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DELTA REPORT

10-K

OCX - ONCOCYTE CORP

10-K - DECEMBER 31, 2023 COMPARED TO 10-K - DECEMBER 31, 2022

The following comparison report has been automatically generated

TOTAL DELTAS	2953
CHANGES	9
DELETIONS	2695
ADDITIONS	249

REFINITIV

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

FORM 10-K

☒ ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the fiscal year ended December 31, 2022
OR
☐ TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the transition period from _____ to _____
Commission file number 1-37648

Oncocyte Corporation

(Exact name of registrant as specified in its charter)

California	**27-1041563**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)

15 Cushing
Irvine, California92618
(Address of principal executive offices) (Zip Code)
Registrant's telephone number, including area code **(949)409-7600**

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	**Trading Symbol**	**Name of each exchange on which registered**
Common Stock, no par value	OCX	The Nasdaq Stock Market LLC

Securities registered pursuant to Section 12(g) of the Act:
None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☐ No ☒
Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes ☐ No ☒
Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐
Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No ☐
Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer ☐	Accelerated filer ☐
Non-accelerated filer ☒	Smaller reporting company ☒
	Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided to Section 13(a) of the Exchange Act. ☐
Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☐
If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements. ☐
Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to §240.10D-1(b). ☐
Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act): Yes ☐ No ☒
The approximate aggregate market value of shares of voting common stock held by non-affiliates computed by reference to the price at which shares of common stock were last sold as of June 30, 2022 was approximately $68.5 million. Shares held by each executive officer

and director and by each person who beneficially owns more than 10% of the outstanding common stock have been excluded in that such persons may under certain circumstances be deemed to be affiliates. This determination of affiliate status is not necessarily a conclusive determination for other purposes.

As of April 5, 2023, there were outstanding 119,278,821 shares of common stock, no par value.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's Proxy Statement for its 2023 to be filed with the Securities and Exchange Commission within 120 days after the end of the fiscal year ended December 31, 2022 are incorporated herein by reference in Part III of this Annual Report on Form 10-K.

Oncocyte Corporation
Table of Contents

PART I

Certain statements contained herein are forward-looking statements, within the meaning of the Private Securities Litigation Reform Act of 1995, including, but not limited to, statements pertaining to future financial and/or operating results, future growth in research, technology, clinical development, and potential opportunities for Oncocyte, along with other statements about the future expectations, beliefs, goals, plans, or prospects expressed by management constitute forward-looking statements. Any statements that are not historical fact (including, but not limited to statements that contain words such as "anticipate," "believe," "can," "continue," "could," "estimate," "expect," "intend," "may," "plan," "project," "seek," "should," "strategy," "target," "will," "would") should also be considered to be forward-looking statements. Forward-looking statements involve risks and uncertainties, including, without limitation, risks inherent in the development and/or commercialization of potential products, uncertainty in the results of clinical trials or regulatory approvals, need and ability to obtain future capital, and maintenance of intellectual property rights. Actual results may differ materially from the results anticipated in these forward-looking statements and as such should be evaluated together with the many uncertainties that affect the businesses of Oncocyte, particularly those mentioned in this Report under "Risk Factors". Except as required by law, Oncocyte undertakes no obligation to update any forward-looking statements to reflect events or circumstances after the date of such statements.

The forward-looking statements include, among other things, statements about:

- the timing and potential achievement of future milestones;
- the timing and our ability to obtain and maintain coverage and reimbursements from the Centers for Medicare and Medicaid Services and other third-party payers;
- our plans to pursue research and development of diagnostic test candidates;
- the potential commercialization of diagnostic tests currently in development;
- the timing and success of future clinical research and the period during which the results of the clinical research will become available;
- the potential receipt of revenue from current sales of our diagnostic tests and/or diagnostic tests in development;
- our assumptions regarding obtaining reimbursement and reimbursement rates of our current diagnostic tests and/or diagnostic tests in development;
- our estimates regarding future orders of tests and our ability to perform a projected number of tests;
- our estimates and assumptions around the patient populations, market size and price points for reimbursement for our diagnostic tests
- our estimates regarding future revenues, operating expenses, and future capital requirements;
- our intellectual property position;
- the impact of government laws and regulations;
- the uncertainties associated with the recent coronavirus (COVID-19) pandemic, including its possible effects on our operations and the demand for our diagnostic tests and Pharma Services;
- our ability to efficiently and flexibly manage our business amid uncertainties related to COVID-19; and
- our competitive position.

Unless the context otherwise requires, all references to "Oncocyte," "we," "us," "our," "the Company" or similar words refer to Oncocyte Corporation, together with our consolidated subsidiaries.

The description or discussion, in this Form 10-K, of any contract or agreement is a summary only and is qualified in all respects by reference to the full text of the applicable contract or agreement.

DetermaIO™, DetermaCNI™, and VitaGraft™ are trademarks of Oncocyte Corporation, regardless of whether the "TM" symbol accompanies the use of or reference to the applicable trademark in this Report.

INDUSTRY AND MARKET DATA

This Annual Report ("Report") on Form 10-K contains market data and industry forecasts that were obtained from industry publications, third party market research and publicly available information. These publications generally state that the information contained therein has been obtained from sources believed to be reliable. While we believe that the information from these publications is reliable, we have not independently verified such information.

This Report also contains estimates and other statistical data made by independent parties and by us relating to market size and growth and other data about our industry. We obtained the industry and market data in this Report from our own research as well as from industry and general publications, surveys and studies conducted by third parties, some of which may not be publicly available. Such data involves a number of assumptions and limitations and contains projections and estimates of the future performance of the industries in

which we operate that are subject to a high degree of uncertainty. We caution you not to give undue weight to such projections, assumptions and estimates.

Item 1. Business

Oncocyte Corporation (referred to in this report as "Oncocyte," "we," "us," and "our") is a partner in the healthcare and life science field to researchers and physicians through Oncocyte's development and acquisitions of proprietary molecular technologies in the fields of oncology and transplantation. Through a series of acquisitions, the Company has built a portfolio of differentiated content with utility in well-established clinical and research markets.

With the increased adoption of precision medicine, healthcare providers are relying on advanced testing to identify patients who will benefit from new, targeted treatments and therapies that are more effective and often have fewer side effects than chemotherapy and other traditional treatments. In addition to identifying these individualized treatment options, researchers and healthcare providers are looking to new technologies to rapidly identify when medical or therapeutic interventions are necessary. The Company is leveraging its experience in oncology and transplant to develop and commercialize diagnostic testing at its licensed and accredited laboratory as well as focusing on the development of distributable kitted formats of these technologies to place in the hands of researchers to study how these tests can be further utilized in other types of cancers in their local communities. Commercialization of these RUO products are expected to occur through a mix of direct sales, partnering and distribution agreements, and licensing.

We have a CLIA certified/ CAP accredited laboratory and Pharma Services lab in Nashville, Tennessee, and a research and development lab in Göttingen, Germany. We may sometimes refer to our technologies as "diagnostic tests." Oncocyte's laboratory developed tests are intended to help support and inform physician decision-making but are not themselves diagnostic or prescriptive of treatment decisions. They are critical to the Company's ability to carry out its mission to improve patient outcomes by providing personalized insights that inform critical decisions throughout the patient care journey. We believe that if clinicians are given the right information and educational tools, they will make the right choices with their patients.

The Company believes that the experience of its team with diverse technologies through its pharma services activities (acquired through Insight Genetics), strong scientific integrity regarding evidence generation and innovation mentality, alongside the company's flexibility in operations and regulatory strategy, will drive its success, differentiate the Company, and are foundational to its future.

The Company is expanding its role in the rapidly evolving healthcare market by strengthening its positions across its portfolio of capabilities, growing strategic opportunities that drive new business, and differentiating its unique offerings, capabilities, and financial performance. To do so, the Company is focusing on executing the following technology priorities, which have evolved to reflect its operations and strategic vision:

1. Strategic Review of Priorities and Capital / Resource Allocation

Spin-off of DetermaRx

As part of our initial strategy on the broader diagnostic continuum, we launched the DetermaRx test via our acquisition of in Razor Genomics, Inc. ("Razor") in September 2019. During February 2021 we acquired all outstanding shares of Razor common stock which made Razor a wholly owned subsidiary of Oncocyte.

In February 2023, we sold approximately 70% of the issued and outstanding equity interests of Razor to buyers who are experienced in the development of early-stage lung cancer diagnostics and the provision of gene-expression-based prognostic tests. As part of the same transaction in February 2023, we transferred to Razor all of the assets and liabilities related to DetermaRx. We continue to retain approximately 30% of the issued and outstanding equity interests of Razor on a fully-diluted basis. For more information regarding this transaction, see "Management's Discussion and Analysis of Financial Condition and Results of Operations" – "Razor Genomics Purchase Agreement."

DetermaRx –

DetermaRx is the first and only test to predict patient's risk of cancer recurrence following surgery and response to chemotherapy in early-stage lung cancer, and was our first test to be commercialized and reimbursed by Medicare. DetermaRx serves an unmet clinical need by helping to guide treatment decisions given the 30-50% mortality rate in patients in the absence of timely chemotherapy treatment. Prior to our transfer to Razor of all of the assets and liabilities related to DetermaRx, in February 2023, we commercialized and performed DetermaRx tests at a CLIA certified laboratory in Irvine.

2. Expand Biomarker Technologies to Drive Advancements for Patient Management – Oncology

The field of oncology receives significant investment in research, development, and treatment, yet it remains an area of great unmet medical need. For patients diagnosed with cancer, immunotherapies, particularly immune checkpoint inhibitors (ICI's) targeting PD-1 and PD-L1, help recruit the body's immune system to attack the growing tumor. Current predictive biomarkers, including PD-L1 and Tumor Mutational Burden or TMB, have shown only limited ability to accurately predict which patients will respond to an immunotherapy.

