Risk Factors Comparison 2024-04-01 to 2023-03-30 Form: 10-K

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Investing in our securities involves a high degree of risk. You should carefully consider the following risk factors and uncertainties together with all of the other information contained in this Annual Report on Form 10- K, including our audited consolidated financial statements and the accompanying notes in Part II Item 8, " Consolidated Financial Statements and Supplementary Data. " If any of the following risks materializes, our business, financial condition, results of operations and growth prospects could be materially adversely affected, and the value of an investment in our common stock may decline significantly. The risks and uncertainties described below are not the only ones we face. Additional risks and uncertainties not presently known to us or that we currently deem immaterial may also materially adversely affect our business, financial condition, results of operations and growth prospects. RISKS RELATED TO OUR BUSINESS AND INDUSTRY If we **If we** are unable to increase the volume of OvaSuite sales,our business,results of operations and financial condition will be adversely affected.We have experienced significant operating losses each year since our inception,and we expect to incur a net loss for fiscal year ~~2024~~ **2023** .Our losses have resulted principally from costs incurred in cost of revenue,sales and marketing,general and administrative costs and research and development.The number of tests performed in ~~2023~~ **2021** and in 2022 was ~~23~~ **17** , ~~990~~ **377** and 21,423,respectively.If we are unable to ~~substantially~~ increase the volume of OvaSuite sales,our business,results of operations and financial condition will be adversely affected.There is substantial doubt about our ability to continue as a going concern,and this may adversely affect our stock price and our ability to raise capital.We have incurred significant losses and negative cash flows from operations since inception and have an accumulated deficit of $ ~~518~~ **498** . ~~3~~ **9** million as of the end of the period covered by this report.We also expect to incur a net loss and negative cash flows from operations in ~~2024~~ **2023** and have limited cash balances.Given these conditions,there is substantial doubt about our ability to continue as a going concern.The substantial doubt about our ability to continue as a going concern may adversely affect our stock price and our ability to raise capital.Our independent registered public accounting firm has also included in its report an explanatory paragraph regarding this uncertainty.We believe that successful achievement of our business objectives will require additional financing.We expect to raise capital through a variety of sources that may include public or private equity offerings,debt financing,collaborations,licensing arrangements,grants and government funding and strategic alliances.However,in part due to our low stock price,additional financing may not be available when needed or on terms acceptable to us.If we are unable to obtain additional capital,we may not be able to continue sales and marketing,research and development,distribution or other operations on the scope or scale of current activity and that could have a material adverse effect on our business,results of operations and financial condition.The accompanying financial statements do not include any adjustments that may be necessary should we be unable to continue as a going concern. ~~We may need to sell additional shares of our common stock or other securities in the future to meet our capital requirements,which could cause significant dilution.Until such time,if ever,as we can generate substantial product revenues,we expect to finance our cash needs through a combination of the issuance of common stock in public or private equity offerings,debt financings,exercise of common stock warrants,collaborations,licensing arrangements,grants and government funding and strategic alliances.Our management believes the successful achievement of our business objectives will require additional financing through one or more of these avenues.To the extent that we raise additional capital through the sale of equity or convertible debt,such financing may be dilutive to stockholders.Debt financing,if available,may involve restrictive covenants and potential dilution to stockholders.Furthermore,a perception that future sales of our common stock in the public market are likely to occur could affect prevailing trading prices of our common stock.As of December 31,2023,we had 10,645,049 shares of our common stock outstanding and 165,861 shares of our common stock reserved for future issuance to employees,directors and consultants pursuant to our employee stock plans,which excludes 759,922 shares of our common stock that were subject to outstanding options and 59,463 restricted stock units.In addition,as of December 31,2023,warrants to purchase 799,985 shares of our common stock were outstanding.These warrants are exercisable at the election of the holders thereof,in accordance with the terms of the related Form of Warrant,at an average exercise price of $ 13.20 per share.On January 26,2024,we closed a follow- on equity offering.In conjunction with the offering,certain of outstanding warrants to purchase up to an aggregate of 366,664 shares at an exercise price of $ 13.20 per share and a termination date of August 25,2027,were amended so that the amended warrants have a reduced exercise price of $ 4.13 per share and a new termination date of January 26,2029.The other terms of the amended warrants remain unchanged.The exercise of all or a portion of our outstanding options and warrants will dilute the ownership interests of our stockholders.We will need to raise additional capital in the future,and if we are unable to secure adequate funds on terms acceptable to us,we may be unable to execute our business plan.We will seek to raise additional capital through the issuance of equity or debt securities in the public or private markets,or through a collaborative arrangement or sale of assets.Additional financing opportunities may not be available to us,or if available,may not be on favorable terms.The availability of financing opportunities will depend,in part,on market conditions,and the outlook for our business.Any future issuance of equity securities or securities convertible into equity could result in substantial dilution to our stockholders,and the securities issued in such a financing may have rights,preferences or privileges senior to those of our common stock.If we are unable to obtain additional capital,we may not be able to continue our sales and marketing,research and development,distribution or other operations on the scope or scale of our current activity.** Failures by third- party payers to reimburse for our products and services or changes in reimbursement rates could materially and adversely affect our business,financial condition and results of operations.In addition,changes in medical society guidelines may also adversely affect payers and result in a material change in coverage,adversely affecting our business,financial condition

and results of operations. **We** ~~The great majority of laboratory tests in the United States~~ are ~~paid~~ **responsible** for ~~by~~ **obtaining payment from** third ~~-~~ party payers.Accordingly,our current revenues are ~~from~~ ,and our future revenues will be dependent upon ~~,~~ third- party reimbursement payments to Aspira Labs.Insurance coverage and reimbursement rates for diagnostic tests are uncertain,subject to change and particularly volatile during the early stages of commercialization.There remain questions as to what extent third- party payers,like Medicare,Medicaid and private insurance companies will provide coverage for ~~our products~~ **Ova1,Overa,Ova1Plus,OvaWatch and Aspira Synergy** and for which indications. ~~Some payers have determined not to cover our tests.~~ While ~~Novitas Solutions,the Medicare Administrative Contractor responsible for paying Medicare claims for all Aspira laboratory tests,has determined to cover Ova1,there is no assurance that they will continue to do so.Moreover,while The Centers for Medicare & Medicaid Services (" CMS ")~~ has issued PAMA reimbursement rates for Ova1 **and Overa** effective January 1,2018,there is no guarantee that **CMS will continue to cover the Ova1 test or that** the payment ~~rates~~ **rate** will ~~not~~ be ~~reduced~~ **comparable to the PAMA rate** .Although the PAMA legislation allows for no more than a 15 % fee reduction between **2021 and** 2023 ~~and 2024~~ ,uncertainty regarding reimbursement rates could create payment uncertainty from other payers as well.The reimbursement rates for Ova1 ~~and~~ **,Overa,Ova1Plus,** OvaWatch **,OvaWatch and Aspira Synergy** are **largely out of our control** ~~reviewed by third- party payers~~ .We have experienced volatility in the coverage and reimbursement of ~~our products~~ **Ova1 and Overa** due to contract negotiation with third- party payers and implementation requirements,and the reimbursement amounts we have received from third- party payers varies from payer to payer,and,in some cases,the variance **is** ~~could be~~ material.Third- party payers,including private insurance companies as well as government payers such as Medicare and Medicaid,have increased their efforts to control the cost,utilization and delivery of healthcare services including increased use of Laboratory Benefits Management firms (" LBM' s ") ~~,who create policy and implement utilization management strategies for their payer clients to ensure tests are medically necessary~~ .In addition,more payers are implementing pre- authorization requirements for our testing.These measures have resulted in reduced payment rates and decreased utilization of ~~our~~ **diagnostic** tests **such as Ova1 and Overa** .Further,the trend among many payers is to limit the size of their lab networks,which is making it more difficult to secure preferred provider contracts for some services.From time to time,Congress has considered and implemented changes to the Medicare fee schedules in conjunction with budgetary legislation,and pricing for tests covered by Medicare is subject to change at any time,although PAMA has established specific dates by which they will make any changes. ~~Even if favorable coverage and reimbursement status is attained for one or more products by governmental and commercial third- party payers,less favorable coverage policies and reimbursement rates may be implemented in the future.~~ Reductions in third- party payer reimbursement rates may occur in the future.Reductions in the price at which ~~our products are~~ **Ova1 and Overa is** reimbursed could have a material adverse effect on our business,results of operations and financial condition.If we are unable to establish and maintain broad coverage and ~~adequate~~ reimbursement for our products or if third- party payers change their coverage or reimbursement policies with respect to our products,our business,financial condition and results of operations could be materially adversely affected. **We will need to raise additional capital in the future,and if we are unable to secure adequate funds on terms acceptable to us,we may be unable to execute our business plan.We will seek to raise additional capital through the issuance of equity or debt securities in the public or private markets,or through a collaborative arrangement or sale of assets.Additional financing opportunities may not be available to us,or if available,may not be on favorable terms.The availability of financing opportunities will depend,in part,on market conditions,and the outlook for our business.Any future issuance of equity securities or securities convertible into equity could result in substantial dilution to our stockholders,and the securities issued in such a financing may have rights,preferences or privileges senior to those of our common stock.If we are unable to obtain additional capital,we may not be able to continue our sales and marketing,research and development,distribution or other operations on the scope or scale of our current activity.