applicable to our business. For example, patients may use social media platforms to comment on the effectiveness of, or adverse experiences with, one of our products, which could result in reporting obligations or the need for us to conduct an investigation. In addition, there is a risk of inappropriate disclosure of sensitive information or negative or inaccurate posts or comments about us or our products on any social networking website. If any of these events were to occur or we otherwise fail to comply with any applicable regulations, we could incur liability, face restrictive regulatory actions or incur other harm to our business. Our collaborators may assert ownership or commercial rights to inventions we develop from our use of the biological materials which they provide to us, or otherwise arising from the collaboration. We collaborate with several institutions, clinicians, and researchers in scientific matters. Also, we rely on numerous third parties to provide us with adhesive patch samples and biological materials that we use to develop tests. If we cannot successfully negotiate sufficient ownership, licensing, and / or commercial rights to any inventions that result from our use of a third- party collaborator' s materials, or if disputes arise with respect to the intellectual property developed with the use of a collaborator' s samples, or data developed in a collaborator' s study, our ability to capitalize on the market potential of these inventions or developments may be limited or precluded altogether. Our ability to protect our discoveries and technologies affects our ability to compete and to achieve profitability. Currently, we rely on a combination of U. S. and foreign patents and patent applications, copyrights, trademarks and trademark applications, confidentiality or non- disclosure agreements, material transfer agreements, licenses, consulting agreements, work- for- hire agreements, and invention assignment agreements to protect our intellectual property rights. We also maintain certain company know- how, trade secrets, and technological innovations designed to provide us with a competitive advantage in the marketplace as trade secrets. As of ~~March 1~~ **February 29** , ~~2023~~ **2024** , we own ~~seven~~ **13** issued ~~or allowed~~ U. S. **utility or design** patents, ~~12~~ **24** pending U. S. **utility or** ~~patent applications (four provisional and eight non- provisional), several corresponding foreign counterpart patents and applications, and two PCT applications, and four~~ design patent applications, ~~relevant to DMT testing methodology~~ **three pending U. S. provisional patent applications, five pending U. S. design patent applications, five issued foreign patents, 45 pending foreign patent applications,** and ~~expression profiles~~ **one PCT application** . While we intend to pursue additional patent applications, it is possible that our pending patent applications and any future applications may not result in issued patents. Even if patents are issued, third parties may independently develop similar or competing technology that avoids our patents. Further, we cannot be certain that the steps we have taken will prevent the misappropriation of our trade secrets and other confidential information as well as the misuse of our patents and other intellectual property, particularly in foreign countries where we have not filed for patent protection. From time- to- time the U. S. Supreme Court, other federal courts, or the USPTO, may change the standards of patentability, and any such changes could have a negative impact on our business. For instance, in 2008, the Court of Appeals for the Federal Circuit issued a decision that methods or processes cannot be patented unless they are tied to a machine or involve a physical transformation. The U. S. Supreme Court later reversed that decision in Bilski v. Kappos, 561 U. S. 593 (2010), finding that the " machine- or- transformation " test is not the only test for determining patent eligibility. The Court, however, declined to specify how and when processes are patentable. In 2012, in the case Mayo Collaborative Services v. Prometheus Laboratories, Inc., 566 U. S. 55 (2012), the U. S. Supreme Court reversed the Federal Circuit' s application of Bilski and invalidated a patent focused on a diagnostic process because the patent claim embodied a law of nature. In 2013, in Association for Molecular Pathology v. Myriad Genetics, the U. S. Supreme Court unanimously ruled that, " [a] naturally occurring DNA segment is a product of nature and not patent eligible merely because it has been isolated, " thereby invalidating Myriad Genetics' patents on the BRCA1 and BRCA2 breast cancer genes. However, the U. S. Supreme Court also held that manipulation of a gene to create something not found in nature, such as a strand of synthetically- produced complementary DNA (" cDNA ") could still be eligible for patent protection. The U. S. Supreme Court noted that method patents, which concern technical procedures for carrying out a certain process, are not affected by the ruling. More recently, the Federal Circuit has ruled on several patent cases — such as Univ. of Utah Research Found. v. Ambry Genetics Corp., 774 F. 3d 755 (Fed. Cir. 2014), Ariosa Diagnostics, Inc. v. Sequenom, Inc., 788 F. 3d 1371 (Fed. Cir. 2015), Genetic Tech. Ltd. v. Merial LLC, 818 F. 3d 1369 (Fed. Cir. 2016), and Cleveland Clinic Found. v. True Health Diagnostics, 859 F. 3d 1352 (Fed. Cir. 2017) — that some diagnostic method claims are patent ineligible. These decisions have narrowed the scope of patent protection available in certain circumstances or weakened the rights of patent owners in certain situations. Some aspects of our technology involve processes that may be subject to this evolving standard and we cannot guarantee that any of our pending process claims will be patentable as a result of such evolving