According to published literature, more than half of PD-L1 positive patients do not respond to immune-checkpoint inhibitors, and 1 in 6 patients who will respond are missed. ICIs are approved in 16 different tumor types, and it is estimated that 4.1 million patients are eligible for these drugs worldwide. Pharmaceutical companies are continuing to invest heavily in this space, with hundreds of clinical trials ongoing, and a number of drugs approved by the FDA, including pembrolizumab (Keytruda), nivolumab (Opdivo), and atezolizumab (Tecentriq).

Although ICI treatments can be highly effective in the right patients, ICI's can also have significant side effects which include exacerbation of latent autoimmune disorders, there is a compelling medical and health economic unmet need for a biomarker that can (1) identify responder populations missed by current biomarkers, (2) inform the use of ICI's in combination with traditional cytotoxic chemotherapy, (3) support patient stratification clinical trials for next generation immunomodulating therapies, and (4) provide a reliable measurement of the tumor immune microenvironment for researchers in biopharma and academia.

DetermaIO –

Through the acquisition of Insight in January 2020, Oncocyte has expanded its oncology portfolio to include a novel gene expression-based test called DetermaIO, which assesses the tumor microenvironment and identifies patients whose immune system is poised to benefit from immunotherapy. DetermaIO measures the expression level of twenty-seven selected genes which are interpreted through the use of a proprietary algorithm (patent pending) which computes a quantitative score ("IO Score") that incorporates information from the immune inflammatory infiltrates within and around the tumor combined with information from the wound response surrounding the tumor.

Oncocyte successfully completed the CLIA Validation of DetermaIO in April 2020. DetermaIO has demonstrated in multiple clinical studies, including a gold-standard randomized clinical trial (RCT) to provide incremental utility beyond established biomarkers used to identify patients who will have a response to ICIs. The test has been successfully validated in four tumor types and across all four major ICIs (Keytruda, Opdivo, Tecentriq and Imfinizi).

As of Q4 2021, this test is currently available as part of a non-clinical early access program with leaders in the immuno-oncology field. A kitted research product format of the underlying technology began proof-of-concept development in the first quarter of 2023.

DetermaIO as a Clinically Validated Laboratory Test

DetermaIO incorporates measurement of activity of genes expressed in immune effector cells, genes expressed in activated wound response cells, and in some cases, genes expressed by the tumor itself. It is the combination of measurement of these three signals that we believe distinguishes DetermaIO from most other approaches. An established threshold is used to classify patients as likely responder or likely non-responder whose association with response to immune therapy has now been validated in several independent clinical studies in multiple different cancer types.

Based on our projected reimbursable pricing model, that the clinical use of DetermaIO will address a potential $3 billion total addressable market ("TAM") opportunity. The actual TAM for DetermaIO in medical practice will depend upon a variety of factors including our ability to demonstrate the efficacy and clinical utility of the test, the extent of physician acceptance of the test, whether the test will be approved for Medicare reimbursement, and, if reimbursement is approved, the actual approved reimbursement price.

DetermaIO's "IO Score" as a Biomarker for Further Research

The early success of ICIs has stimulated deeper investigation into the mechanism by which tumors evade the immune system which has revealed a complex interplay between tumor evasion strategies, the activity of immune effector cells and the tissue repair mechanisms that modulate anti-tumor activity. The balance between signal from the tumor, signals from the inflammatory cells invading the tumor, and signals from the wound response are now understood to account for resistance to ICI's and are the target of second-generation therapeutic strategies to overcome resistance.

We believe DetermaIO is a direct measure the status of the tumor immune microenvironment and as such identifies those tumors poised to respond to the addition of ICI's. We believe that the integration of the signal from the "Hot" component of the tumor with the "Cold" immune repressive features, and in some cases the exclusion of immune cells altogether, an immune desert, is superior to measuring any of these physiologies alone.

There are approximately 3,000 PD-1/PD-L1 targeted therapy clinical trials ongoing that are expected to recruit over 500,000 patients. This represents a potential $1 billion market opportunity for immune-therapy clinical trial services to pharma companies developing ICIs which could be supported by our laboratory in Nashville and/or through a future kitted RUO product.

DetermaCNI –

Therapy response monitoring is an emerging estimated $6B clinical opportunity in the US. Current standard of care, CT/MRI imaging, can struggle to differentiate between progression and pseudo-progression, where a tumor will appear larger but is a side-effect of the immunotherapy working. Minimally invasive blood-based monitoring technology, like DetermaCNI, provides physicians a secondary data point to assess the effectiveness of therapy.

The test converts cell-free DNA (cfDNA) next-generation sequencing (NGS) results into a proprietary genome-wide copy number instability (CNI) score which can be used to monitor and guide ongoing treatment decisions. This test is differentiated from other monitoring tests in two ways; (1) it does not require tumor tissue upfront which can be hard or impossible to obtain, and (2) the test measures copy number variation instead of mutations identified in a patient's diagnostic biopsy specimen.

3. Expand Biomarker Technologies to Drive Advancements for Patient Management – Transplant

Clinicians have limited options in assessing graft health post-transplantation. Traditional methods to assess transplant organ damage are imprecise, invasive, and/or inadequate. Donor-derived cell-free DNA (dd-cfDNA) is one of the best investigated biomarkers, with an increasing number of clinical validation studies published. Most of these studies focused on the percentage of the total cfDNA in the patients' plasma [dd-cfDNA(%)], however, changes in host cfDNA, which represents the denominator in the percentage calculations, over time adds an additional source of possible uncertainty. If the denominator (concentration of total cfDNA in plasma) is not constant, or at least does not have a narrow window under all conceivable clinical conditions, dd-cfDNA(%) values can change without a change in the value of the analyte. To remove this variable and cause of uncertainty, Oncocyte has introduced VitaGraft, a test to measure not only the percentage of dd-cfDNA, but also the absolute quantification dd-cfDNA, expressed as copies/mL.

VitaGraft –

Through the acquisition of Chronix Biomedical, we gained access to two patents in the field of the detection and quantification of donor derived cell-free DNA (dd-cfDNA) in patients after organ transplantation. The dd-cfDNA biomarker has been shown to be a very valuable tool to the traditional surveillance of graft health after transplantation and is currently an estimated $2B reimbursed market in the United States under a blanket LCD.

VitaGraft as a Clinically Validated Laboratory Test

In October 2021, our patent filing for the use of digital PCR for the quantification of dd-cfDNA was issued by the USPTO. Oncocyte successfully completed the technology transfer to our laboratory in Nashville in Q2 2022. The assay is analytically and clinically validated in three major solid organ transplant types (kidney, liver and heart) by peer reviewed international publications. Oncocyte has submitted to MolDx for reimbursement for its kidney and liver tests. These tests are currently available as part of a non-clinical early access program with leaders in the transplantation field.

VitaGraft's dd-cfDNA Quantification as a Biomarker for Further Research

Several questions remain unanswered in transplant graft management and offer interesting areas for research. Among these are, immunosuppression dosing optimization, the utility of absolute quantification in long-term management, and the viability of xenograft and 3-D printed organs. To support these and other areas of groundbreaking research, we have initiated the development an RUO product and are planning to have a prototype completed by the end of Q1 2023. In parallel, we are actively seeking discussions with potential platform partners to join our development efforts.

4. Billing, Coverage, and Reimbursement for our Laboratory Tests

As of December 31, 2022, DetermaRx was Oncocyte's only commercialized clinical test. We are currently in the process of developing and commercializing DetermaIO, VitaGraft and DetermaCNI.

In August 2020, Noridian Healthcare Solutions, LLC, CMS' Medicare Administrative Contractor ("MAC") for laboratories located in California, delivered a final coverage and pricing decision. This decision and coverage by other MACs is important because approximately 70% of patients for whom the test is indicated are eligible for Medicare coverage. However, in the absence of reimbursement by a health insurance plan or Medicare, patients who would be candidates for the use of our tests may decline to use our tests, and physicians may be reluctant to prescribe our tests, due to the cost of the test to the patients. Because of this patient cost factor, revenues from any new cancer test that we market may experience slow growth until the test is approved for reimbursement by larger payer plans which cover many patients.

Medicare

For diagnostics tests, Medicare or CMS reimbursement approval is critical. CMS relies on a network of Medicare Administrative Contractors ("MACs") to make Local Coverage Decisions approving a test for reimbursement. The Molecular Diagnostics Services ("MolDx") Program was developed by Palmetto GBA (the previous MAC for California) to identify and establish coverage and reimbursement for molecular diagnostics tests. The program has developed guidelines for the level of evidence of efficacy required to be obtained through clinical trials. Palmetto, which contracted with CMS to administer the MolDx, issues Local Coverage Determinations that affect coverage, coding, and billing of many molecular tests and the current MAC for California, Noridian Healthcare Solutions, LLC, has adopted the coverage policies from Palmetto. MACs also serve as the primary operational contact between the Medicare Fee-For-Service program, for paying Medicare claims, and approximately 1.5 million health care providers enrolled in the program. Delays in obtaining MAC approval, or any changes made related to any favorable Local Coverage Determinations, could have a material adverse impact on our business.

Private Third-Party Payers

In addition to seeking Medicare reimbursement approval, we will seek reimbursement approval from private payers such as health insurance companies and HMOs. Private payers generally will determine whether to approve a diagnostic test for reimbursement based on the published results of clinical validity and clinical utility studies, and may base their decision on whether to cover a test, and at what level to reimburse, on the MAC's local coverage determination. Obtaining private payer medical coverage generally takes twelve to twenty-four months from the time that sufficient evidence is demonstrated. In the interim we will bill commercial payers and appeal any denials using the published clinical evidence supporting the utility of the test.