** Failure to continue coverage of Ova1 through Novitas, ~~our~~ **the Company' s** Medicare Administrative ~~Contractor~~ **Carrier** for Ova1 ~~,~~could materially and adversely affect our business,financial condition and results of operation.Since 2013,Ova1 has been listed as a covered service in the Biomarkers for Oncology Local Coverage Determination (~~the~~ " ~~Biomarkers for Oncology~~ LCD ") issued by Novitas, ~~the~~ **a** Medicare Administrative ~~Contractor responsible~~ **Carrier.Earlier this year,Novitas issued a statement** for **public comment regarding** ~~payment of Medicare claims for all Aspira Labs tests.In June 2023,in conjunction with~~ the ~~publication~~ **potential creation** of a **new** ~~final " Genetic Testing for Oncology "~~ LCD ~~(the " Genetic Testing LCD "),Novitas announced~~ that ~~it intended to retire~~ **could impact services previously included in** the Biomarkers for Oncology LCD ~~effective July 17,~~ **beginning in the second quarter of** 2023 ~~,and that at that time,non- genetic tests currently identified as covered in that LCDs (like Ova1) would be considered for payment based on Medicare medically reasonable and necessary threshold for coverage~~ . **In related public statements** ~~On July 6,2023~~ ,Novitas ~~issued~~ **indicated** a ~~statement announcing that~~ **potential retirement of** the ~~Genetic Testing LCD would not go into effect on July 17,2023 as planned,and that a new proposed LCD would be published for public comment.Novitas issued a replacement proposed LCD for public comment on July 27,2023.The~~ Biomarkers for Oncology ~~LCD remains in effect.All OvaSuite tests (Ova1,Overa,Ova1Plus and OvaWatch) are protein- based multivariate index assays and were not impacted by the now- withdrawn Genetic Testing~~ LCD.While we do not believe Novitas intends to eliminate Ova1 coverage,it ~~is impossible~~ **has not provided additional information to allow us** to assess the likelihood or potential impact,if any, **that** ~~of future actions to be taken by Novitas with respect to the release of a replacement Genetics Testing LCD,or~~ a change to ~~the content or status of~~ the Biomarkers for Oncology LCD ~~,~~ **would have** on the coverage and related revenue of Ova1,and such impact may be material to our business,results of operations and financial condition.We are monitoring developments closely and believe additional due process would be required if the activities contemplated by Novitas change the coverage determination for Ova1.Failure to expand commercial,Medicare or Medicaid coverage for **Ova1Plus** ~~our products could materially~~ and **OvaWatch** ~~adversely affect our business,financial condition and results of operations~~ . ~~We have~~ **The Company has** implemented strategies to expand payer coverage for ~~our~~ **its** ovarian cancer risk assessments,including securing coverage for OvaWatch that is consistent with existing coverage for ~~Ova1~~ **Ova1Plus** . ~~In~~

~~November 2023,CMS approved our request to provide reimbursement for OvaWatch that is consistent with the reimbursement for Ova1 at $ 897 per test.However,there~~ **There** can be no assurances that ~~we~~ **the Company** will be able to secure additional payer coverage for ~~Ova1 and~~ **Ova1Plus,nor can there be assurances that** comparable coverage **will be available** for OvaWatch ~~,or that that the reimbursement rate for OvaWatch will not be reduced~~ .Failure to expand payer coverage ~~and maintain adequate reimbursement rates~~ may have a significant negative impact on product adoption and our results of operations **.We may need to sell additional shares of our common stock or other securities in the future to meet our capital requirements,which could cause significant dilution.Until such time,if ever,as we can generate substantial product revenues,we expect to finance our cash needs through a combination of the issuance of common stock in public or private equity offerings,debt financings,exercise of common stock warrants,collaborations,licensing arrangements,grants and government funding and strategic alliances.As discussed in " Risks Related to our Business and Industry," our management believes the successful achievement of our business objectives will require additional financing through one or more of these avenues.To the extent that we raise additional capital through the sale of equity or convertible debt,such financing may be dilutive to stockholders.Debt financing,if available,may involve restrictive covenants and potential dilution to stockholders.Furthermore,a perception that future sales of our common stock in the public market are likely to occur could affect prevailing trading prices of our common stock.As of December 31,2022,we had 124,594,888 shares of our common stock outstanding and 3,576,486 shares of our common stock reserved for future issuance to employees,directors and consultants pursuant to our employee stock plans,which excludes 9,828,424 shares of our common stock that were subject to outstanding options.In addition,as of December 31,2022,warrants to purchase 12,000,000 shares of our common stock were outstanding.These warrants are exercisable at the election of the holders thereof,in accordance with the terms of the related Form of Warrant,at an average exercise price of $ 0.88 per share.The exercise of all or a portion of our outstanding options and warrants will dilute the ownership interests of our stockholders.We have increased our authorized shares for issuance which could cause significant dilution.As discussed in " Risks Related to our Business and Industry," our management believes the successful achievement of our business objectives may require additional financing through one or a combination of the issuance of common stock in public or private equity offerings,debt financings,exercise of common stock warrants,collaborations,licensing arrangements,grants and government funding and strategic alliances.To effectuate that,we sought and obtained authorization from stockholders to increase our authorized shares by 50,000,000 for a total of 200,000,000,for issuance on February 6,2023.Such an increase may be dilutive to stockholders,and further may affect the prevailing trading prices of our common stock.We are currently developing multiple tests as LDTs,and intend to develop and perform LDTs at Aspira Labs in the future.Should FDA disagree that our tests are LDTs in the future,commercialization of our diagnostic tests may be adversely affected,which would negatively affect our results of operations and financial condition.We also intend to develop and perform LDTs at Aspira Labs in the future.The FDA considers an LDT to be a test that is designed,developed,validated,and used within a single laboratory.The FDA has historically taken the position that it has the authority to regulate LDTs as medical devices under the FDC Act,but it has generally exercised enforcement discretion with regard to LDTs.This means that even though the FDA believes it can impose regulatory requirements on LDTs,such as requirements to obtain premarket approval,de novo classification or 510 (k) clearance of LDTs,it has generally chosen not to enforce those requirements to date.Separately,the Centers for Medicare & Medicaid Services oversees clinical laboratory operations through the CLIA program.FDA has indicated that it may seek to increase its regulation of LDTs.Any future rulemaking,guidance,or other oversight of LDTs and clinical laboratories that develop and perform them,if and when finalized,may affect the sales of our products and how customers use our products,and may require us to change our business model in order to maintain compliance with these laws.Legislative proposals addressing the FDA' s oversight of LDTs have been previously introduced,and we expect that new legislative proposals will be introduced from time to time.The likelihood that Congress will pass such legislation and the extent to which such legislation may affect the FDA' s plans to regulate LDTs as medical devices,by either giving FDA explicit authority to do so or,alternatively,stating that FDA does not have authority to regulate LDTs,is difficult to predict.In June 2021,Congress introduced legislation called the Verifying Accurate,Leading- edge IVCT Development Act (the " VALID Act "),which would have established a new risk- based regulatory framework for in vitro clinical tests (" IVCTs "),a category which would have included IVDs,LDTs,collection devices and instruments used with such tests.This legislation was not enacted during that session of Congress,but could be introduced again in the future.In the meantime,the regulation by the FDA of our tests that are positioned as LDTs remains uncertain.If FDA premarket clearance,de novo classification or approval is required for any of the tests we are developing or may develop in the future as LDTs,we may be forced to stop selling our tests or be required to modify claims or make such other changes while we work to obtain FDA clearance,approval or de novo classification.Our business,results of operations and financial condition would be negatively affected until such review were completed and clearance,approval or de novo classification to market were obtained.If premarket clearance,approval,or de novo classification is required by the FDA or if we decide to voluntarily pursue FDA premarket clearance,approval or de novo classification of our future LDTs,there can be no assurance that any tests we develop in the future will be cleared,approved or classified on a timely basis,if at all.Obtaining FDA clearance,approval or de novo classification for diagnostics can be expensive,time consuming and uncertain,and for higher- risk devices generally takes several years and requires detailed and comprehensive scientific and clinical data.In addition,medical devices are subject to ongoing FDA obligations and continued regulatory oversight and review.Ongoing compliance with FDA regulations for those tests would increase the cost of conducting our business and subject us to heightened regulation by the FDA and penalties for failure to comply with these requirements.It is unclear how FDA will apply the guidance document to our current software and to**

software that we may develop in the future.It is also unclear whether FDA will apply the final guidance to CDS software that is used by clinical laboratories as part of an LDT,since LDTs have historically been subject to FDA enforcement discretion .We may not succeed in improving existing or developing additional diagnostic products,and,even if we do succeed in developing additional diagnostic products,the diagnostic products may never achieve significant commercial market acceptance.Our technologies are new and complex and are subject to change as new discoveries are made.New discoveries and advancements in the diagnostic field are essential if we are to foster the adoption of our product offerings.Development of our existing technologies remains a substantial risk to us due to various factors,including the scientific challenges involved within our laboratory,as well as products that are offered in a decentralized platform such as Aspira Synergy,our ability to find and collaborate successfully with others working in the diagnostic field, ~~our ability to obtain sufficient samples to complete the design and development of our algorithms~~ and competing technologies,which may prove more successful than our technologies,as well as failure to complete analytical and clinical validation studies and failure to demonstrate sufficient clinical utility to continue to build positive medical policy among payers.Our failure to achieve the intended development outcome either ourselves or through a collaboration may result in an impact to our commercial success of **the EndoCheck** ~~our risk assessment screens for endometriosis~~ or other product launches.Our success depends on our ability to continue to develop and commercialize diagnostic products.There is considerable risk in developing diagnostic products based on our biomarker discovery efforts,as candidate biomarkers may fail to demonstrate clinical validity in larger clinical studies or may not achieve acceptable levels of analytical accuracy.For example,markers being evaluated for one or more next- generation diagnostic tests may not be validated in downstream pre- clinical or clinical studies,once we undertake and perform such studies.In addition,development of products combining biomarkers with imaging,patient risk factors or other risk indicators carry higher than average risks due to technical,clinical and regulatory uncertainties.While we have a published proof of concept on combining Ova1 and imaging,for example,our ability to develop,verify and validate an algorithm that generalizes to routine testing populations cannot be guaranteed. **Also,outcomes of prospective and retrospective trials for OvaWatch serial monitoring,which are essential for clinical validation,are uncertain.