standards. In addition, this combination of decisions has created uncertainty as to the value of certain issued patents, in particular patents in the molecular biology analysis and diagnostic space. Moreover, there is additional uncertainty around the evolving standard in light of the USPTO Revised Patent Subject Matter Eligibility Guidance issued in Jan. 2019. It should also be noted that in 2010, the Secretary' s Advisory Committee on Genetics, Health and Society voted to approve a report entitled " Gene Patents and Licensing Practices and Their Impact on Patient Access to Genetic Tests. " That report defines " patent claims on genes " broadly to include claims to isolated nucleic acid molecules as well as methods of detecting particular sequences or mutations. The report also contains six recommendations, including the creation of an exemption from liability for infringement of patent claims on genes for anyone making, using, ordering, offering for sale, or selling a test developed under the patent for patient care purposes, or for anyone using the patent- protected genes in the pursuit of research. The report also recommended that HHS should explore, identify, and implement mechanisms that will encourage more voluntary adherence to current guidelines that promote nonexclusive in- licensing of diagnostic genetic and genomic technologies. It is unclear whether HHS will act upon these recommendations, or if the recommendations would result in a change in law or process that could negatively impact our patent portfolio or future R & D. If acted upon, implementation of such provisions could have a material negative impact on our business. We may face intellectual property infringement claims that could be time- consuming and costly to defend, and could result in the loss of significant rights, the implementation of an injunction, and the assessment of treble damages. From time- to- time we may face intellectual property infringement or misappropriation claims from third parties. Some of these claims may lead to litigation. The outcome of any such litigation can never be guaranteed, and an adverse outcome could affect us negatively. For example, were a third party to succeed on an infringement claim against us, we may be required to pay substantial damages, including treble damages if such infringement were found to be willful. In addition, we could face an injunction barring us from conducting the allegedly infringing activity, including an order preventing us from offering the DMT and future planned tests in the marketplace. The outcome of the litigation could require us to enter into a license agreement which may not be pursuant to acceptable or commercially reasonable or practical terms or which may not be available at all. It is also possible that an adverse finding of infringement against us may require us to dedicate substantial resources and time in developing non- infringing alternatives, which may or may not be possible. In the case of diagnostic tests, we would also need to include non- infringing technologies, which would require us to re- validate the test. Any such re- validation, in addition to being costly and time- consuming, may be unsuccessful. Finally, we may initiate claims to assert or defend our own intellectual property against third parties. Any intellectual property litigation, irrespective of whether we are the plaintiff or the defendant, and regardless of the outcome, is expensive and time- consuming, and could divert and distract our management' s attention from our business and negatively affect our operating results or financial condition. Tax Risks Related to Our Business Our ability to use our net operating losses to offset future taxable income may be subject to certain limitations. Our U. S federal net operating loss (" NOL "), carryforwards, may be unavailable to offset future taxable income because of restrictions under U. S. tax law. Our NOLs generated in tax years ending on or prior to December 31, 2017 are only permitted to be carried forward for 20 taxable years under applicable U. S. federal tax law, and therefore could expire unused. Under tax legislation commonly referred to as the Tax Cuts and Jobs Act (" TCJA "), as modified by the Coronavirus Aid, Relief, and Economic Security Act (" CARES ") Act, our U. S. federal NOLs generated in tax years ending after December 31, 2017 may be carried forward indefinitely and NOLs arising in taxable years beginning after December 31, 2017 and before January 1, 2021 may be carried back to each of the five taxable years preceding the tax year of such loss, but NOLs arising in taxable years beginning after December 31, 2020 may not be carried back. In addition, under the TCJA, as modified by the CARES Act, for taxable years beginning after December 31, 2020, the deductibility of federal NOLs generated in taxable years beginning after December 31, 2017 is