Reimbursement rates paid by private third-party payers can vary based on whether the provider is considered to be an "in-network" provider, a participating provider, a covered provider, an "out-of-network" provider or a non-participating provider. Currently, we are out-of-network with all commercial payers. These definitions can vary among payers. An in-network provider usually has a contract with the payer or benefits provider. This contract governs, among other things, service-level agreements and reimbursement rates. In certain instances, an insurance company may negotiate an in-network rate for our testing. An in-network provider may have rates that are lower per test than those that are out-of-network, and that rate can vary widely. Rates vary based on the payer, the testing type and often the specifics of the patient's insurance plan. If a laboratory agrees to contract as an in-network provider, it generally expects to receive quicker payment and access to additional covered patients. However, it is likely that we will initially be considered an "out-of-network" or non-participating provider by payers who cover the vast majority of patients until we can negotiate contracts with the payers.

We cannot predict whether, or under what circumstances, payers will reimburse for patients for our tests or whether our efforts to appeal denied claims will be successful. While we have a rigorous process for prior authorization and appeals to overturn denials and to get contracted with commercial payers, full or partial denial of coverage by payers, or reimbursement at inadequate levels, would have a material adverse impact on our business and on market acceptance of our tests.

Billing and Collection

Where there is a private or governmental third-party payer coverage policy in place, we will bill the payer and the patient in accordance with the established policy. Our efforts in obtaining reimbursement based on individual claims, including pursuing appeals or reconsiderations of claims denials, could take a substantial amount of time, and bills may not be paid for many months, if at all. Furthermore, if a third-party payer denies coverage after final appeal, payment may not be received at all.

Where there is no coverage policy in place, we will pursue reimbursement on a case-by-case basis. In some cases, if not prohibited by law or regulation, we may bill physicians, hospitals and other laboratories directly for the services that they order. However, laws and regulations in certain states prohibit laboratories from billing physicians or other purchasers for testing that they order. Some states may allow laboratories to bill physicians directly but may prohibit the physician and, in some cases, other purchasers from charging more than the purchase price for the services, or may allow only for the recovery of acquisition costs, or may require disclosure of certain information on the invoice. An increase in the number of states that impose similar restrictions could adversely affect us by encouraging physicians to perform laboratory services in-house or by causing physicians to refer services to other laboratories that are not subject to the same restrictions. Adoption or expansion of laws and regulations that limit our ability to bill and obtain reimbursement for the full costs of our services would have a material adverse impact on our business and on market acceptance of our tests.

Corporate Information

We were incorporated in September 2009 in the state of California. Our principal executive offices are located at 15 Cushing, Irvine, California 92618. Our telephone number is (949) 409-7600. Our website is www.Oncocyte.com. Information contained on, or that can be accessed through, our website, is not, and shall not be deemed to be, incorporated into or be considered a part of this Report.

Competition

Our industry is highly competitive and characterized by rapid technological change. Key competitive factors in our industry include, among others, the ability to successfully complete clinical studies, the ability to obtain any required regulatory approval, average selling prices of competing tests, CLIA laboratory capacity and costs, intellectual property and patent rights, and sales and marketing capabilities. We are an early-stage company with a limited operating history and many of our competitors have substantially more resources than we do, including financial, technical and sales resources. In addition, many of our competitors have more experience than we have in the development and commercialization of diagnostics. We are also competing with academic institutions, governmental agencies and private organizations that are conducting research in the field of diagnostics. Our competition will be determined in part by the potential indications for which our lead test candidates are developed and ultimately marketed. Additionally, the timing of market introduction of our diagnostic tests or of competitors' tests may be an important competitive factor.

The DetermaIO test competes with multiple biomarkers already in clinical use or in development for predicting response to immunotherapy. The most commonly used clinical tests employed in the immunotherapy response market are PD-L1 expression testing and TMB. We believe, however, the current standard of care for PD-L1 testing has important limitations. According to published literature, more than half of PD-L1 positive patients do not respond to immune- checkpoint inhibitors, and 1 in 6 patients who will respond are missed (referred to as a "false negative"). Furthermore, data presented at recent oncology medical conferences suggests that TMB is not a reliable predictor of immunotherapy response. Further, data presented at SITC (discussed previously), suggested that DetermaIO outperformed both PD-L1 and TMB in predicting response to checkpoint inhibitors in patients with NSCLC. In 2021, we presented data at four major scientific conferences supporting the association of DetermaIO and response to checkpoint inhibitor therapy and comparing to PD-L1 and TMB. Notably data presented at both ESMO and SABCS demonstrated the predictive value of the test.

DetermaCNI competes with tumor-informed tests that are on market for treatment monitoring as well as blood-only targeted panels. We believe we are differentiated from the former in that the test requires no tissue. DetermaCNI is differentiated from targeted approaches because it assesses changes across the whole genome broadly as opposed to changes in a subset of genes and is applicable in both adjuvant and neo-adjuvant patient scenarios versus tests that monitor Minimal Residual Disease (MRD) which are typically only used when the tumor is removed.

VitaGraft competes with multiple other tests from competitors that measure donor derived cell-free DNA. While our competitors have an established customer base, we believe that VitaGraft has a competitive advantage due to its ability to provide a faster turnaround time for results. Based on our research of customer needs, we believe that this fast turnaround time is critical to inform timely, critical medical decisions.

Facilities

Oncocyte leases a building located at 15 Cushing in Irvine, California that serves as Oncocyte's principal executive and administrative offices. Oncocyte operates a CLIA certified laboratory in Nashville, Tennessee. Through the acquisition of Chronix Biomedical, Oncocyte also has a research and development facility in Göttingen, Germany, which serves as the center of excellence for the company's blood based monitoring program.

Materials

There is a limited number of manufacturers of molecular testing equipment and related chemical reagents necessary for the provision of our cancer tests. Additionally, the chemical reagents used with the testing equipment we chose are available only from the equipment manufacturer. This situation poses a risk to us. After encountering inconsistent results using testing equipment and reagents from one manufacturer, we switched to testing equipment from a different manufacturer. If issues were to arise with the testing equipment or with the reagents we are using, causing us to acquire different testing equipment again, we would need to conduct additional laboratory studies to determine whether our previous test results can be reproduced using the new equipment. If similar issues were to arise after commercialization of a test, we could experience a disruption for a period of time in providing the tests to patients and we would lose revenues and potentially market share as a result.

Patents and Trade Secrets

We rely primarily on patents and contractual obligations with employees and third parties to protect our proprietary rights. We have sought, and intend to continue to seek, appropriate patent protection for important and strategic components of our proprietary technologies by filing patent applications in the United States and certain foreign countries. There can be no assurance that any of our patents will guarantee protection or market exclusivity for our diagnostic tests and diagnostic test candidates. We may also use license agreements both to access technologies developed by other companies and universities and to convey certain intellectual property rights to others. Our financial success will be dependent in part on our ability to obtain commercially valuable patent claims and to protect our intellectual property rights and to operate without infringing upon the proprietary rights of others.

Through our acquisition of Insight Genetics in January 2020 and Chronix in April 2021, we obtained exclusive rights to additional intellectual property, including trade secrets, registered trademarks, domain names, copyrights, issued and reissued patents and pending applications, and software material, and have since the Insight Genetics acquisition filed our own patents to protect DetermaIO.

Through our acquisition of Chronix in April 2021, we obtained intellectual property rights to 10 patent families in the field of detection of cell-free tumor DNA and quantification of donor derived cell-fee DNA, with numerous already issued patents in the United States and European Union, expiring between April 2031 and October 2034. In addition, we obtained trade secrets, registered trademarks, domain names, copyrights and proprietary software material.

In addition to relying on patents, we will rely on trade secrets, know-how, continuing technological advancement, and licensing opportunities to maintain our competitive position. The molecular diagnostics that we are developing use gene expression classifiers or algorithms, which are mathematical models that weight the biomarkers to produce a score. We will treat the mathematical models as trade secrets. We have entered into intellectual property, invention, and non-disclosure agreements with our employees, and it is our practice to enter into confidentiality agreements with our consultants. There can be no assurance, however, that these measures will prevent the unauthorized disclosure or use of our trade secrets and know-how, or that others may not independently develop similar trade secrets and know-how or obtain access to our trade secrets, know-how, or proprietary technology.

General Risks Related to Obtaining and Enforcing Patent Protection

Our patents and patent applications are directed to compositions of matter, formulations, methods of use and/or methods of manufacturing. The patent positions of pharmaceutical and biotechnology companies, including ours, are generally uncertain and involve complex legal and factual questions. Our business could be negatively impacted by any of the following:

- The claims of any patents that are issued may not provide meaningful protection, may not provide a basis for commercially viable diagnostic tests or may not provide us with any competitive advantages;
- Our patents may be challenged by competitors or other third parties and if the third parties are successful in their challenge, the patents could be invalidated, permitting third parties to use the patented inventions to compete with us;

- Others may have patents that relate to our technology or business that may prevent us from marketing our diagnostic test candidates unless we are able to obtain a license to those patents;
- Patent applications to which we have rights may not result in issued patents and the information disclosed in those applications could be used by our competitors;
- Changes in government regulations or patent laws; and
- We may not be successful in developing additional proprietary technologies that are patentable.

In addition, others may independently develop similar or alternative technologies, duplicate any of our technologies and, if patents are licensed or issued to us, design around the patented technologies licensed to or developed by us. Moreover, we could incur substantial costs in litigation if we have to defend ourselves in patent lawsuits brought by third parties or if we initiate such lawsuits.