** In addition,our efforts to develop other diagnostic tests,such as **EndoCheck** ~~EndoMDx and OvaMDx~~ ,are in the **discovery** ~~early development~~ phase,and future pre- clinical or clinical studies may not support our ~~early data.While the discovery phase has been completed for EndoCheck,it is still pending pre- clinical or clinical studies to support~~ early data.If successful,the regulatory pathway and clearance / approval process may require extensive discussion with applicable authorities and possibly advisory panels.These pose considerable risk in projecting launch dates,requirements for clinical evidence and eventual pricing and return on investment.Although we are engaging important stakeholders representing gynecologic oncology,benign gynecology,patient advocacy,women' s health research,legislators,payers,and others,success,timelines and value will be uncertain and require active management at all stages of innovation and development.Clinical testing is expensive,can take many years to complete and can have an uncertain outcome.Clinical failure can occur at any stage of the testing.Clinical trials for our next generation ovarian cancer tests,and other future diagnostic tests,may produce negative or inconclusive results,and we may decide,or regulators may require us,to conduct additional clinical and / or non- clinical testing on these tests.In addition,the results of our clinical trials may identify unexpected risks relative to safety or efficacy,which could complicate,delay or halt clinical trials,or result in the denial of regulatory approval by the FDA and other regulatory authorities.If we do succeed in developing additional diagnostic tests with acceptable performance characteristics,we may not succeed in achieving commercial market acceptance for those tests.Our ability to successfully commercialize our OvaSuite products and Aspira Synergy platform will depend on many factors,including:? our ability to drive adoption of our products;? our success in establishing new clinical practices or changing previous ones;? our ability to develop business relationships with diagnostic or laboratory companies that can assist in the commercialization of these products in the U.S.and globally;and ? the scope and extent of the agreement by Medicare and third- party payers to provide full or partial reimbursement coverage for our products,which may impact patients' willingness to pay for our products and may influence physicians' decisions to recommend or use our products.These factors present obstacles to commercial acceptance of our existing and potential diagnostic products,for which we will have to spend substantial time and financial resources to overcome,and there is no guarantee that we will be successful in doing so.Our inability to do so successfully would prevent us from generating revenue from OvaSuite and developing future diagnostic products.In October 2022,we announced the launch of a comarketing arrangement for ~~the~~ Ova1Plus ~~workflow~~ with ~~BRL~~ **BioReference Laboratories** .Under terms of the agreement,the Aspira and ~~BRL~~ **BioReference** sales teams **will** collaborate to sell Ova1Plus to gynecologists and other women' s healthcare providers nationwide.If we are unable to collaborate successfully,it may affect our ability to improve adoption of our Ova1Plus test or to successfully secure additional commercial collaborations.The diagnostics market is competitive,and we may not be able to compete successfully,which would adversely impact our ability to generate revenue.Our principal competition currently comes from the many clinical options available to medical personnel involved in clinical decision making.For example,rather than ordering an OvaSuite test for a woman with an adnexal mass,obstetricians,gynecologists and gynecologic oncologists may choose a different clinical option or none at all.If we are not able to convince clinicians that these products provide significant improvement over current clinical practices ~~or to change their ordering habits~~ ,our ability to commercialize OvaSuite products will be adversely affected.Competitive offerings include Fujirebio Diagnostics' FDA cleared ROMA test.ROMA combines two tumor markers and menopausal status into a numerical score using a publicly available algorithm.ROMA is a competitive test with ~~the~~ **Ova1,Overa and** Ova1Plus ~~workflow~~ that has adversely impacted and may continue to materially adversely impact our revenue.In addition,competitors, **Becton Dickinson,** Abbott Laboratories, ~~Angle plc,Anixa Biosciences,Inc.,~~ AOA ~~Dx,Becton Dickinson & Co.,ClearNote Health~~ ,Exact Sciences ~~Corp.~~ **(Thrive)** ,Grail, **Anixa,Angle,** InterVenn ~~Biosciences~~ and others have publicly disclosed that they have been or are currently working on ovarian cancer diagnostic assays.Academic institutions periodically report new findings in ovarian cancer diagnostics that may have commercial value. ~~A number of diagnostic and academic organizations have announced plans~~

~~or published studies related to the development of a non- invasive diagnostic tool for the identification of endometriosis.Competitors for our endometriosis offerings include,but are not limited to,DotLab,Endodiag,HERA Biotech and Ziwig.~~ Our failure to compete with any competitive diagnostic assay if and when commercialized could adversely affect our business,financial condition and results of operations.We have priced ~~our~~ **OvaSuite** products at a point that recognizes the value- added by its increased sensitivity for detecting ovarian malignancy.If others develop a test that is viewed to be similar to any of these products in safety and efficacy but is priced at a lower point,we and / or our strategic partners may have to lower the price of that product in order to effectively compete,which would impact our margins and potential for profitability. ~~We are currently offering and developing multiple tests as LDTs and intend to develop and perform LDTs at Aspira Labs in the future.Should FDA disagree that our tests are LDTs or finalize regulations that require PMA approval or 510 (k) clearance of such tests,their commercialization would be adversely affected,which would negatively affect our results of operations and financial condition.The FDA considers an LDT to be a test that is designed,developed,validated,and used within a single laboratory.The FDA has historically taken the position that it has the authority to regulate LDTs as medical devices under the FDC Act,but it has generally exercised enforcement discretion with regard to LDTs.This means that even though the FDA believes it can impose regulatory requirements on LDTs,such as requirements to obtain premarket approval,de novo classification or 510 (k) clearance of LDTs,it has generally chosen not to enforce those requirements.On October 3,2023 proposed FDA regulations were published in the Federal Register that would phase out the FDA' s enforcement discretion approach to LDTs over a period of four years.The proposed regulation would classify all LDTs as medical devices,which would require us to adhere to a more stringent regulatory framework,including premarket clearance or approval requirements,quality system regulations,and post- market surveillance obligations.If the proposed regulation is finalized,we would be required to submit an application to obtain PMA approval,de novo classification or 510 (k) clearance for certain of our LDTs unless this requirement is modified or reversed as a result of legislation or litigation.Compliance with these additional regulatory requirements would be time- consuming and expensive,potentially diverting resources from other aspects of our business,and would potentially affect the sales of our products and how customers use our products and may require us to change our business model in order to maintain compliance with these laws.Moreover,failure to comply with these and other FDA regulations could result in legal actions,including fines and penalties.The FDA has indicated it plans to finalize the proposed rule in the second quarter of 2024,though we cannot be certain that the FDA will finalize the proposed rule on this timeline or at all.If adopted in its proposed form or otherwise,the regulation of LDTs as medical devices could have a significant negative impact on our operations and financial performance.Legislative proposals addressing the FDA' s oversight of LDTs have been previously introduced,and we expect that new legislative proposals will be introduced from time to time.The likelihood that Congress will pass such legislation and the extent to which such legislation may affect the FDA' s plans to regulate LDTs as medical devices,by either giving FDA explicit authority to do so or,alternatively,stating that FDA does not have authority to regulate LDTs,is difficult to predict.In June 2021,Congress introduced the VALID Act,which would have established a new risk- based regulatory framework for in vitro clinical tests (" IVCTs "),a category which would have included IVDs,LDTs,collection devices and instruments used with such tests.This legislation was not enacted during that session of Congress,but was reintroduced in 2023.In the meantime,the regulatory environment for LDTs is uncertain.If FDA disagrees that tests we perform or may in the future perform are LDTs,we may be forced to stop selling our tests or be required to modify claims or make such other changes while we work to obtain FDA clearance,approval or de novo classification.Our business,results of operations and financial condition would be negatively affected until such a review were completed and clearance,approval or de novo classification to market were obtained.If premarket clearance,approval,or de novo classification is required by the FDA or if we decide to voluntarily pursue FDA premarket clearance,approval or de novo classification of our LDTs,there can be no assurance that any tests we develop will be cleared,approved or classified on a timely basis,if at all.Obtaining FDA clearance,approval or de novo classification for diagnostics can be expensive,time consuming and uncertain,and for higher- risk devices generally takes several years and requires detailed and comprehensive scientific and clinical data.In addition,medical devices are subject to ongoing FDA obligations and continued regulatory oversight and review.Ongoing compliance with FDA regulations for those tests would increase the cost of conducting our business and subject us to heightened regulation by the FDA and penalties for failure to comply with these requirements.~~ Our diagnostic tests and software are subject to ongoing regulation by the FDA,and any delay by or failure of the FDA to authorize our diagnostic tests submitted to the FDA may adversely affect our business,results of operations and financial condition.Our activities related to diagnostic products are,or have the potential to be,subject to regulatory oversight by the FDA under provisions of the FDC Act and regulations thereunder,including regulations governing the development,marketing,labeling,promotion,manufacturing and export of our products.Failure to comply with applicable requirements can lead to sanctions,including withdrawal of products from the market,recalls,refusal to authorize government contracts,product seizures,civil money penalties,injunctions and criminal prosecution.The FDC Act requires that medical devices introduced to the United States market,unless exempted by regulation,be authorized by FDA pursuant to either the premarket notification pathway,known as 510 (k) clearance,the de novo classification pathway,or the PMA pathway.The FDA granted a request for a de novo authorization for Ova1 in September 2009,and we commercially launched Ova1 in March 2010.In March 2016,we received FDA 510 (k) clearance for a second- generation biomarker panel known as Ova1 Next Generation,which we call Overa.Ova1 was the first FDA- cleared blood test for the pre- operative assessment of ovarian masses.With respect to devices reviewed through the 510 (k) process,we may not market a device until it is determined that our product is substantially equivalent to a legally marketed device known as a predicate device.A 510 (k) submission may involve the presentation of a substantial volume of data,including clinical and analytical data,as well as extensive information regarding software.The FDA may agree that the product is substantially equivalent to a predicate device and allow the product to be marketed in the United States.On the other hand,the FDA may determine that the device is not substantially equivalent and require a PMA or de novo classification,or require further information,such as additional test data,including data from clinical