limited to 80 % of current year taxable income. Certain states do not conform to the TCJA, as modified by the CARES Act (depending on the applicable jurisdiction). In addition, under Section 382 of the Internal Revenue Code of 1986, as amended (the " IRC "), a corporation that undergoes an " ownership change " is subject to limitations on its ability to utilize tax attribute carryforwards to offset future taxable income. Our existing NOL and R & D tax credit carryforwards may be subject to limitations arising from previous ownership changes, and if we underwent an ownership change in connection with or after the Business Combination, our ability to utilize NOLs could be further limited by Section 382 of the IRC. Future changes in our stock ownership, some of which are outside of our control, could result in an ownership change under Section 382 of the IRC. There is also a risk that due to regulatory changes, such as suspensions on the use of NOLs, or other unforeseen reasons, our existing and any future NOLs could expire or otherwise be unavailable to offset future income tax liabilities. We have not conducted a study to assess whether an ownership change has occurred or whether there have been multiple ownership changes since inception due to the significant complexity and cost associated with such a study. In addition, we have not performed an R & D tax credit study to confirm the accuracy of applicable carryforwards and completion of such a study may reduce carryforward available to offset future taxable income. Changes in tax laws or in their implementation or interpretation may adversely affect our business and financial condition. In recent years, numerous legislative, judicial, and administrative changes have been made in the provisions of federal and state income tax laws applicable to holders of our common stock. In particular, the comprehensive tax reform legislation enacted in December 2017 pursuant to the TCJA, among other things, contains significant changes to corporate taxation, including reduction of the corporate tax rate from a top marginal rate of 35 % to a flat rate of 21 %, limitation on the deductibility of interest expense to 30 % of adjusted earnings (except for certain small businesses), limitation of the deduction for NOLs generated in taxable years beginning after December 31, 2017 to 80 % of current year taxable income, elimination of NOL carrybacks, one time taxation of offshore earnings at reduced rates regardless of whether they are repatriated, reduction or elimination of U. S. tax on foreign earnings (subject to certain important exceptions), immediate deductions for certain new investments instead of deductions for depreciation expense over time, eliminating the option to deduct research and development expenditures currently and requiring corporations to capitalize and amortize them over five years, and modifying or repealing many business deductions and credits. The CARES Act modifies

certain provisions of the TCJA. Under the CARES Act, NOLs arising in taxable years beginning after December 31, 2017 and before January 1, 2021 may be carried back to each of the five taxable years preceding the tax year of such loss, but NOLs arising in taxable years beginning after December 31, 2020 may not be carried back. In addition, the CARES Act eliminates the limitation on the deduction of NOLs to 80 % of current year taxable income for taxable years beginning before January 1, 2021, and increases the amount of interest expense that may be deducted to 50 % of adjusted taxable income for taxable years beginning in 2019 or 2020. **Furthermore, President Biden signed the Inflation Reduction Act of 2022 (the " IRA ") into law in August 2022, which contained certain tax measures, including an excise tax of 1 % on certain corporate stock buy- backs.** Regulatory guidance under the TCJA **an the IRA** is and continues to be forthcoming, and such regulatory guidance could adversely affect our business and financial condition. In addition, the impact of such regulatory guidance on holders of our common stock is also uncertain and could be adverse. It is uncertain if and to what extent various states will conform to the TCJA **, the IRA,** and such regulatory guidance. You are urged to consult with your legal and tax advisors with respect to such legislation and the potential tax consequences of investing in our common stock. There is no assurance that we will continue satisfying the listing requirements of the Nasdaq Capital Market. Our common stock is listed on the Nasdaq Capital Market. To maintain our listing we are required to satisfy continued listing requirements. There can be no assurance we will continue satisfying such continued listing requirements, which include that the closing bid price of our common stock be at least $ 1 per share, that we have at least 300 round lot holders and at least 500, 000 publicly held shares, that the market value of our publicly held securities be at least $ 1 million, and that we meet one of these standards: stockholders' equity of at least $ 2. 