The United States Supreme Court's decisions in *Mayo Collaborative Services v. Prometheus Laboratories, Inc.* and *Association for Molecular Pathology v. Myriad Genetics* may limit our ability to obtain patent protection on diagnostic methods that merely recite a correlation between a naturally occurring event and a diagnostic outcome associated with that event. Our cancer diagnostic tests are based on the presence of certain genetic markers for a variety of cancers. In *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*, the Supreme Court ruled that patent protection is not available for simple the use of a mathematical correlation of the presence of a well-known naturally occurring metabolite as a means of determining proper drug dosage. The claims in the contested patents that were the subject of that decision were directed to measuring the serum level of a drug metabolite and adjusting the dosing regimen of the drug based on the metabolite level. The Supreme Court said that a patent claim that merely claimed a correlation between the blood levels of a drug metabolite and the best dosage of the drug was not patentable subject matter because it did no more than recite a correlation that occurs in nature.

In *Association for Molecular Pathology v. Myriad Genetics*, the Supreme Court ruled that the discovery of the precise location and sequence of certain genes, mutations of which can dramatically increase the risk of breast and ovarian cancer, was not patentable. Knowledge of the gene location and sequences was used to determine the genes' typical nucleotide sequence, which, in turn, enabled the development of medical tests useful for detecting mutations in these genes in a particular patient to assess the patient's cancer risk. But the mere discovery of an important and useful gene did not render the genes patentable as a new composition of matter.

Also, in *Ariosa Diagnostics, Inc. v. Sequenom, Inc.*, the Federal Circuit ruled that a method for detecting a paternally inherited nucleic acid of fetal origin performed on a maternal serum or plasma sample from a pregnant female was not patent eligible subject matter under the framework set forth in *Mayo Collaborative Services v. Prometheus Laboratories, Inc*. The court examined the elements of the claim to determine whether the claim contained an inventive concept sufficient to transform the claimed naturally occurring phenomenon into a patent eligible application and found that the method steps did not support patentability because they used conventional amplification and detection techniques. Although the claims can be distinguished from the claims at issue in *Mayo Collaborative Services v. Prometheus Laboratories, Inc*., the court was bound by the language of the Supreme Court decision to hold Sequenom's claims unpatentable.

In *Illumina, Inc. v. Ariosa Diagnostics, Inc.*, the Federal Circuit reversed and remanded the lower court and found that claims directed to methods of preparing plasma to isolate extracellular fetal DNA, based on the inventors' discovery that fetal DNA strands in maternal plasma are relatively short compared to maternal DNA, were directed to patent-eligible subject matter. The majority reasoned that the claimed methods include process steps that lead to a DNA fraction that is different from the naturally-occurring fraction present in the mother's blood due to enrichment of cell-free fetal DNA. Thus, the process achieves more than simply observing that fetal DNA is shorter than maternal DNA or detecting the presence of that phenomenon. The majority noted that the inclusion of specific techniques for carrying out the steps of the method, illustrated the concrete nature of the claimed process steps. These concrete process steps were used, not merely to observe the presence of the phenomenon that fetal DNA is shorter than maternal DNA, but to exploit that discovery in a method for preparation of a mixture enriched in fetal DNA and thus supported a finding of patent eligible subject matter.

While the cases discussed above are instructive, the United States Patent and Trademark Office (the "USPTO") has also issued guidelines in light of the Supreme Court decisions indicating that process claims having a natural principle as a limiting step will be evaluated to determine if the claim includes additional steps that practically apply the natural principle such that the claim amounts to significantly more than the natural principle itself. Because the diagnostic tests that we are developing combine an innovative methodology with newly discovered compositions of matter, we are hopeful that this Supreme Court decision will not preclude the availability of patent protection for our diagnostic tests. However, there is no guarantee that such pending patent applications will issue nor that our existing patents would survive a challenge in light of the above-referenced case law.

The USPTO has also issued multiple Subject Matter Eligibility Updates to provide further guidance in determining subject matter eligibility. The Subject Matter Eligibility Updates include new Subject Matter Eligibility Examples for the Life Sciences. These examples provide favorable exemplary subject matter eligibility analysis of hypothetical claims covering diagnostic tests and claims drawn from case law. This update from the USPTO does not change our opinion on our ability to obtain meaningful patent protection.

There is a risk that any patent applications that we file and any patents that we hold or later obtain could be challenged by third parties and declared invalid or infringing of third-party claims. A patent interference proceeding may be instituted with the USPTO when more than one person files a patent application covering the same technology, or if someone wishes to challenge the validity of an issued patent filed before March 16, 2013. At the completion of the interference proceeding, the USPTO will determine which competing applicant is entitled to the patent, or whether an issued patent is valid. Patent interference proceedings are complex, highly contested legal proceedings, and the USPTO's decision is subject to appeal. This means that if an interference proceeding arises with respect to any of our patent applications, we may experience significant expenses and delay in obtaining a patent, and if the outcome of the proceeding is unfavorable to us, the patent could be issued to a competitor rather than to us. In addition to interference proceedings, the USPTO can review issued patents at the request of a third party seeking to have the patent invalidated. Currently an inter partes review proceeding will allow third parties to challenge the validity, based on issues of novelty and non-obviousness, in view of patents and printed publications, of an issued patent where there is a reasonable likelihood of invalidity. This means that patents owned or licensed by us may be lost if the outcome of the review is unfavorable to us.

Post Grant Review under the America Invents Act makes available opposition-like proceedings in the United States. As with the USPTO interference proceedings, Post Grant Review proceedings will be very expensive to contest and can result in invalidation of a recently issued patent. To invoke a post-grant review, a challenge must be filed within nine months of a patent's issuance or reissuance. Post-grant review can be sought based on any grounds that can be used to challenge the validity of a patent claim, with the exception of failure to disclose the best mode. Also, a derivation proceeding may be instituted by the USPTO or an inventor alleging that a patent or application was derived from the work of another inventor.

Oppositions to the issuance of patents may be filed under European patent law and the patent laws of certain other countries. As with the USPTO interference proceedings, these foreign proceedings can be very expensive to contest and can result in significant delays in obtaining a patent or can result in a denial of a patent application.

The enforcement of patent rights often requires litigation against third party infringers, and such litigation can be costly to pursue. Even if we succeed in having new patents issued or in defending any challenge to issued patents, there is no assurance that our patents will be comprehensive enough to provide us with meaningful patent protection against our competitors. Further, should we sue a third party infringer for patent infringement, the infringer may assert counter claims and attempt to invalidate some or all of the asserted patent claims. There is always some risk that such a counter claim could result in invalidation of one or more claims of an asserted patent.

Government Regulation

CLIA—Clinical Laboratory Improvement Amendments of 1988 and State Regulation

We expect that DetermaIO, VitaGraft and DetermaCNI will be regulated under the Clinical Laboratory Improvements Amendment ("CLIA") as laboratory developed tests or "LDTs". In 1988, Congress enacted CLIA, which established quality standards for all laboratories that provide testing services to ensure the accuracy, reliability and timeliness of patient test results regardless of where the test is performed.

Under CLIA, a laboratory is defined as any facility that performs laboratory testing on specimens derived from humans for the purpose of providing information for the diagnosis, prevention or treatment of disease, or the impairment of, or assessment of health of human beings. Because we meet this definition, CLIA requires that we hold a certificate applicable to the complexity of the categories of testing we perform and that we comply with certain standards. Laboratories performing high complexity testing are required to meet more stringent requirements than laboratories performing less complex tests. CLIA regulations require clinical laboratories like ours to comply with various operational, personnel, facilities administration, quality, and proficiency testing requirements intended to ensure that testing services are accurate, reliable and timely. CLIA certification is a prerequisite for reimbursement eligibility for services provided to state and federal health care program beneficiaries. CLIA is user-fee funded. Therefore, all costs of administering the program must be covered by the regulated facilities, including certification and survey costs.

FDA Regulation of Diagnostic Tests

We have designed, developed, and are validating our tests as LDTs and consequently believe our tests are governed under the CLIA regulations, as administered by CMS, as well as by applicable state laws.

Historically, the FDA had exercised enforcement restraint with respect to most LDTs and had not required laboratories that offer LDTs to comply with FDA requirements for medical devices, such as registration, device listing, quality systems regulations, premarket clearance or premarket approval, and post-market controls.

In recent years, the FDA has stated it intends to end its policy of enforcement restraint and begin regulating certain LDTs as medical devices. In October 2014, the FDA issued two draft guidance documents, entitled “Framework for Regulatory Oversight of Laboratory Developed Tests (LDTs)” and “FDA Notification and Medical Device Reporting for Laboratory Developed Tests (LDTs)”, respectively, that set forth a proposed risk-based regulatory framework that would apply varying levels of FDA oversight to LDTs.

The FDA has indicated that it does not intend to modify its policy of enforcement restraint until the draft guidance documents are finalized. Subsequently, in January 2017, the FDA issued a Discussion Paper on LDTs (“Discussion Paper”), in which it outlined a substantially revised “possible approach” to the oversight of LTDs. The risk-based approach outlined focuses on new and significantly modified high and moderate risk LDTs and low risk LDTs, LDTs for rare diseases, traditional LDTs, LDTs intended solely for public health surveillance, certain LDTs used in CLIA certified labs, and LDTs intended solely for forensic use would not be expected to comply with premarket review, quality systems, and registration and listing requirements unless necessary to protect public health. With respect to the post-market surveillance of LDTs, the FDA’s Discussion Paper recommends that laboratories initially report serious adverse events for all tests except the exempted categories of tests, which include LDTs intended for public health surveillance, some stem cell/tissue/organ transplantation LDTs, and LDTs intended solely for forensic use. The Discussion Paper notes that it is not a final version of the 2014 draft guidance and that it does not intend to represent the FDA’s formal position but rather describes the evolution of the agency’s thinking about the regulatory framework for LDTs.

Responding to the COVID-19 pandemic, in August, 2020, the Department of Health and Human Services (“HHS”), the parent agency for FDA, formally rescinded FDA guidance and other informal statements concerning FDA’s premarket review of LDTs and announced that the FDA “will not require premarket review of [LDTs] absent notice-and comment rulemaking, as opposed through guidance documents, compliance manuals, website statements, or other informal issuances.” It is unclear at this time whether the Biden administration will revise or rescind this policy.