studies,before it is able to make a determination regarding substantial equivalence.By requesting additional information,the FDA can delay market introduction of our products.Delays in receipt of or failure to receive any necessary 510 (k) clearance,de novo classification,or PMA,or the imposition of stringent restrictions on the labeling and sales of our products,could have a material adverse effect on our business,results of operations and financial condition.If the FDA determines that a PMA is required for any of our potential future clinical products,the application will require extensive clinical studies,manufacturing information and could require review by an FDA advisory panel comprising experts outside the FDA.Clinical studies to support a 510 (k) submission,de novo classification or a PMA application would need to be conducted in accordance with FDA requirements.Failure to comply with FDA requirements could result in the FDA' s refusal to accept the submission or denial of the application.We cannot ensure that any necessary 510 (k) clearance,de novo classification,or PMA will be granted on a timely basis,or at all.To the extent we seek FDA 510 (k) clearance,de novo classification or FDA pre- market approval for other diagnostic tests,any delay by or failure of the FDA to clear,classify,or approve those diagnostic tests may adversely affect our consolidated revenues,results of operations and financial condition.Certain ~~changes to medical devices that a manufacturer makes after receiving a 510 (k) clearance,de novo classification,or PMA may trigger the need for additional FDA authorization.In the case of a 510 (k)- cleared device,FDA requires a new marketing authorization for significant changes or modifications made in the design,components,method of manufacture or intended use of a device,including changes or modifications to a 510 (k)- cleared device that could significantly affect the device' s safety or effectiveness,or would constitute a major change or modification in the device' s intended use.The type of submission needed — 510 (k),de novo classification,or PMA — will depend on the specific modification the manufacturer seeks to make.FDA expects the manufacturer to make the determination of whether a new marketing application is needed by applying existing agency guidance,but FDA may independently review,and may disagree with,our decision.If we make modifications to our marketed devices,we may be required to seek additional clearances,de novo classifications,or PMAs which,if not granted,would prevent us from selling the modified device.If we conclude that a modification does not require submission of a new marketing application and FDA disagrees with the decision,we may be required to submit new 510 (k) notifications,de novo classification requests,or premarket approval applications and may be required to cease marketing of or to recall the modified devices until marketing authorization is obtained and could additionally be subject to regulatory fines or penalties.Any recall or FDA requirement that we seek additional approvals or clearances could result in significant delays,fines,increased costs associated with modification of a product,loss of revenue and potential operating restrictions imposed by the FDA.Certain~~ of our software algorithms have been authorized for marketing by FDA as part of our cleared or de novo classified tests.If any of the software that we use in our LDTs or that we make available to third parties is determined by FDA to be non- exempt clinical decision support software,this could impede our ability to offer our tests or distribute our software to third parties and we could incur substantial costs and delays associated with trying to obtain premarket 510 (k) clearance,de novo classification,or premarket review and incur costs associated with complying with post- market controls.If we or our suppliers fail to comply with FDA requirements for production,marketing and post- market monitoring of our products,we may not be able to market our products and services and may be subject to stringent penalties,product restrictions or recall.Failure to comply with FDA requirements for post- market monitoring of our products may affect the commercialization of our products,therefore adversely affecting our business.The FDA granted the request for de novo classification for Ova1 in September 2009 and cleared Overa in March 2016.Post- market surveillance studies were conducted to further analyze performance of Ova1 and Overa.These studies have been completed and closed with the FDA.Additionally,if the FDA were to view any of our actions as non- compliant,it could initiate enforcement actions,such as a warning letter and possible imposition of penalties.For instance,we are subject to a number of FDA requirements,including compliance with the FDA' s QSR requirements,which establish extensive requirements for quality assurance and control as well as manufacturing procedures.Failure to comply with these regulations could result in enforcement actions for us or our potential suppliers.Adverse FDA actions in any of these areas could significantly increase our expenses and reduce our revenue.We will need to undertake steps to maintain our operations in line with the FDA' s QSR requirements.Some components of Ova1 and Overa are manufactured by other companies and we are required to ensure that,to the extent that we incorporate those components into our finished Ova1 and Overa products **(or Ova1Plus,which is a reflex testing service in which both Ova1 and Overa are used)** ,we use those components in compliance with QSR.Any failure to do so would have an adverse effect on our ability to commercialize ~~the~~ **Ova1,Overa or** Ova1Plus ~~workflow~~ .Our suppliers ~~that~~ **' manufacturing facilities,since they** manufacture finished **kits** ~~devices at their manufacturing facilities~~ that we use in ~~our products~~ **Ova1,Overa** and ~~services~~ **Ova1Plus,** are subject to periodic regulatory inspections by the FDA and other federal and state regulatory agencies.Our facility also is subject to FDA inspection.We or our suppliers may not satisfy such regulatory requirements,and any such failure to do so may adversely affect our business,financial condition and results of operations.If our suppliers fail to produce acceptable or sufficient stock,fail to supply stock due to supply shortages,make changes to the design or labeling of their biomarker kits or discontinue production of existing biomarker kits or instrument platforms,we may be unable to meet market demand for OvaSuite products.The commercialization of our OvaSuite tests depends on the supply of seven different immunoassay kits from third- party manufacturers that run on automated instruments.Failure by any of these manufacturers to produce kits that meet our specifications and pass our quality control measures might lead to back- order and / or loss of revenue due to missed sales and customer dissatisfaction.In addition,if the design or labeling of any kit were to change,continued OvaSuite supply could be threatened since new validation and submission to the FDA for ~~review~~ **510 (k) clearance** could be required as a condition of sale.Discontinuation of any of these kits could require identification,validation and **510 (k)** submission ~~to FDA~~ of a revised OvaSuite design.Likewise,discontinuation or failure to support or service the instruments may pose risk to ongoing operations.Changes in healthcare policy could increase our costs and adversely impact sales of and reimbursement for our tests,which would have an adverse effect on our business,financial condition and results of operations.PAMA established a Medicare reimbursement system for clinical laboratories beginning in 2018 that is based on rates paid to laboratories by private

payers.The CMS also issued various regulations and guidance to implement PAMA that require certain laboratories to report information ~~on~~ the rates private payers pay them for laboratory tests,including Multianalyte Assays with Algorithmic Analyses.In addition to these changes,a number of states are also contemplating significant reform of their healthcare reimbursement policies ~~.We expect that there will be additional health reform initiatives by legislators at both the federal and state levels,regulators and third- party payers to reduce costs while expanding individual healthcare benefits.Certain of these changes could impose additional limitations on the rates we will be able to charge for our current and future products or the amounts of reimbursement available for our current and future products from governmental agencies or other third- party payers~~ .We cannot predict whether future healthcare initiatives will be implemented at the federal or state level,or the effect any future legislation or regulation will have on us.Other changes to healthcare laws may adversely affect our business,financial condition and results of operations.We are subject to environmental laws and potential exposure to environmental liabilities.We are subject to various international,federal,state and local environmental laws and regulations that govern our operations,including the handling and disposal of non- hazardous and hazardous wastes,the recycling and treatment of electrical and electronic equipment,and emissions and discharges into the environment.Failure to comply with such laws and regulations could result in costs for corrective action,penalties or the imposition of other liabilities.We are also subject to laws and regulations that impose liability and clean- up responsibility for releases of hazardous substances into the environment.Under certain of these laws and regulations,a current or previous owner or operator of property may be liable for the costs to remediate hazardous substances or petroleum products on or from its property,without regard to whether the owner or operator knew of,or caused,the contamination,as well as incur liability to third parties affected by such contamination.The presence of,or failure to remediate properly,such substances could adversely affect the value and the ability to transfer or encumber such property.The operation of Aspira Labs requires us to comply with numerous laws and regulations,which is expensive and time- consuming and could adversely affect our business,financial condition and results of operations,and any failure to comply could result in exposure to substantial penalties and other harm to our business.In June 2014,we launched a clinical laboratory,Aspira Labs,in Texas.Clinical laboratories that perform tests on human subjects in the United States for the purpose of providing information for the diagnosis,prevention or treatment of disease or the assessment of human health must be certified under CLIA and licensed or permitted under applicable state laboratory laws.CLIA is a federal law that regulates the quality of clinical laboratory testing by requiring laboratories to comply with various technical,operational,personnel and quality requirements intended to ensure that the services provided are accurate,reliable and timely.A few states,including New York State ~~,~~ may require that additional quality standards be met and that detailed review of scientific validations and technical procedures for tests occur.In the future,the federal government may change the way that clinical laboratory tests are regulated,which may adversely affect our business,financial condition and results of operations.Aspira Labs holds a CLIA Certificate of Accreditation and a state laboratory license or permit in California,Maryland,New York,Pennsylvania and Rhode Island.This allows the lab