5 million; market value of listed securities of at least $ 35 million; or net income from continuing operations of $ 500, 000 in the most recently completed fiscal year or in two of the three most recently completed fiscal years. The delisting of our common stock for whatever reason could, among other things, substantially impair our ability to raise additional capital; result in the loss of interest from institutional investors, the loss of confidence in our company by investors and employees, and in fewer financing, strategic and business development opportunities; and result in potential breaches of agreements under which we made representations or covenants relating to our compliance with applicable listing requirements. Claims related to any such breaches, with or without merit, could result in costly litigation, significant liabilities and diversion of our management' s time and attention and could have a material adverse effect on our financial condition, business and results of operations. In addition, the delisting of our common stock for whatever reason may materially impair our stockholders' ability to buy and sell shares of our common stock and could have an adverse effect on the market price of, and the efficiency of the trading market for, our common stock. Any future issuance of our equity securities could dilute the interests of our then existing security holders and could substantially decrease the trading price of our securities. We may issue equity or equity- linked securities for a number of reasons, including to finance our operations and business strategy, to adjust our ratio of debt to equity, to satisfy our obligations upon the exercise of then- outstanding options or other equity- linked securities, if any, or for other reasons. We currently have **registered** ~~the ability to offer and sell~~ up to $ ~~300~~ **299** . ~~0~~ **7** million of common stock, preferred stock, warrants, senior debt, subordinated debt, rights or units under an effective universal shelf registration statement. **Our ability to utilize our effective universal shelf registration statement, including the $ 74. 7 million of capacity remaining under the 2022 Sales Agreement is limited by our compliance with the baby shelf rules. As of the filing of this Annual Report on Form 10- K, our public float is less than $ 75 million, and under SEC regulations, for so long as our public float remains less than $ 75 million, the amount we can raise through primary public offerings of securities in any twelve- month period using shelf registration statements subject to the baby shelf rules is limited to an aggregate of one- third of our public float. As of February 23, 2024, our public float was approximately $ 43. 2 million, based on 34, 008, 061 shares of outstanding common stock held by non- affiliates and at a price of $ 1. 27 per share, which was the last reported sale price of our common stock on the Nasdaq Capital Market on February 23, 2024.** Sales of substantial amounts of shares of our common stock or other securities under our current universal shelf registration statement **or otherwise** could lower the market price of our common stock and impair our ability to raise capital. We may amend the terms of our publicly traded warrants currently trading on the Pink Market under the ticker symbol " DMTKW, " or the publicly traded warrants, in a manner that may be adverse to holders with the approval by the holders of a majority of the then outstanding publicly traded warrants, and as a result, the exercise price of the publicly traded warrants could be increased, the exercise period could be shortened and the number of shares purchasable upon exercise of a publicly traded warrant could be decreased, all without your approval. Our publicly traded warrants are subject to the Warrant Agreement **, dated June 19, 2017, by and between the Company and Continental Stock Transfer & Trust Company (the " Warrant Agreement ")** . The Warrant Agreement provides that the terms of the publicly traded warrants may be amended without the consent of any holder to cure any ambiguity or correct any defective provision, but requires the approval by the holders of a majority of the then outstanding publicly traded warrants to make any change that adversely affects the interests of the registered holders. Accordingly, we may amend the terms of the publicly traded warrants in a manner adverse to a holder if holders of a majority of the then outstanding publicly traded warrants approve of such amendment. Although our ability to amend the terms of the publicly traded warrants with the consent of a majority of the then outstanding publicly traded warrants is unlimited, examples of such amendments could be amendments to, among other things, increase the exercise price of the publicly traded warrants, shorten the exercise period or decrease the number of shares of common stock purchasable upon exercise of the publicly traded warrants. We may redeem your unexpired publicly traded warrants prior to their exercise at a time that is disadvantageous to you, thereby making your publicly traded warrants worthless. We have the ability to redeem our outstanding publicly traded warrants at any time prior to their expiration, at a price of $ 0. 01 per warrant, provided that the last reported sales price of our common stock equals or exceeds $ 36. 00 per share for any 20 trading days within a 30- trading day period ending on the third trading day prior to the date we give notice of redemption. To the extent that the publicly traded warrants become redeemable by us, we may exercise our redemption right even if we are unable to register or qualify the underlying securities for sale under all applicable state securities laws.