It is unclear at this time when or if the FDA will finalize its plans to end enforcement discretion, via notice and comment rulemaking or otherwise, and even then, new regulatory requirements are expected to be phased-in over time. Nevertheless, the FDA may attempt to regulate certain LDTs on a case-by-case basis at any time.

On June 24, 2021, bi-partisan members of both the House and Senate re-introduced the Verifying Accurate, Leading-edge IVCT Development ("VALID") Act, which features a precertification program. The term IVCT refers to in vitro clinical tests, a category that w comprises both test kits and lab-developed tests. The VALID Act includes precertification proposed by the FDA, a process through which diagnostic developers could receive premarket approval or clearance for one test representative of a group of tests using the same technology and have other elements in common. Approval of that representative test would precertify other tests in the group and allow the lab to launch them without premarket review. The VALID Act would also create a new system for labs and hospitals to use to submit their tests electronically to the FDA for approval, which is aimed at reducing the amount of time it takes for the agency to approve such tests, and establish a new program to expedite the development of diagnostic tests that can be used to address a current unmet need for patients. The introduced Valid Act also includes specific language designed to address public health emergencies, including COVID-19. If enacted, the impact of the VALID Act will be minimal for IVD manufacturers because of the alignment between the VALID Act and existing medical device statutory and regulatory requirements and the fact that such requirements have been enforced for IVD manufacturers for decades; however, it will have a significant impact on clinical laboratories as laboratories will need to comply with many new requirements, including: registration and listing with the FDA; quality requirements; investigational studies; premarket review and approval; adverse event reporting; and corrections and removals (recalls). While the VALID Act outlines a framework for these elements (among others), the law, if enacted, would direct the FDA to promulgate regulations and issue guidance documents within two (2) years of its enactment, and establishes an effective date for the new IVCT regulatory system as four (4) years after enactment, giving clinical laboratories and others ample opportunity to participate in shaping and preparing for the new IVCT regulatory program.

On May 18, 2021, Senator Rand Paul re-introduced a bill, called the Verified Innovative Testing in American Laboratories ("VITAL") Act of 2021, which strikes a counterpoint to the proposed VALID Act. VITAL seeks to update existing federal lab standards under the CLIA, specifically stating that all aspects of lab-developed testing procedures would be regulated by the US Health and Human Services Secretary under the Public Health Services Act, and that no aspects of lab-developed testing procedures would be regulated under the Federal Food, Drug, and Cosmetic Act, including during a public health emergency.

While we cannot predict whether the either VALID Act or the VITAL Act as proposed, or any modified version of either act will be enacted into law, it is expected that some form of the acts will be incorporated into a broader health care legislative package. The likelihood that Congress will pass legislation and the extent to which such legislation may affect the FDA's plans to regulate certain LDTs as medical devices is difficult to predict at this time. Until the VALID Act, VITAL Act, or other legislation is passed reforming the federal government's regulation of LDTs, it is unknown how the FDA may regulate our tests in the future and what testing and data may be required to support any required clearance or approval.

If the FDA ultimately regulates certain LDTs, whether via final guidance, final regulation, or as instructed by Congress, our tests may be subject to certain additional regulatory requirements. Complying with the FDA's requirements can be expensive, time-consuming, and subject us to significant or unanticipated delays. Insofar as we may be required to obtain premarket clearance or approval to perform or continue performing an LDT, we cannot assure that we will be able to obtain such authorization. Even if we obtain regulatory clearance or approval where required, such authorization may not be for the intended uses that we believe are commercially attractive or are critical to the commercial success of our tests. As a result, the application of the FDA's requirements to our tests could materially and adversely affect our business, financial condition, and results of operations.

Notwithstanding the FDA's current position with respect to oversight of our tests, we may voluntarily decide to pursue FDA pre-market review for our current tests and tests we may offer in the future if we determine that doing so would be appropriate from a strategic perspective.

Failure to comply with applicable FDA regulatory requirements may trigger a range of enforcement actions by the FDA including warning letters, civil monetary penalties, injunctions, criminal prosecution, recall or seizure, operating restrictions, partial suspension or total shutdown of operations, and denial of or challenges to applications for clearance or approval, as well as significant adverse publicity.

State Laboratory Licensing

In addition to federal certification requirements of laboratories under CLIA, we are required to maintain licensure under Tennessee law for our laboratory in Nashville, Tennessee. State laws generally include standards for the day-to-day operation of a clinical reference laboratory, including the training and skills required of personnel and quality control. In addition, those laws often mandate proficiency testing, which involves testing of specimens that have been specifically prepared for the laboratory.

Some states require licensure of out-of-state laboratories that accept specimens from those states. Our laboratories will need to pass various state inspections in order to get licensed to provide LDTs in each of state that requires licensure. CLIA provides that a state may adopt laboratory regulations that are more stringent than those under federal law, and two states, New York and Washington, have met that standard and therefore substitute for the federal CLIA program. In addition, some, but not all, states require a separate state license or permit, which must be obtained in addition to a CLIA certificate, and some states require a laboratory doing business in that state to be licensed even if the laboratory is located in another state.

Our laboratories are licensed by the appropriate state agencies in the states in which we do business, if such licensure is required. If a laboratory is out of compliance with state laws or regulations governing licensed laboratories, a state may impose penalties, which penalties vary from state to state but may include suspension, limitation, revocation or annulment of the license, assessment of financial penalties or fines, or imprisonment. We believe that we are in material compliance with all applicable licensing laws and regulations.

We may become aware from time to time of certain states that require out-of-state laboratories to obtain licensure to accept specimens from patients within the state. If we identify any other state with such requirements, or if we are contacted by any other state advising us of such requirements, we intend to follow all instructions from the state regulators regarding compliance with such requirements.

International Laboratory Licensing

We also maintain laboratory operations in Germany and could expand our laboratory operations to other foreign jurisdictions. Therefore, we are subject to laboratory quality regulations and accreditation standards in Germany, and will be subject to such regulations and standards in any other jurisdictions where we may operate. These requirements may vary by jurisdiction and differ from those in the United States, and may require us to implement additional compliance measures.

In Vitro Diagnostics

In the future, we may elect to develop IVDs, which are regulated by the FDA as medical devices. Medical devices marketed in the United States are subject to the regulatory controls under CLIA, the Federal Food, Drug, and Cosmetic Act, and regulations adopted by the FDA. Some requirements, known as premarket requirements, apply to medical devices before they are marketed, and other requirements, known as post-market requirements, apply to medical devices after they are marketed.

The particular premarket requirements that must be met to market a medical device in the United States will depend on the classification of the device under FDA regulations. Medical devices are categorized into one of three classes, based on the degree of risk they present. Devices that pose the lowest risk are designated as Class I devices; devices that pose moderate risk are designated as Class II devices and are subject to general controls and special controls; and the devices that pose the highest risk are designated as Class III devices and are subject to general controls and premarket approval.

A premarket submission to the FDA will be required for some Class I devices, most Class II devices; and all Class III devices. Most Class I and some Class II devices are exempt from premarket submission requirements. Some Class I and most Class II devices may be marketed after a 510(k) premarket notification, while a more extensive PMA is required to market Class III devices.

Until regulatory requirements suggested by the FDA or required by any new legislation are phased in, our current LDTs will not require FDA filing before launch and we will continue to follow the CLIA certification and inspection pathway.

If the new requirements are phased in or if we elect to develop IVDs, our future screenings diagnostics may require a 510(k) submission or a Premarket Approval (“PMA”) application to the FDA. In a 510(k) submission, the device sponsor must demonstrate that the new device is “substantially equivalent” to a predicate device in terms of intended use, technological characteristics, and performance testing. A 510(k) requires demonstration of substantial equivalence to another device that is legally marketed in the United States. Substantial equivalence means that the new device is at least as safe and effective as the predicate. A device is substantially equivalent if, in comparison to a predicate it (a) has the same intended use as the predicate and has the same technological characteristics as the predicate; or (b) has the same intended use as the predicate, has different technological characteristics, and the information submitted to the FDA does not raise new questions of safety and effectiveness, and is demonstrated to be at least as safe and effective as the legally marketed predicate device.

A claim of substantial equivalence does not mean the new and predicate devices must be identical. Substantial equivalence is established with respect to intended use, design, energy used or delivered, materials, chemical composition, manufacturing process, performance, safety, effectiveness, labeling, biocompatibility, standards, and other characteristics. A device may not be marketed in the United States until the submitter receives a letter declaring the device substantially equivalent. If the FDA determines that a device is not substantially equivalent, the applicant may resubmit another 510(k) with new data, or request a Class I or II designation through the FDA's *de novo* process that allows a new device without a valid predicate to be classified into Class I or II if it meets certain criteria, or file a reclassification petition, or submit a PMA.

A new 510(k) submission is required for changes or modifications to an existing approved device, where the modifications could significantly affect the safety or effectiveness of the device or the device is to be marketed for a new or different indication for use.

A PMA for Class III devices is the most stringent type of premarket submission. Before the FDA approves a PMA, the sponsor must provide valid scientific evidence demonstrating reasonable assurance of safety and effectiveness for the device's intended use.

Health Insurance Portability and Accountability Act and Other Data Privacy and Security Laws

Under the Health Insurance Portability and Accountability Act of 1996 ("HIPAA"), as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, also called HITECH, HHS has issued regulations to protect the privacy and security of protected health information ("PHI") and to address breach notification requirements. HIPAA also regulates standardization of data content, codes and formats used in health care transactions and standardization of identifiers for health plans and providers. Penalties for violations of HIPAA regulations include civil and criminal penalties.