to perform Ova1 ~~and ,~~ Overa **and Ova1Plus** testing ~~(through the Ova1Plus workflow)~~ on a national basis.We are subject to periodic surveys and inspections to maintain our CLIA certification,and such certification is also required to obtain payment from Medicare,Medicaid and certain other third- party payers.Failure to comply with CLIA or state law requirements may result in the imposition of corrective action or the suspension or revocation of our CLIA certification or state licenses.If our CLIA certification or state licenses are suspended or revoked or our right to bill the Medicare and Medicaid programs or other third-party payers is suspended,we would no longer be able to sell our tests,which would adversely affect our business,financial condition and results of operations.In addition,no assurance can be given that Aspira Labs' suppliers or commercial partners will remain in compliance with applicable CLIA and other federal or state regulatory requirements for laboratory operations and testing.Aspira Labs' facilities and procedures and those of Aspira Labs' suppliers and commercial partners are subject to ongoing regulation,including periodic inspection by regulatory and other government authorities.The principal sanction under CLIA is suspension,limitation or revocation of a lab' s CLIA certificate.CMS also may impose the following alternative sanctions:(a) directed plan of correction,(b) state onsite monitoring,and / or (c) civil monetary penalty.In addition,the government may bring suit to enjoin any activity of any laboratory that has been found with deficiencies during a survey if CMS has reason to believe that continuation of the activity would constitute a significant hazard to the public health.Finally,criminal sanctions may be imposed on an individual who is convicted of intentionally violating any CLIA requirement.Our clinical laboratory business is also subject to regulation at both the federal and state level in the United States,as well as regulation in other jurisdictions outside of the United States,including:? Medicare and Medicaid coverage,coding and payment regulations applicable to clinical laboratories;? ~~The~~ **the** Federal Anti- Kickback Statute ~~(" AKS ")~~ ,the Eliminating Kickbacks in Recovery Act (" EKRA "),and state anti- kickback prohibitions;? the federal physician self- referral prohibition,commonly known as the Stark Law,and state self- referral prohibitions;? the Medicare civil monetary penalty and exclusion ~~penalty~~ **requirements** ;? the Federal False Claims Act civil and criminal penalties and state equivalents;? the federal fraud,waste and abuse laws and state equivalents; ~~? the federal Physician Payments Sunshine Act,~~ and ? the Federal Health Insurance Portability and Accountability Act of 1996 (" HIPAA ") as amended by the Health Information Technology for Economic and Clinical Health Act of 2009 (" HITECH ").Many of these laws and regulations prohibit a laboratory from making payments or furnishing other benefits to influence the referral of tests (by physicians or others) that are billed to Medicare,Medicaid or certain other federal or state healthcare programs.The penalties for violation of these laws and regulations may include monetary fines,criminal and civil penalties and / or suspension or exclusion from participation in Medicare,Medicaid and other federal healthcare programs.Several states have similar laws that may apply even in the absence of government payers.HIPAA and HITECH and similar state laws seek to protect the privacy and security of individually identifiable health information,and penalties for violations of these laws may include required reporting of breaches,monetary fines and criminal or civil penalties.In 2020,Congress passed the Consolidated Appropriations Act and included a section called the " No Surprises Act." The No Surprises Act prohibits a health care provider from billing a commercially insured patient more than in- network cost- sharing

amounts when a service originated from an in- network hospital or ambulatory surgery center,even if the provider is out- of- network with the patient' s health plan.It also requires a provider to provide a good faith estimate of expected charges to an uninsured or self- pay patient upon the patient' s request or when a patient schedules a service.Several states have similar laws that aim to protect patients from unexpected health care charges.Civil penalties of up to $ 10,000 per occurrence can be imposed for knowing violations of the No Surprises Act that are not remediated within a certain timeframe,and states may impose their own penalties for violations of their surprise billing laws.While we seek to conduct our business in compliance with all applicable laws and develop compliance policies to address risk as appropriate,many of the laws and regulations applicable to us are vague or indefinite and have not been interpreted by governmental authorities or the courts.These laws or regulations also could in the future be interpreted or applied by governmental authorities or the courts in a manner that could require us to change our operations.Any action brought against us for violation of these or other laws or regulations (including actions brought by private qui tam " whistleblower " plaintiffs),even if successfully defended,could divert management' s attention from our business,damage our reputation,limit our ability to provide services,decrease demand for our services and cause us to incur significant expenses for legal fees and damages.If we fail to comply with applicable laws and regulations,we could suffer ~~significant~~ civil ~~,~~ **and** criminal ~~and administrative~~ penalties,fines,recoupment of funds received by us,exclusion from participation in federal or state healthcare programs,and the loss of various licenses, ~~accreditations,~~ certificates and authorizations necessary to operate our business ~~,contractual damages,reputational harm,diminished profits and future earnings,additional reporting obligations and oversight if we become subject to a corporate integrity agreement or other agreement~~ .We also could potentially incur additional liabilities from third- party claims.If any of the foregoing were to occur,it could have a material adverse effect on our business,financial condition and results of operations.Our ability to utilize our net operating loss carryforwards and certain other tax attributes may be limited.We have significant net operating loss (" NOL ") carryforwards as of December 31, ~~2023~~ **2022 for** which ~~are subject to~~ a full valuation allowance **has been provided** due to our history of operating losses.Section 382 of the Internal Revenue Code of 1986,as amended (" Section 382 "),as well as similar state provisions restrict our ability to use our NOL carryforwards to offset taxable income due to ownership change limitations that have occurred in the past or that could occur in the future.These ownership changes **may** also ~~may~~ limit the amount of tax credit carryforwards that can be utilized annually to offset future tax liabilities. ~~Our~~ **Legislation commonly referred to as the Tax Cuts and Jobs Act (H.R.1) was enacted on December 22,2017.As a result of the Tax Cuts and Jobs Act of 2017,federal NOLs arising before January 1,2018,and federal NOLs arising after January 1,2018,are subject to different rules.The Company' s** pre- 2018 federal NOLs will expire in varying amounts from 2023 through 2037,if not utilized ~~,~~ **;** and can offset 100 % of future taxable income for regular tax purposes.Any federal NOLs arising ~~on or~~ after January 1,2018,can **generally** be carried forward indefinitely **and can** ~~but such federal NOL carryforwards are permitted to be used in any taxable year to~~ offset ~~only~~ up to 80 % of **future** taxable income ~~in such year~~ . ~~Portions of our state~~ **State** NOLs will expire in varying amounts from 2023 through 2037 if not utilized. ~~Our~~ **The Company' s** ability to use ~~our~~ **its** NOLs during this period will be dependent on ~~our~~ **the Company' s** ability to generate taxable income,and **the** ~~portions of our~~ NOLs could expire before ~~we~~ **the Company** ~~generate~~ **generates** sufficient taxable income.We believe we have experienced ownership changes in the past for purposes of these limitations,and we estimate that a substantial portion of our existing federal NOL and tax credit carryforwards are subject to annual limitation.Additional issuances or sales of our common stock, ~~and~~ **or** certain other transactions involving our stock that are outside of our control,could cause additional ownership changes.Any current or future ~~limitations~~ **limitation** on the use of our NOLs or tax credit carryforwards could,depending on the extent of such limitation,result in our retaining less cash during any year in which we have taxable income than we would be entitled to retain if such limitations did not apply,which could adversely impact our results of operations and financial condition **.RISKS RELATED TO THE COVID- 19 PANDEMIC The novel coronavirus outbreak and the COVID- 19 pandemic have adversely impacted,and are expected to further adversely impact,our business,results of operations and financial condition,and such future adverse impact may be material.In addition,other health epidemics,outbreaks or pandemics may adversely affect our business,results of operations and financial condition.We face risks related to health epidemics and other outbreaks,including the global outbreak of the novel coronavirus and the disease caused by it,COVID- 19,as well as its variants.If infection rates rise or if significant action is taken to contain the pandemic again in the future,we will likely experience similar impacts as we had in previous years,which include test volume decreases,challenges for our sales force,including limiting the ability to make in- person sales calls,shortages of skilled labor,and difficulty recruiting participants in studies,and as a result,our business,results of operations and financial condition are likely to be adversely affected.To the extent our testing volumes decrease or we are unable to collect from patient payers,our revenues,cash flows from operations and liquidity will be adversely impacted.There is no assurance that sales or collections will not be adversely affected by new outbreaks of COVID- 19 or other health epidemics** .RISKS RELATED TO INTELLECTUAL PROPERTY AND PRODUCT LIABILITY If we fail to maintain our rights to utilize intellectual property directed to diagnostic biomarkers,we may not be able to offer diagnostic tests using those biomarkers.One aspect of our business plan is to develop diagnostic tests based on certain biomarkers,which we have the right to utilize through licenses with our academic collaborators,such as the Johns Hopkins University School of Medicine ~~,~~ **and** the University of Texas M.D.Anderson Cancer Center ~~,Harvard' s Dana- Farber Cancer Institute,Brigham & Women' s Hospital,and Medical University of Lodz~~ .In some cases,our collaborators own the entire right to the biomarkers.In other cases,we co- own the biomarkers with our collaborators.If,for any reason,we lose our license to biomarkers owned entirely by our collaborators,we may not be able to use those biomarkers in diagnostic tests.If we lose our exclusive license to biomarkers co- owned by us and our collaborators,our collaborators may license their share of the intellectual property to a third party that may compete with us in offering diagnostic tests,which would materially adversely affect our business,results of operations and financial condition.If a third party infringes on our proprietary rights,we may lose any competitive advantage we have as a result of diversion of our time,enforcement costs