Redemption of the outstanding publicly traded warrants could force you (i) to exercise your publicly traded warrants and pay the exercise price therefor at a time when it may be disadvantageous for you to do so, (ii) to sell your publicly traded warrants at the then- current market price when you might otherwise wish to hold your publicly traded warrants or (iii) to accept the nominal redemption price which, at the time the outstanding publicly traded warrants are called for redemption, is likely to be substantially less than the market value of your publicly traded warrants. Because we have no current plans to pay cash dividends on our shares for the foreseeable future, you may not receive any return on investment unless you sell your shares for a price greater than that which you paid for it. We may retain future earnings, if any, for future operations, expansion and debt repayment and have no current plans to pay any cash dividends for the foreseeable future. Any decision to declare and pay dividends in the future will be made at the discretion of our board of directors and will depend on, among other things, our results of operations, financial condition, cash requirements, contractual restrictions and other factors that our board of directors may deem relevant. In addition, our ability to pay dividends may be limited by covenants of any existing and future outstanding indebtedness we or our subsidiaries incur. As a result, you may not receive any return on an investment in our shares unless you sell your shares of the Company for a price greater than that which you paid for them. If securities or industry analysts ~~do not publish or~~ cease publishing research or reports about us, our business, or our market, or if they change their recommendations regarding our securities adversely, the price and trading volume of our securities could decline. The trading market for our securities will be influenced by the research and reports that industry or securities analysts may publish about us, our business, market or competitors. If ~~no securities or industry analysts publish reports about us, our share price and trading volume would likely be negatively impacted. If~~ any of the analysts who ~~may~~ cover us change their recommendation regarding our shares of common stock adversely **(including by reducing their price target with respect to our common stock, which we have experienced)** , or provide more favorable relative recommendations about our competitors, the price of our shares of common stock **may** ~~would likely~~ decline. If any analyst who may cover us were to cease coverage of us or fail to regularly publish reports on us, we could lose visibility in the financial markets, which in turn could cause our share price or trading volume to decline. Provisions of our charter documents or Delaware law could delay or prevent an acquisition of us, even if the acquisition would be beneficial to our stockholders, and could make it more difficult for you to change our management. Provisions in our Amended and Restated Certificate of Incorporation and our bylaws may discourage, delay or prevent a merger, acquisition or other change in control that our stockholders may consider favorable, including transactions in which our stockholders might otherwise receive a premium for their shares. In addition, these provisions may frustrate or prevent any attempt by our stockholders to replace or remove our current management by making it more difficult to replace or remove our board of directors. These provisions include: • a classified board of directors so that not all directors are elected at one time; • a prohibition on stockholder action through written consent; • no cumulative voting in the election of directors; • the exclusive right of our board of directors to elect a director to fill a vacancy however created, whether by the expansion of our board of directors, the resignation, death or removal of a director, or otherwise; • a requirement that special meetings of our stockholders be called only by our board of directors, the chairman of our board of directors, the chief executive officer or, in the absence of a chief executive officer, the president; • an advance notice requirement for stockholder proposals and nominations; • the authority of our board of directors to issue preferred stock with such terms as our board of directors may determine; and • a requirement of approval of at least 75 % of all outstanding shares of our capital stock entitled to vote to amend any bylaws by stockholder action, or to amend specific provisions of our certificate of incorporation. In addition, Delaware law prohibits a publicly held Delaware corporation from engaging in a business combination with an interested stockholder, generally a person who, together with his, her or its affiliates, owns or within the last three years has owned 15 % or more of the company' s voting stock, for a period of three years after the date of the transaction in which the person became an interested stockholder, unless the business combination is approved in a prescribed manner. Accordingly, Delaware law may discourage, delay or prevent a change in control of the Company. In addition, our Amended and Restated Certificate of Incorporation, to the fullest extent permitted by law, provides that the Court of Chancery of the State of Delaware will be the exclusive forum (the " Delaware Chancery forum provision "), for: any derivative action or proceeding brought on our behalf; any action or proceeding asserting a breach of fiduciary duty owed to us, our stockholders, or any of our current or former directors, officers or other employees; any action or proceeding asserting a claim against us or any of our current or former directors, officers or other employees, arising out of or pursuant to the Delaware General Corporation Law, our Amended and Restated Certificate of Incorporation, or our bylaws; any action or proceeding to interpret, apply, enforce or determine the validity of our Amended and Restated Certificate of Incorporation or our Bylaws; any action or proceeding as to which the Delaware General Corporation Law confers jurisdiction to the Court of Chancery of the State of Delaware; or any action asserting a claim against us that is governed by the internal affairs doctrine. This exclusive forum provision does not apply to suits brought to enforce a duty or liability created by the Securities Act, the Exchange Act, or