The HIPAA privacy regulations cover the use and disclosure of PHI by covered entities as well as business associates, which are persons or entities that perform certain functions for or on behalf of a covered entity that involve the creation, receipt, maintenance, or transmittal of PHI. Business associates are defined to include a subcontractor to whom a business associate delegates a function, activity, or service, other than in the capacity of the business associate's workforce. As a general rule, a covered entity or business associate may not use or disclose PHI except as permitted or required under the privacy regulations. The privacy regulations also set forth certain rights that an individual has with respect to his or her PHI, including rights to access or amend certain records, to request restrictions on the use or disclosure of PHI, or to request an accounting of disclosures of his or her PHI.

Covered entities and business associates must also comply with HIPAA's security regulations, which establish minimum requirements for safeguarding the confidentiality, integrity, and availability of PHI that is electronically transmitted or electronically stored. In addition, HITECH established, among other things, certain breach notification requirements with which covered entities and business associates must comply. In particular, a covered entity must notify any individual whose unsecured PHI is breached according to the specifications set forth in the breach notification rule. A covered entity must also notify the Secretary of the U.S. Department of Health and Human Services and, under certain circumstances, the media of a breach of unsecured PHI.

CMS and the Office of Civil Rights issued a final rule in February 2014 to amend both the HIPAA and CLIA regulations. The final rule amended the HIPAA privacy rule to remove the CLIA laboratory exceptions, and as a result, HIPAA-covered laboratories are now required to provide individuals, upon request, with access to their completed test reports. Under the 2014 rule, CLIA laboratories and CLIA-exempt laboratories may provide copies of a patient's completed test reports that, using the laboratory's authentication process, can be identified as belonging to that patient. These changes to the CLIA regulations and the HIPAA Privacy Rule were intended to provide individuals with a greater ability to access their health information. CLIA laboratories must create and maintain policies, procedures, and other documentation necessary to inform patients of the right to access laboratory test reports and how to exercise that right. In December 2020, aiming to remove regulations that impede communication and data exchange between providers and health plans and expand individuals' rights to access their own digital health information, HHS proposed further changes to the HIPAA privacy rule. These most recently proposed updates of the HIPAA privacy rule are subject to public comment period until May 6, 2021.

The HIPAA privacy, security, and breach notification regulations establish a uniform federal "floor" and do not supersede state laws that are more stringent or provide individuals with greater rights with respect to the privacy or security of, and access to, their records containing PHI or insofar as such state laws apply to personal information that is broader in scope than PHI as defined under HIPAA. Thus, in addition to the federal privacy regulations, there are a number of state laws regarding the privacy and security of health information and personal data that are applicable to clinical laboratories, and more states are considering these laws. The compliance requirements of these laws, including additional breach reporting requirements, and the penalties for violation vary widely and new privacy and security laws in this area are evolving. For example, California has implemented comprehensive privacy laws and regulations. The California Confidentiality of Medical Information Act imposes restrictive requirements regulating the use and disclosure of health information and other personally identifiable information. In addition to fines and penalties imposed upon violators, some of these state laws also afford private rights of action to individuals who believe their personal information has been misused. California's patient privacy laws, for example, provide for penalties of up to $250,000 and permit injured parties to sue for damages. In addition to the California Confidentiality of Medical Information Act, California also recently enacted the California Consumer Privacy Act of 2018, or CCPA, which became effective January 1, 2020. The CCPA establishes a comprehensive privacy framework for covered businesses in the State of California, by creating an expanded definition of personal information, establishing new data privacy rights for consumers imposing special rules on the collection of consumer data from minors, and creating a new and potentially severe statutory damages framework for violations of the CCPA and for businesses that fail to implement reasonable security procedures and practices to prevent data breaches. While data subject to HIPAA and federal regulations governing the conduct of clinical trials is exempt from CCPA, certain of our business activities may be

subject to CCPA. The CCPA provides for civil penalties for violations, as well as a private right of action for data breaches that result from a business' failure to implement and maintain reasonable data security procedures.

State laws regarding the privacy and security of personal information are also evolving. For example, on November 3, 2020, California passed the California Privacy Rights Act ("CPRA") through a ballot initiative. The CPRA will create a new California Privacy Protection Agency, an "independent watchdog" whose mission is both to "vigorously enforce" the CPRA and "ensure that businesses and consumers are well-informed about their rights and obligations." Among other things, the CPRA will create a new category of "sensitive personal information" and offer consumers the right to limit processing of such information, impose purpose limitation, data minimization, data retention, and security compliance obligations on regulated businesses, and add or modify the rights available to consumers, including by providing a right to correct the information a business holds about them. The CPRA's amendments to the CCPA will take effect on January 1, 2023, and will generally apply to personal information collected by businesses on or after January 1, 2022. Similarly, Colorado and Virginia have also passed comprehensive state privacy laws that are set to go into effect in 2023. In addition, every U.S. state has a data breach notification law that requires entities to report certain security breaches to affected consumers and, in some instances, state regulators and consumer reporting agencies. Failure to comply with applicable state laws that impose privacy, security, or breach notification requirements could result in significant civil or criminal penalties, administrative actions, or private causes of action by individuals, and adversely affect our business, results of operations and reputation.

Similar health care and data privacy laws and regulations exist in Europe and other jurisdictions, including reporting requirements detailing interactions with and payments to healthcare providers and requirements regarding the collection, distribution, use, security, and storage of personally identifiable information and other data relating to individuals, including the GDPR, which went into effect in May 2018. The GDPR applies to any company established in the EEA, as well as to those outside the EEA, if they collect and use personal data in connection with the offering of goods or services to individuals in the EEA or the monitoring of their behavior. Companies that must comply with the GDPR face increased compliance obligations and risk, including more robust regulatory enforcement of data protection requirements and potential fines for noncompliance of up to €20 million or 4% of the annual global revenues of the noncompliant company, whichever is greater. The GDPR provides that EU and EEA member states may introduce further conditions, including limitations, to the processing of genetic, biometric or health data, which could limit our ability to collect, use and share personal data, or could cause our compliance costs to increase, ultimately having an adverse impact on our business. Among other requirements, the GDPR regulates transfers of personal data subject to the GDPR to third countries that have not been found to provide adequate protection to such personal data, including the United States, and the efficacy and longevity of current transfer mechanisms between the European Union, or EU, and the United States remains uncertain. For example, in 2016, the EU and United States agreed to a transfer framework for data transferred from the EU to the United States, called the Privacy Shield, but the Privacy Shield was invalidated in July 2020 by the Court of Justice of the European Union.

Further, from January 1, 2021, companies have to comply with the GDPR and also the UK GDPR, which, together with the amended UK Data Protection Act 2018, retains the GDPR in UK national law. The UK GDPR mirrors the fines under the GDPR, e.g. fines up to the greater of €20 million (£17.5 million) or 4% of global turnover. On June 6, 2021, the European Commission implemented an adequacy decision enabling data transfers from EU member states to the United Kingdom without additional security measures. However, this adequacy decision includes a so-called "sunset-clause" stipulating that it will expire after four (4) years, and providing that the Commission will monitor the UK's legal situation and could intervene at any point if it determines the UK has deviated from the level of protections in place at the time of the decision. The revocation or expiration of the Commission's adequacy decision for the UK could require additional measures to ensure adequate protection and GDPR compliance and may lead to additional costs and increases our overall risk exposure.

Physician Referral Prohibitions

Under a federal law directed at "self-referral," commonly known as the Stark Law, there are prohibitions, with certain exceptions, on Medicare and Medicaid payments for laboratory tests referred by physicians who personally, or through a family member, have a "financial relationship"—including an investment or ownership interest or a compensation arrangement—with the clinical laboratory performing the tests. Several Stark Law exceptions are relevant to arrangements involving clinical laboratories, including: (1) fair market value compensation for the provision of items or services; (2) payments by physicians to a laboratory for clinical laboratory services; (3) certain space and equipment rental arrangements that satisfy certain requirements, and (4) personal services arrangements that satisfy certain requirements. The laboratory cannot submit claims to the Medicare Part B program for services furnished in violation of the Stark Law, and Medicaid reimbursements may be at risk as well. Penalties for violating the Stark Law include the return of funds received for all prohibited referrals, fines, civil monetary penalties and possible exclusion from the federal health care programs. Many states have comparable laws that are not limited to Medicare and Medicaid referrals.

On November 20, 2020, CMS issued a final rule to modernize and clarify the regulations that interpret self-referral law. The final rule was issued in conjunction with the CMS Patients over Paperwork initiative and the HHS Regulatory Sprint to Coordinated Care and establishes exceptions to the physician self-referral law for certain value-based compensation arrangements between or among physicians, providers, and suppliers. It also establishes a new exception for certain arrangements under which a physician receives limited remuneration for items or services actually provided by the physician; establishes a new exception for donations of cybersecurity technology and related services; and amends the existing exception for electronic health records (EHR) items and services. While the final rule presents significant opportunities for new arrangements, it also necessitates revisions to current arrangements involving healthcare providers, others involved in the healthcare industry, and patients.

Corporate Practice of Medicine

A number of states, including California, do not allow business corporations to employ physicians to provide professional services. This prohibition against the “corporate practice of medicine” is aimed at preventing corporations such as us from exercising control over the medical judgments or decisions of physicians. The state licensure statutes and regulations and agency and court decisions that enumerate the specific corporate practice rules vary considerably from state to state and are enforced by both the courts and regulatory authorities, each with broad discretion. If regulatory authorities or other parties in any jurisdiction successfully assert that we are engaged in the unauthorized corporate practice of medicine, we could be required to restructure our contractual and other arrangements. In addition, violation of these laws may result in sanctions imposed against us and/or the professional through licensure proceedings, and we could be subject to civil and criminal penalties that could result in exclusion from state and federal health care programs.