and the loss of the exclusivity of our proprietary rights.Our success depends in part on our ability to maintain and enforce our proprietary rights.We rely on a combination of patents,trademarks,copyrights and trade secrets to protect our technology and brand.We have submitted a number of patent applications covering biomarkers that may have diagnostic or therapeutic utility.Our patent applications may or may not result in additional patents being issued.If third parties engage in activities that infringe on our proprietary rights,we may incur significant costs in asserting our rights,and the attention of our management may be diverted from our business.We may not be successful in asserting our proprietary patient rights,which could result in our patents being held invalid or a court holding that the competitor is not infringing,either of which may harm our competitive position.We cannot be sure that competitors will not design around our patented technology.We also may not be successful in asserting our proprietary trademark rights,which could result in significant rebranding costs,not being able to obtain a federal trademark registration,or a court holding that the competitor is not infringing,any of which may harm our competitive position.We cannot be sure that competitors will not use a similar mark.We also rely upon the skills,knowledge and experience of our technical personnel.To help protect our rights,we require all employees and consultants to enter into confidentiality agreements that prohibit the disclosure of confidential information.These agreements may not provide adequate protection for our trade secrets,knowledge or other proprietary information in the event of any unauthorized use or disclosure.If any trade secret,knowledge or other technology not protected by a patent were to be disclosed to or independently developed by a competitor,it could have a material adverse effect on our business,consolidated results of operations and financial condition.If others successfully assert their proprietary rights against us,we may be precluded from making and selling our products or we may be required to obtain licenses to use their technology.Our success depends on avoiding infringing on the proprietary technologies of others.If a third party were to assert claims that we are violating its patents,we might incur substantial costs defending ourselves in lawsuits against charges of patent infringement or other allegations of unlawful use of another' s proprietary technology.Any such lawsuit may involve considerable management and financial resources and may not be decided in our favor.If we are found liable,we may be subject to monetary damages or an injunction prohibiting us from using the technology.We may also be required to obtain licenses under patents owned by third parties and such licenses may not be available to us on commercially reasonable terms,if at all.If a third party were to assert claims that we are violating its trademarks,we might incur substantial costs defending ourselves in lawsuits against charges of trademark infringement.Any such lawsuit may involve considerable management and financial resources and may not be decided in our favor.If we are found liable,we may be subject to monetary damages or an injunction prohibiting us from using the mark.We may also be required to rebrand or enter into a co- existence agreement with a third party,which may be commercially restrictive or unreasonable.Our diagnostic efforts may cause us to have significant product liability exposure.The testing,manufacturing and marketing of medical diagnostic tests entail an inherent risk of product liability claims.Potential product liability claims may exceed the amount of our insurance coverage or may be excluded from coverage under the terms of the policy.We will need to increase our amount of insurance coverage in the future if we are successful at introducing new diagnostic products,and this will increase our costs.If we are held liable for a claim or for damages exceeding the limit of our insurance coverage,we may be required to make substantial payments.This may have an adverse effect on our business,financial condition and results of operations.Certain of our patent registrations will expire,which may cause us to have significant competition.Our success depends in part on our ability to own and assert our patent registrations to maintain and enforce our proprietary rights,including defending against infringement actions.We have some patent registrations covering biomarkers that may be expiring,and our strategy to continue to seek protection and file patent applications may or may not result in additional patents being issued.If any such patent registration is no longer protectable and could be exploited by a competitor,it could have a material adverse effect on our business,consolidated results of operations and financial condition.RISKS RELATED TO **OWNING** ~~THE RESTATEMENT OF~~ OUR **STOCK** ~~2022 YEAR END FINANCIAL STATEMENTS~~ We ~~face risks related to the restatement of our previously issued consolidated financial statements and financial information as of and for the fiscal year ended December 31,2022,as well as for the interim financial information as of September 30,2022 and for the three and nine months then ended (collectively," the Affected Periods ").As discussed in the Note 3 to the consolidated financial statements in our Form 10- K / A filed October 26,2023,we reached a determination to restate certain financial information and related note disclosures in our previously issued consolidated financial statements for the Affected Periods.As a result,we~~ have **identified** ~~become subject to~~ **two** ~~a number of additional risks and uncertainties,which may affect investor confidence in the accuracy of our financial disclosures and may raise reputational issues for our business.We expect to continue to face many of the risks and challenges related to the restatement,including the processes undertaken to effect the restatement may not have been adequate to identify and correct all errors in our historical financial statements and,as a result,we may discover additional errors and our financial statements remain subject to the risk of future restatement.We cannot assure that all of the risks and challenges described above will be eliminated or that general reputational harm will not persist.If one or more of the foregoing risks or challenges persist,our business,operations and financial condition are likely to be materially and adversely affected.We may face litigation and other risks as a result of the restatement and~~ material weaknesses in our internal control over financial reporting. **If** ~~As part of the restatement,~~ we ~~identified a~~ **are unable to remediate the** material ~~weakness~~ **weaknesses** ~~in~~ **, our** ~~-~~ **or if we experience additional material weaknesses or other deficiencies in the future,or otherwise fail to maintain an effective system of** internal control over financial reporting **,then these** ~~.As a result of such~~ material ~~weakness~~ **weaknesses could continue to adversely affect** ~~,the restatement,and other matters raised or~~ **our** ~~that may~~ **ability to report our results of operations and financial condition accurately and** in **a timely manner.Our management is responsible** ~~the future be raised by the SEC,we face potential~~ for **establishing** ~~litigation or other disputes which may include,among others,claims invoking the federal~~ and **maintaining adequate** ~~state securities laws,or other claims arising from the restatement and the material weakness in our~~ internal control over financial reporting **designed to provide reasonable assurance regarding the reliability of financial reporting** and the preparation **of financial statements for external purposes in accordance with GAAP.Our management is**

likewise required,on a quarterly basis,to evaluate the effectiveness of our internal controls and to disclose any changes and material weaknesses identified through such evaluation of those internal controls.A material weakness is a deficiency,or a combination of deficiencies over information systems and a lack of timely execution of certain internal controls over financial reporting and disclosures.Management evaluated the effectiveness of our disclosure controls and procedures as of December 31,2022.Management concluded that our disclosure controls and procedures were not effective as of December 31,2022,due to two material weaknesses in the internal control over financial reporting related to multiple design deficiencies and a lack of a timely operation of certain internal controls over financial reporting and disclosures.Internal controls related to the operation of technology systems are critical to maintaining adequate internal control over financial reporting.As disclosed in Part II,Item 9A,management identified a material weakness in the design and operation of internal control related to information technology general controls (ITGCs) due to the lack of timely identification of certain information technology (IT) systems that are hosted by third- party service organizations and are used to process and record certain revenue and expense transactions and support our financial reporting processes resulting in the lack of certain internal controls over these IT systems and over data and reports accumulated in such IT systems.Additionally,management identified a material weakness in the design and operation of certain internal controls over financial reporting that were not performed timely in connection with the year- end close and reporting process to ensure the completeness and accuracy of the consolidated financial statements.While there can be no assurance that our efforts will be successful,we plan to remediate the material weaknesses during fiscal 2023.Our ability to comply with the annual internal control report requirements will depend on the effectiveness of our financial reporting and data systems and controls across our company.To effectively manage our IT environment and financial reporting environment,we will need to continue to improve our operational,financial,and management controls,and our reporting systems and procedures.The above material weaknesses did not result in a misstatement;however,they could result in a misstatement of our account balances or disclosures that would result in a material misstatement of our annual or interim financial statements that would not be prevented or detected.To remediate the material weakness in internal control over financial reporting related to the design of controls for system implementations,we have and will continue to update the design and review of controls for system implementations,continue to leverage internal expertise in systems implementation for the design of controls,and work with qualified external advisors to support these efforts.To remediate the material weakness in internal control over financial reporting related to timely evaluation of the accounting treatment and disclosure of our contracts,we have and will continue to implement new procedures and testing for review of our accounting treatment of contracts.We intend to continue to take steps to remediate the material weaknesses.We cannot assure you that the measures we have taken to date,and are continuing to implement,will be sufficient to remediate the material weaknesses we have identified or avoid potential future material weaknesses.If the steps we take do not correct the material weaknesses in a timely manner,we will be unable to conclude that we maintain effective internal control over financial reporting.Accordingly,there could continue to be a reasonable possibility that a material misstatement of our financial statements would not be prevented or detected on a timely basis.If we fail to remediate our existing material weaknesses or identify new material weaknesses in our internal controls over financial reporting,if we are unable to comply with the requirements of Section 404 of the Sarbanes- Oxley Act in a timely manner,if we are unable to conclude that our internal controls over financial reporting are effective,or if our independent registered public accounting firm is unable to express an opinion as to the effectiveness of our internal controls over financial reporting,investors may lose confidence in the accuracy and completeness of our financial reports and the market price of our common stock could be negatively affected.As a result of such failures,we could also become subject to investigations by The Nasdaq Stock Market,the SEC or other regulatory authorities,and become subject to litigation from investors and stockholders,which could harm our reputation and financial condition or divert financial and management resources from our regular business activities. fail to maintain compliance with the Nasdaq minimum listing requirements, our common stock will be subject to delisting. Our ability to publicly or privately sell equity securities and the liquidity of our common stock could be adversely affected if our common stock is delisted. The continued listing standards of the Nasdaq Capital Market require, among other things, that the ~~minimum price~~ **Market Value** of ~~a listed~~ **Listed Securities** ~~company' s stock~~ be at **least** ~~or above~~ $ ~~1. 