any claim for which the federal courts have exclusive jurisdiction. The Delaware Chancery forum provision may limit a stockholder' s ability to bring a claim in a judicial forum that it finds favorable for disputes with us or any of our directors, officers, or other employees, which may discourage lawsuits with respect to such claims. Alternatively, if a court were to find the exclusive forum provisions contained in our Amended and Restated Certificate of Incorporation to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions, which could harm our business, results of operations and financial condition. Further, on March 18, 2020, the Delaware Supreme Court ruled that provisions of a Delaware corporation' s certificate of incorporation that designate a federal forum for securities claims brought pursuant to the Securities Act, or federal forum provisions, are valid and enforceable under Delaware law (the " March 2020 Ruling "). Consistent with the March 2020 Ruling, on April 12, 2020, our board of directors approved a Certificate of Amendment to our Amended and Restated Certificate of Incorporation (the " 2020 Certificate of Amendment "), which was approved by our stockholders at our 2020 annual meeting of stockholders on May 26, 2020. We filed the 2020 Certificate of Amendment with the Delaware Secretary of State on May 27, 2020. The 2020 Certificate

of Amendment added a federal forum provision to our Amended and Restated Certificate of Incorporation, which now provides that, unless we consent in writing to the selection of an alternative forum, the federal district courts of the United States of America shall, to the fullest extent permitted by law, be the sole and exclusive forum for the resolution of any complaint asserting a cause of action arising under the Securities Act. Various U. S. Supreme Court cases offer support for the argument that federal forum provisions do not violate federal policy. However, the March 2020 Ruling applies only to claims brought in Delaware state courts, and it is not binding on any other state court or the federal courts. Therefore, we are unable to predict whether a state court in any other state or a federal court would enforce a federal forum provision such as the one set forth in the 2020 Certificate of Amendment. We adopted the 2020 Certificate of Amendment to reduce the costs and inefficiencies to the Company that would result from a Securities Act claim being litigated in both state and federal courts, which was permissible under our Amended and Restated Certificate of Incorporation before the 2020 Certificate of Amendment was adopted. Such simultaneous state and federal litigation could also result in inconsistent judgments and rulings, and the adoption of the 2020 Certificate of Amendment could reduce this risk. However, the federal forum provision set forth in the 2020 Certificate of Amendment may discourage Securities Act claims or limit a stockholder' s ability to submit claims in a judicial forum that the stockholder finds favorable, and may result in additional costs for a stockholder seeking to bring such a claim. Provisions in our charter and other provisions of Delaware law could limit the price that investors are willing to pay in the future for shares of our common stock. **The** ~~We expect the~~ price of our common stock **has been and** may **continue to** be volatile and may fluctuate substantially. The stock market in general and, especially in recent history, the market for life sciences companies in particular, have experienced extreme volatility that has often been unrelated to companies' operating performance. During the 12- month period ~~ending~~ **ended** December 31, ~~2022~~ **2023**, the closing prices of our common stock as reported on the Nasdaq Capital Market were in the range of $ 1. ~~63~~ **18** to $ ~~17~~ **6**. ~~55~~ **20** per share. In addition, the stock market in general has recently experienced relatively large price and volume fluctuations in response to the macroeconomic environment, and geopolitical concerns. The market price for our common stock may be influenced by many factors, including: • the results of our efforts to ~~develop and~~ commercialize the DMT ~~; • actual or anticipated results from, and any delays in, any future clinical trials, as well as results of regulatory reviews relating to the approval of any test candidates we may choose to develop that require such approval~~ ; • commencement or termination of any collaboration or licensing arrangement; • disputes or other developments relating to proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our technology; • announcements by us or our competitors of significant acquisitions, strategic partnerships, joint ventures and capital commitments; • additions or departures of key scientific or management personnel; • variations in our financial results or those of companies that are perceived to be similar to us; • ~~new products, product candidates or new uses for existing products introduced or announced by our competitors, and the timing of these introductions or announcements; •~~ results of clinical trials of product candidates of our competitors; • general economic and market conditions and other factors that may be unrelated to our operating performance or the operating performance of our competitors, including changes in market valuations of similar companies; • regulatory or legal developments **related to our business or operations** in the United States and other countries; • changes in the structure of healthcare payment systems; • ~~Delay~~ **delay** or failure to obtain coverage policy decisions from commercial payors; • conditions or trends in the life sciences industry; • actual or anticipated changes in earnings estimates, **guidance** ~~development timelines~~ or recommendations by securities analysts; • announcement or expectation of additional financing efforts; • sales of common stock by us or our stockholders in the future, as well as the overall trading volume of our common stock; and • other factors described in this " Risk Factors " section. In the past, following periods of volatility in companies' stock prices, securities class- action litigation has often been instituted against such companies. Such litigation, if instituted against us, could result in substantial costs and diversion of management' s attention and resources, which could materially and adversely affect our business and financial condition.