Federal and State Fraud and Abuse Laws

A variety of federal and state laws prohibit fraud and abuse. These laws are interpreted broadly and enforced aggressively by various state and federal agencies, including CMS, the Department of Justice, the Office of Inspector General for HHS, and various state agencies. In addition, the Medicare and Medicaid programs increasingly use a variety of contractors to review claims data and to identify improper payments as well as fraud and abuse. These contractors include Recovery Audit Contractors, Medicaid Integrity Contractors and Zone Program Integrity Contractors. In addition, CMS conducts Comprehensive Error Rate Testing audits, the purpose of which is to detect improper Medicare payments. Any overpayments identified must be repaid unless a favorable decision is obtained on appeal. In some cases, these overpayments can be used as the basis for an extrapolation, by which the error rate is applied to a larger universe of claims, and which can result in even higher repayments.

The federal Anti-Kickback Statute prohibits, among other things, knowingly and willfully offering, paying, soliciting, receiving, or providing remuneration, directly or indirectly, to induce or in return for either the referral of an individual, or the furnishing, recommending, or arranging for the purchase, lease or order of any health care item or service reimbursable, in whole or in part, under a federal health care program. The definition of "remuneration" has been broadly interpreted to include anything of value, including gifts, discounts, credit arrangements, payments of cash, ownership interests and providing anything at less than its fair market value. Recognizing that the Anti- Kickback Statute is broad and may technically prohibit many innocuous or beneficial arrangements within the health care industry, the Office of Inspector General for HHS has issued a series of regulatory "safe harbors." These safe harbor regulations set forth certain requirements that, if met, will assure immunity from prosecution under the federal Anti-Kickback Statute. Although full compliance with these provisions ensures against prosecution under the federal Anti-Kickback Statute, the failure of a transaction or arrangement to fit within a specific safe harbor does not necessarily mean that the transaction or arrangement is illegal or that prosecution under the federal Anti-Kickback Statute will be pursued.

Federal civil and criminal false claims laws, including the False Claims Act, prohibit any person from knowingly presenting, or causing to be presented, a false claim for payment to the federal government or knowingly making, or causing to be made, a false statement to get a false claim paid. Violations of the False Claims Act can result in very significant monetary penalties and treble damages. Over the past few years, several healthcare companies have been prosecuted under these laws for a variety of alleged promotional and marketing activities, including without limitation, allegedly providing free trips, free goods, sham consulting fees and grants and other monetary benefits to prescribers. In addition, the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal False Claims Act. Most states also have statutes or regulations similar to the federal anti-kickback law and false claims laws, which apply to items and services reimbursed under Medicaid and other state programs, or, in several states, apply regardless of the payor.

Federal civil monetary penalties laws impose civil fines for, among other things, the offering or transfer of remuneration to a Medicare or state healthcare program beneficiary if the person knows or should know it is likely to influence the beneficiary's selection of a particular provider, practitioner, or supplier of services reimbursable by Medicare or a state healthcare program, unless an exception applies.

The Eliminating Kickbacks in Recovery Act ("EKRA") specifically targets laboratories, clinics, recovery centers, and other clinical treatment centers from accepting or paying kickbacks for referrals. EKRA is broader than the federal Anti-Kickback Statute because it applies to private health insurance plans in addition to the federal health care programs, and it prohibits arrangements that may otherwise be exempt from liability under the Anti-Kickback Statute's safe harbors, including certain compensation arrangements with laboratory sales and marketing personnel.

HIPAA also created new federal crimes, including health care fraud and false statements relating to health care matters. The health care fraud statute prohibits knowingly and willfully executing a scheme to defraud any health care benefit program, including private third-party payers. A violation of this statute is a felony and may result in fines, imprisonment or exclusion from federal health care programs, such as the Medicare and Medicaid programs. The false statements statute prohibits knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for health care benefits, items or services. A violation of this statute is a felony and may result in fines, imprisonment or exclusion from federal health care programs.

Many states have laws similar to the federal laws described above, and state laws may be broader in scope and may apply regardless of payer.

Additionally, the U.S. Foreign Corrupt Practices Act ("FCPA") prohibits U.S. corporations and their representatives from offering, promising, authorizing or making payments to any foreign government official, government staff member, political party or political candidate in an attempt to obtain or retain business abroad. The scope of the FCPA includes interactions with certain healthcare professionals in many countries. Other countries have enacted similar anti-corruption laws and/or regulations.

Other Regulatory Requirements

Our laboratory will be subject to federal, state and local regulations relating to the handling and disposal of regulated medical waste, hazardous waste and biohazardous waste, including chemical, biological agents and compounds, blood samples and other human tissue. Typically, we will use outside vendors who are contractually obligated to comply with applicable laws and regulations to dispose of such waste. These vendors will be licensed or otherwise qualified to handle and dispose of such waste.

The Occupational Safety and Health Administration has established extensive requirements relating to workplace safety for health care employers, including requirements to develop and implement programs to protect workers from exposure to blood-borne pathogens by preventing or minimizing any exposure through needle stick or similar penetrating injuries.

On May 1, 2020, the Office of the National Coordinator for Health Information Technology promulgated final regulations under the authority of the 21st Century Cures Act that impose new conditions to obtain and maintain certification of certified health information technology and prohibit certain covered actors, including operators of laboratories which are considered "health care providers" under the final regulation, from engaging in activities that are likely to interfere with the access, exchange, or use of electronic health information (information blocking). The final regulations further defined exceptions for activities that are permissible, even though they may have the effect of interfering with the access, exchange, or use of electronic health information. The information blocking effective date is April 5, 2021. Under the 21st Century Cures Act, health care providers that violate the information blocking prohibition will be subject to appropriate disincentives, which HHS services has yet to establish through required rulemaking. Developers of certified information technology and health information networks and health information exchanges, however, may be subject to civil monetary penalties of up to $1 million per violation. The HHS Office of Inspector General has the authority to impose such penalties and on April 24, 2020 published a proposed rule to codify its new authority in regulation, which the agency proposed would become effective 60 days after it issues a final rule, but in no event before November 2, 2020. HHS Office of Inspector General has not yet issued a final rule.

Employees

As of December 31, 2022, we employed 76 persons, of which 75 were on a full-time basis and one was on a part-time basis.

Item 1A. Risk Factors

Our business is subject to various risks, including those described below. You should consider the following risk factors, together with all of the other information included in this Report, which could materially adversely affect our proposed operations, our business prospects, and financial condition, and the value of an investment in our business. There may be other factors that are not mentioned here or of which we are not presently aware that could also affect our business operations and prospects.

Summary of Risk Factors

Risks Related to Our Capital Resources

- We may incur significant cash payment and common stock issuance obligations under our agreements arising from our investments in Razor, Insight and Chronix.
- We have incurred operating losses since inception, and we do not know if we will attain profitability.
- It is likely that we will need to issue additional equity or debt securities in order to raise additional capital needed to pay our operating expenses.

Risks Related to Our Business Operations

- Our revenues in the near term will depend on our ability to commercialize a small number of diagnostic tests.
- The research and development work we are doing is costly, time consuming, and uncertain as to its results.
- Sales of our diagnostic tests could be adversely impacted by the reluctance of physicians to adopt the use of our tests and by the availability of competing diagnostic tests.
- We have limited capital, marketing, sales, and regulatory compliance resources for the commercialization of our diagnostic tests.
- We may face technology transfer challenges and expenses in adding new tests to our portfolio and in expanding our reach into new geographical areas on new instrument platforms.
- If our laboratory facilities become damaged or inoperable, or we are must vacate any facility, our ability to provide services and pursue our research and development and commercialization efforts may be jeopardized.
- There is a limited number of manufacturers of molecular diagnostic testing equipment and related chemical reagents necessary for the provision of our diagnostic tests.
- If we fail to enter into and maintain successful strategic alliances for diagnostic tests that we elect to co-develop, co-market, or out-license, we may have to reduce or delay our diagnostic test development or increase our expenditures.
- We may become dependent on possible future collaborations to develop and commercialize many of our diagnostic test candidates and to provide the manufacturing, regulatory compliance, sales, marketing and distribution capabilities required for the success of our business.
- Failure to adequately protect, or disputes relating to, trademarks could harm our business.
- Our business could be adversely affected if we lose the services of the key personnel upon whom we depend.
- Our business and operations could suffer in the event of system failures.
- Security breaches and other disruptions could compromise our information and expose us to liability, and could cause our business and reputation to suffer.
- Failure of our internal control over financial reporting could harm our business and financial results.
- We are subject to laws and regulations governing corruption, which will require us to develop, maintain and implement costly compliance programs.
- We may in the future be subject to litigation, which could harm our stock price, business, results of operations and financial condition.
- We may undertake strategic acquisitions in the future, and difficulties integrating such acquisitions could damage our ability to achieve or sustain profitability.
- We are subject to state laws in California that require gender and diversity quotas for boards of directors of public companies headquartered in California.

Risks Related to Our Industry

- Our operations as a clinical laboratory are subject to oversight by CMS under CLIA, as well as certain state agencies, and any failure to maintain our CLIA or applicable state permits and licenses may affect our ability to commercialize our diagnostic tests.
- If the FDA takes the position that any of our tests are not within the scope of its policy on enforcement discretion for laboratory-developed tests, or otherwise determines that it will seek to actively regulate one or more of our diagnostic tests, responding to such a regulatory position could lead to delays in commercialization, or (if encountered after commercialization) requirements to halt the commercial provision of our tests until FDA marketing authorization is obtained.
- We will also need to obtain FDA and other regulatory approvals for any IVDs that we may develop, in order to market those IVD tests.
- Clinical trial failures can occur at any stage of the testing and we may experience numerous unforeseen events during, or as a result of, the clinical trial process that could delay or prevent commercialization of our current or future diagnostic tests.
- The commercial success of our diagnostic tests depends on the availability and sufficiency of third-party payer coverage and reimbursement, which may be limited or unavailable.
- Changes in healthcare laws and policies may have a material adverse effect on our financial condition, results of operations and cash flows.
- Because of certain Medicare billing policies, we may not receive complete reimbursement for tests provided to Medicare patients.
- Long payment cycles of Medicare, Medicaid and other third-party payers, or other payment delays, could hurt our cash flows and increase our need for working capital.
- Private health insurance company policies may deny coverage or limit the amount they will reimburse us for the performance of our diagnostic tests.
- We will be required to comply with federal and state laws governing the privacy of health information, and any failure to comply with these laws could result in material criminal and civil penalties.
- If we are successful in commercializing our diagnostic tests, we will be obligated to comply with numerous additional federal and state statutes and regulations pertaining to our business and be subject to government oversight and scrutiny for our compliance with such laws. Laboratory and health care regulatory compliance efforts are expensive and time-consuming, and failure to maintain compliance with applicable laws could result in enforcement action which could be detrimental to our business.