00, or the Bid Price~~ **35 million pursuant to Nasdaq Listing Rule 5550 (a) (2) (" MVLS** Requirement **")** ~~. If the minimum bid price is below $ 1. 00 for a period of more than 30 consecutive trading days, the listed company will fail to be in compliance with Nasdaq Capital Market' s listing rules and, if it does not regain compliance within the 180- day grace period, will be subject to delisting~~ . On ~~June 1~~ **July 11** , ~~2022~~ **2023** , we received a deficiency letter from the Listing Qualifications Department of The Nasdaq Stock Market stating that we were not in compliance with the **MVLS** ~~Bid Price~~ Requirement. **In accordance with Nasdaq** ~~We did not regain compliance on or prior to November 28, 2022, and on November 29, 2022, we received a written notice from the~~ Listing ~~Qualifications Department of The~~ **Rule 5810 (c) (3) (C),** Nasdaq **provided us with** ~~Stock Market that we had been granted an additional~~ 180 calendar days, or until ~~May 29~~ **January 8** , ~~2023~~ **2024** ~~(as the first trading day following such period)~~ , to regain compliance with the **MVLS** ~~Bid Price~~ Requirement. ~~In order to~~ **On September 12, 2023, we received notice from Nasdaq that we have** ~~regain~~ **regained** compliance ~~, the bid price of our common stock must close at a price of at least $ 1.~~ **There is no assurance that** ~~00 per share for a minimum of 10 consecutive trading days within the 180 day grace period. If~~ we **will maintain** ~~fail to regain~~ compliance ~~,~~ **with the MVLS Requirement** ~~our~~ **or** ~~common stock will be subject to~~ **any of the other Nasdaq continued** ~~delisting~~ **listing requirements** . Delisting from the Nasdaq Capital Market could adversely affect our ability to raise additional financing through the public or private sale of equity securities, would significantly affect the ability of investors to trade our securities and would negatively affect the value and liquidity of our common stock. Delisting could also have other negative results, including the potential loss of confidence by employees, the loss of institutional investor interest and fewer business development opportunities. Unless our

common stock continues to be listed on a national securities exchange it will become subject to the so- called " penny stock " rules that impose restrictive sales practice requirements. If we are unable to maintain the listing of our common stock on the Nasdaq Capital Market or another national securities exchange, our common stock could become subject to the so- called " penny stock " rules if the shares have a market value of less than $ 5. 00 per share. The SEC has adopted regulations that define a penny stock to include any stock that has a market price of less than $ 5. 00 per share, subject to certain exceptions, including an exception for stock traded on a national securities exchange. The SEC regulations impose restrictive sales practice requirements on broker- dealers who sell penny stocks to persons other than established customers and accredited investors. For transactions covered by this rule, the broker- dealer must make a special suitability determination for the purchaser and must have received the purchaser' s written consent to the transaction prior to sale. This means that if we are unable **to** maintain the listing of our common stock on a national securities exchange, the ability of stockholders to sell their common stock in the secondary market could be adversely affected. If a transaction involving a penny stock is not exempt from the SEC' s rule, a broker- dealer must deliver a disclosure schedule relating to the penny stock market to each investor prior to a transaction. The broker- dealer also must disclose the commissions payable to both the broker- dealer and its registered representative, current quotations for the penny stock, and, if the broker- dealer is the sole market- maker, the broker- dealer must disclose this fact and the broker- dealer' s presumed control over the market. Finally, monthly statements must be sent disclosing recent price information for the penny stock held in the customer' s account and information on the limited market in penny stocks. If we are unable to increase the..... resources from our regular business activities. The liquidity and trading volume of our common stock may be low, and our ownership is concentrated, which could adversely impact the trading price of our common stock and our stockholders' ability to obtain liquidity. The liquidity and trading volume of our common stock has at times been low in the past and may again be low in the future. If the liquidity and trading volume of our common stock is low, this could adversely impact the trading price of our common stock and our stockholders' ability to obtain liquidity in their shares of our common stock. Our stock issuances since May 2013 have primarily involved a significant issuance of stock to a limited number of investors, significantly increasing the concentration of our share ownership in a few holders. According to publicly available information, ~~provided on Schedules 13D and 13G, as filed on December 30, 2021, January 13, 2022, February 14, 2022, February 16, 2022 and February 15, 2023,~~ we estimate that a total of five ~~persons~~ **investors** beneficially own approximately ~~45~~ **40** . 0 % of our outstanding common stock. ~~Under the~~ **In addition, pursuant to a stockholders agreement we entered into in connection with a** May 2013 ~~stockholders agreement~~ **private placement** , one of our stockholders has the right to designate a director to be nominated by us to serve on our Board of Directors, and ~~t~~ **the** stockholder has **not** exercised this right **for 2023** . **Furthermore** ~~In addition~~ , ~~a~~ **this** ~~Stockholders~~ **stockholder** ~~Agreement~~ **agreement** ~~we entered into in connection with a May 2013 private placement~~ gives two ~~of the primary~~ investors ~~in that private placement~~ the right to participate in future equity offerings ~~, including the offering of common stock being made pursuant to this prospectus supplement~~ , on the same terms as other investors. In addition, the ~~Stockholders~~ **stockholders** ~~Agreement~~ **agreement** prohibits us from taking certain material actions without the consent of **at least** one of the primary investors in the May 2013 private placement. These material actions include: ? making any acquisition with a value greater than $ 2 million; ? offering, selling or issuing securities senior to our common stock or any securities that are convertible into or exchangeable or exercisable for securities ranking senior to our common stock; ? taking any action that would result in a change in control of the company or an insolvency event; and ? paying or declaring dividends on any **of our** securities ~~of the company~~ or distributing any **of our** assets ~~of the company~~ other than in the ordinary course of business or repurchasing any **of our** outstanding securities ~~of the company~~ . ~~?~~ **The foregoing rights terminate for a primary investor when that investor ceases to beneficially own less than 50 % of the shares and warrants (taking into account shares issued upon exercise of the warrants), in the aggregate, that were purchased at the closing of the 2013 private placement. We believe that the rights of one of the primary investors have so terminated.** As a result of the foregoing, a limited number of stockholders will be able to affect the outcome of, or exert significant influence over, all matters requiring stockholder approval, including the election and removal of directors and any change in control involving us. In addition, this concentration of ownership of our common stock could have the effect of delaying or preventing a change in control of us or otherwise discouraging or preventing a potential acquirer from attempting to obtain control of us. This, in turn, could have a negative effect on the market price of our common stock. It could also prevent our stockholders from realizing a premium over the market prices for their shares of common stock. Moreover, the interests of this concentration of ownership may not always coincide with our interests or the interests of other stockholders. In addition, the interests of the parties to the ~~Stockholders~~ **stockholders** ~~Agreement~~ **agreement** could conflict with or differ from our interests or the interests of other stockholders. The concentration of ownership also contributes to the low trading volume and volatility of our common stock. Our stock price has been, and may continue to be, highly volatile. The trading price of our common stock has been highly volatile. During the 12 months ended December 31, ~~2022~~ **2023** , the closing trading price of our common stock ranged from a high of $ ~~1~~ **8** . ~~81~~ **70** per share to a low of $ ~~0~~ **2** . **40** ~~30 per share. During the three months ended December 31, 2022, the closing trading price of our common stock ranged from a high of $ 0. 41 per share to a low of $ 0. 30~~ per share. The trading price of our common stock could continue to be subject to wide fluctuations in price in response to various factors, many of which are beyond our control, including: ? failure to significantly increase revenue and volumes of OvaSuite or Aspira Synergy; ? actual or anticipated period- to- period fluctuations in financial results; ? failure to achieve, or changes in, financial estimates by securities analysts; ? announcements or introductions of new products or services or technological innovations by us or our competitors; ? failure to complete clinical studies that validate clinical utility sufficiently to increase positive medical policy among payers at large; ? publicity regarding actual or potential discoveries of biomarkers by others; ? comments or opinions by securities analysts or stockholders; ? the inclusion of our common stock in stock market indices such as the Russell 3000 Index; ? conditions or trends in the pharmaceutical, biotechnology or life science industries; ? announcements by us of significant acquisitions and divestitures, strategic partnerships, joint ventures or capital commitments; ? developments

regarding our patents or other intellectual property or that of our competitors; ? litigation or threat of litigation; ? additions or departures of key personnel; ? limited daily trading volume; ? our ability to continue as a going concern; ? economic and other external factors, disasters or crises; and ? our announcement of future fundraisings. In addition, the stock market in general and the market for diagnostic technology companies, in particular, have experienced significant price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of those companies. These broad market and industry factors may adversely affect the market price of our common

stock, regardless of our operating performance. In the past, following periods of volatility in the market price of a company' s securities, securities class action litigation has often been instituted. A securities class action suit against us could result in substantial costs, potential liabilities and the diversion of our attention and our resources. Anti- takeover provisions in our charter, bylaws, other agreements and under Delaware law could make a third- party acquisition of the Company difficult. Certain provisions of our certificate of incorporation and bylaws may have the effect of making it more difficult for a third party to acquire, or of discouraging a third party from attempting to acquire, control of us, even if a change of control might be deemed beneficial to our stockholders. Such provisions could limit the price that certain investors might be willing to pay in the future for our securities. Our certificate of incorporation eliminates the right of stockholders to call special meetings of stockholders or to act by written consent without a meeting, and our bylaws require advance notice for stockholder proposals and director nominations, which may preclude stockholders from bringing matters before an annual meeting of stockholders or from making nominations for directors at an annual meeting of stockholders. Our certificate of incorporation authorizes undesignated preferred stock, which makes it possible for our board of directors, without stockholder approval, to issue preferred stock with voting or other rights or preferences that could adversely affect the voting power of holders of common stock. In addition, the likelihood that the holders of preferred stock will receive dividend payments and payments upon liquidation could have the effect of delaying, deferring or preventing a change in control. In connection with our private placement offering of common stock and warrants in May 2013, we entered into a stockholders agreement which, among other things, includes agreements limiting our ability to effect a change in control without the consent of at least one of the two primary investors in that offering. These and other provisions may have the effect of deferring hostile takeovers or delaying changes in control or management of us. The amendment of any of the provisions of either our certificate of incorporation or bylaws described in the preceding paragraph would require not only approval by our board of directors and the affirmative vote of at least 66 2 / 3 % of our then outstanding voting securities, but also the consent of at least one of the two primary investors in the May 2013 offering. We are also subject to certain provisions of Delaware law that could delay, deter or prevent a change in control of the Company. These provisions could make a third- party acquisition of the Company difficult and limit the price that investors might be willing to pay in the future for shares of our common stock. Because we do not intend to pay dividends, our stockholders will benefit from an investment in our common stock only if it appreciates in value. We have never declared or paid any cash dividends on our common stock. We currently intend to retain our future earnings, if any, to finance the expansion of our business and do not expect to pay any cash dividends in the foreseeable future. As a result, the success of an investment in our common stock will depend entirely upon any future appreciation. There is no guarantee that our common stock will appreciate in value or even maintain the price at which our stockholders purchased their shares. The exercise of all or a portion of our outstanding options will dilute the ownership interests of our stockholders. OPERATIONAL RISKS Because our business is highly dependent on key executives and employees, our inability to recruit and retain these people could hinder our business plans. We are highly dependent on our executive officers and certain key employees. Our executive officers and key employees are employed at will by us. Any inability to engage new executive officers or key employees could impact operations or delay or curtail our research, development and commercialization objectives. To continue our research and product development efforts, we need people skilled in areas such as clinical operations, regulatory affairs and clinical diagnostics. Competition for qualified employees is intense. To continue our commercialization objectives and reach our financial and operational goals, we require skilled sales individuals with familiarity in our industry. We have from time to time experienced, and may in the future experience, shortages of certain types of qualified employees. If we lose the services of any executive officers or key employees, our ability to achieve our business objectives could be harmed, which in turn could adversely affect our business, financial condition and results of operations. We have and may continue to experience turnover in certain executive officer and key employee roles. Business interruptions could limit our ability to operate our business. Our operations, as well as those of the collaborators on which we depend, are vulnerable to damage or interruption from fire; natural disasters, including earthquakes, weather related supply chain delivery disruptions, computer viruses, cyber- attacks, human error, power shortages, telecommunication failures, international acts of terror, foreign or domestic conflicts, epidemics or pandemics such as the COVID- 19 pandemic, and other similar events. Although we have certain business continuity plans in place, we have not established a formal comprehensive disaster recovery plan, and our back- up operations and business interruption insurance may not be adequate to compensate us for losses we may suffer. A significant business interruption could result in losses or damages incurred by us and require us to cease or curtail our operations. The operation of Aspira Labs and our Aspira Synergy business depends on the effectiveness and availability of our information systems, including the information systems we use to provide services to our customers and to store employee data, and failures of these systems, including in connection with cyber- attacks, may materially limit our operations or have an adverse effect on our reputation. The information systems we use for our Aspira Labs business are comprised of systems we have purchased or developed, our legacy information systems and, increasingly, web- enabled and other integrated information systems. In using these information systems, we may rely on third- party vendors to provide hosting services, where our infrastructure is dependent upon the reliability of their underlying platforms, facilities and communications systems. We also plan to utilize integrated information systems that we provide customers access to or install for our customers in conjunction with our delivery of services. The addition of our decentralized technology transfer business may also be affected by these information systems. As the breadth and complexity of Aspira Labs' information system grows, we will be increasingly exposed

to the risks inherent in maintaining the stability of our legacy systems due to prior customization, attrition of employees or vendors involved in their development, and obsolescence of the underlying technology as well as risks from the increasing number and scope of external data breaches on companies generally. Because certain customers and clinical trials may be dependent upon these legacy systems, we will also face an increased level of embedded risk in maintaining the legacy systems and limited options to mitigate such risk. We are also exposed to risks associated with the availability of all of our information systems, including: ? discontinued vendor support of legacy systems; ? disruption, impairment or failure of data centers, telecommunications facilities or other key infrastructure platforms, including those maintained by third- party vendors; ? security breaches of, cyber- attacks on and other failures or malfunctions in our internal systems, including our employee data and communications, critical application systems and their associated hardware; and ? excessive costs, excessive delays and other deficiencies in systems development and deployment. The materialization of any of these risks may impede the processing of data, the delivery of databases and services, and the day- to- day management of our Aspira Labs business and could result in the corruption, loss or unauthorized disclosure of proprietary, confidential or other data. While we have invested and continue to invest in disaster recovery plans, security initiatives, and risk management in line with applicable regulations and industry standards, they might not adequately protect us in the event of a system failure, cyber- attack, cyber- breach, data breach or other adverse event. Despite any precautions we take, damage from fire, floods, hurricanes, the outbreak or escalation of war, acts of terrorism, power loss, telecommunications failures, computer viruses, break- ins and similar events at our various computer facilities or those of our third- party vendors could result in interruptions in the flow of data to us and from us to our customers. Corruption or loss of data may result in the need to repeat a trial at no cost to the customer, but at significant cost to us, the termination of a contract or damage to our reputation. As our business continues its efforts to expand globally, these types of risks may be further increased by instability in the geopolitical climate of certain regions, underdeveloped and less stable utilities and communications infrastructure, and other local and regional factors. Additionally, significant delays in system enhancements or inadequate performance of new or upgraded systems could damage our reputation and harm our business. Although we carry property and business interruption insurance which we believe is customary for our industry, our coverage might not be adequate to compensate us for all losses that may occur. Unauthorized disclosure of sensitive or confidential data, whether through systems failure or employee or distributor negligence, cyber- attacks, fraud or misappropriation, could damage our reputation and cause us to lose customers and, to the extent any such unauthorized disclosure compromises the privacy and security of individually identifiable health information, could also cause us to face sanctions and fines under HIPAA of 1996 as amended by HITECH. Similarly, we have been and expect that we will continue to be subject to attempts to gain unauthorized access to or through our information systems or those we internally or externally develop for our customers, including a cyber- attack by computer programmers and hackers who may develop and deploy viruses, worms or other malicious software programs, process breakdowns, denial- of- service attacks, malicious social engineering or other malicious activities, or any combination of the foregoing. These concerns about security are increased when information is transmitted over the Internet. Threats include cyber- attacks such as computer viruses, worms or other destructive or disruptive software, and any of these could result in a degradation or disruption of our services or damage to our properties, equipment and data. They could also compromise data security. If such attacks are not detected immediately, their effect could be compounded. These same risks also apply to Aspira Labs. Successful attacks could result in negative publicity, significant remediation and recovery costs, legal liability and damage to our reputation and could have an adverse effect on our business, financial condition and results of operations. We selectively explore acquisition opportunities and strategic alliances relating to other businesses, products or technologies. We may not be successful in integrating other businesses, products or technologies with our business. Any such transaction also may not produce the results we anticipate, which could adversely affect our business, financial condition and results of operations. We selectively explore and may pursue acquisition and other opportunities to strengthen our business and grow our company. We may enter into business combination transactions, make acquisitions or enter into strategic partnerships, joint ventures or alliances, any of which may be material. The market for acquisition targets and strategic alliances is highly competitive, which could make it difficult to find appropriate merger or acquisition opportunities. If we are required to raise capital by incurring debt or issuing additional equity for any reason in connection with a strategic acquisition or investment, financing may not be available or the terms of such financing may not be favorable to us and our stockholders, whose interests may be diluted by the issuance of additional stock. The process of integration may produce unforeseen regulatory issues and operating difficulties and expenditures and may divert the attention of management from the ongoing operation of our business and harm our reputation. We may not successfully achieve the integration objectives, and we may not realize the anticipated cost savings, revenue growth and synergies in full or at all, or it may take longer to realize them than expected, any of which could negatively impact our business, financial condition and results of operations. Future litigation by or against us could be costly and time- consuming to prosecute or defend. 32