Risks Related to Intellectual Property

- We rely on patents and trade secrets, and our financial success will depend, in part, on our ability to obtain commercially valuable patent claims, protect our intellectual property rights and operate without infringing upon the proprietary rights of others.
- We may not be able to obtain patent protection for our diagnostic tests if our pending U.S. patent applications are found to be directed to unpatentable subject matter.
- Changes to the patent laws in the United States and other jurisdictions could diminish the value of patents in general, thereby impairing our ability to protect our diagnostic tests.
- Other companies or organizations may challenge our patent rights or may assert patent rights that prevent us from developing and commercializing our diagnostic tests.
- If we are unable to protect the confidentiality of our trade secrets, the value of our technology could be materially adversely affected, and our business would be harmed.
- We may become involved in lawsuits to protect or enforce our patents or other intellectual property, which could be expensive, time-consuming and unsuccessful.
- We may not be able to enforce our intellectual property rights throughout the world.
- If we are sued for infringing intellectual property rights of third parties, such litigation could be costly and time consuming and could prevent or delay us from developing or commercializing our diagnostic tests.
- Patent terms may be inadequate to protect our competitive position on our diagnostic tests for an adequate amount of time.

Risks Related to the COVID-19 Pandemic

- The recent COVID-19 global pandemic and the actions taken in response thereto could harm our business and our results of operations and financial condition could be adversely impacted thereby.

Risks Related to Our Common Stock

- We have identified a material weakness in our internal control over financial reporting.
- Our common stock may be delisted from The Nasdaq Capital Market which could negatively impact the price of our common stock, liquidity and our ability to access the capital markets.
- The price of our stock may rise and fall rapidly.
- Since we don't pay dividends, our stock may not be a suitable investment for those needing dividend income.
- Securities analysts may not initiate coverage or continue to cover our common stock, and this may have a negative impact on the market price of our shares.
- You may experience dilution of your ownership interests if we issue additional shares of common stock or preferred stock.
- Our former parent company may sell its Oncocyte shares to raise capital to finance its operations.

Risks Related to Our Capital Resources

We may incur significant cash payment and common stock issuance obligations under our agreements arising from our investments in Insight and Chronix.

Under the Merger Agreement pursuant to which we acquired Insight, as described in Note 3 to the consolidated financial statements included elsewhere in this Report, we have agreed to pay contingent consideration of up to $6.0 million in any combination of cash or shares of Oncocyte common stock if certain milestones related to DetermaIO are achieved (the "Contingent Consideration"), which consist of (i) a $1.5 million clinical trial completion and data publication milestone, (ii) $3.0 million for an affirmative final local coverage determination from CMS for a specified lung cancer test, and (iii) up to $1.5 million for achieving certain CMS reimbursement milestones.

As additional consideration for the acquisition of Chronix, we have agreed to pay to holders of other classes and series of Chronix stock (i) up to $14 million in any combination of cash or Oncocyte common stock if certain milestones are achieved, (ii) earnout consideration of up to 15% of net collections for sales of specified tests and products during certain five to ten-year earnout periods, and (iii) up to 75% of net collections during a seven-year earnout period from the sale or license of Chronix's patents to a third party for use in transplantation medicine.

To meet these various cash payment obligations, we may need to sell additional shares of our common stock or other securities to raise the cash needed, or we may have to divert cash on hand that we would otherwise use for other business and operational purposes which could cause us to delay or reduce activities in the development and commercialization of our cancer tests. Any shares of common stock or other securities we sell to raise cash to meet our cash payment obligations will dilute the interests of our common stockholders.

We have incurred operating losses since inception, and we do not know if we will attain profitability.

Since our inception in September 2009, we have incurred operating losses and negative cash flows and we expect to continue to incur losses and negative cash flows in the future. Our net losses for the years ended December 31, 2022 and 2021 were $72.9 million and $64.1 million, respectively, and we had an accumulated deficit of $260.7 million as of December 31, 2022. We finance our operations primarily through sales of our common stock. There is no assurance that we will be able to obtain any additional financing that we may need, or that any such financing that may become available will be on terms that are favorable to us and our shareholders. Ultimately, our ability to generate sufficient operating revenue to earn a profit depends upon our success in developing and marketing or licensing our diagnostic tests and technology.

It is likely that we will need to issue additional equity or debt securities in order to raise additional capital needed to pay our operating expenses until such time as our revenues are sufficient to finance our operating expenses.

- We plan to continue to incur substantial research and development expenses and we anticipate that we will be incurring significant sales and marketing costs as we develop and commercialize our diagnostic tests. Our research and development expenses may also increase if we work to develop tests for additional types of cancer or for other cancer related diagnostic purposes. The period of time for which our current cash and marketable securities will be sufficient to finance our operations will depend on the extent to which we expend funds on commercializing our tests and conducting new research and development programs. We will need to raise additional capital to pay operating expenses unless we are able to generate sufficient revenues from diagnostic test sales, royalties, and license fees to meet our operating expenses.
- Our ability to raise additional equity or debt capital will depend not only on the successful completion of development of our diagnostic tests and receiving reimbursement approval from Medicare and other third-party payers for those tests, but also will depend on access to capital and conditions in the capital markets. Obtaining Medicare reimbursement approval for our diagnostic tests could take two to three years, and investors may be reluctant to provide us with additional capital until we obtain Medicare reimbursement approval for those tests or until we can demonstrate that private payers such as health insurance companies or HMOs are willing to pay for the use of our diagnostic tests at prices sufficient for us to earn a reasonable return on our investments in our diagnostic test portfolio. There is no assurance that we will be able to raise capital at times and in amounts needed to finance the development and commercialization of our diagnostic tests and general operations. Even if capital is available, it may not be available on terms that we or our shareholders would consider favorable.
- Sales or other issuances of additional equity securities by us could result in the dilution of the interests of our shareholders.

Risks Related to Our Business Operations

Our revenues in the near term will depend on our ability to commercialize a small number of diagnostic tests.

Our near-term commercial efforts will focus on maximizing the opportunities for VitaGraft and DetermaIO and DetermaCNI. Our reliance on a small group of diagnostic tests as sources of revenue could limit our future revenue, make it more difficult for us to finance our operations, and impair our prospects for profitability and growth. DetermaIO and VitaGraft are currently available only in early access for non-clinical use. We plan to continue development of all three products for clinical and research use. However, there is no assurance that our development plans for VitaGraft, DetermaIO or DetermaCNI will be successful or that we will be generate sufficient revenues from commercialization of our diagnostic tests to finance our operations and earn a profit.

The research and development work we are doing is costly, time consuming, and uncertain as to its results.

We incurred research and development expenses amounting to approximately $7.3 million and $5.0 million during years ended December 31, 2022 and 2021, respectively. The current focus of our research and development efforts is the development of DetermaIO, VitaGraft and DetermaCNI. If we are successful in developing a new technology or diagnostic tests for additional types of cancer, refinement of the new technology or diagnostic tests and definition of the practical applications and limitations of the technology or diagnostic tests may take years and require the expenditure of large sums of money. There is no assurance that we will be successful in completing the development of our current diagnostic tests or in developing additional diagnostic tests regardless of the amount of our expenditures.

Sales of our diagnostic tests could be adversely impacted by the reluctance of physicians to adopt the use of our tests and by the availability of competing diagnostic tests.

Physicians and hospitals may be reluctant to try a new diagnostic test due to the high degree of risk associated with the application of new technologies and diagnostic tests in the field of human medicine, especially if the new tests differ from the current standard of care for detecting cancer in patients. Competing tests for the initial diagnosis, reoccurrence diagnosis and optimal treatment of cancer are being manufactured and marketed by established companies and by other smaller biotechnology companies. In order to compete with other diagnostic tests, particularly any that sell at lower prices, our tests will have to provide medically significant advantages or be more cost effective. Even if we are able to overcome physician reluctance and compete with products that are currently on the market, our competitors may succeed in developing new safer, more accurate or more cost-effective diagnostic tests that could render our diagnostic tests and technologies obsolete or noncompetitive.

We have limited capital, marketing, sales, and regulatory compliance resources for the commercialization of our diagnostic tests.

We are building our own marketing and sales capability for our diagnostic tests, and are devoting significant financial and management resources to recruiting, training, and managing our sales force and building a health care regulatory compliance program. However, due to our limited capital resources, we may need to enter into marketing arrangements with other diagnostic companies for one or more of our tests in domestic or foreign markets. Under such marketing arrangements we may license marketing rights to one or more of our diagnostic tests to other diagnostic companies or to one or more joint venture companies that may be formed to market our tests, and we might receive only a royalty on sales or an equity interest in a joint venture company. As a result, our revenues from the sale of our tests through such arrangements may be substantially less than the amount of revenues and gross profits that we might receive if we were to market our tests ourselves.

We may face technology transfer challenges and expenses in adding new tests to our portfolio and in expanding our reach into new geographical areas on new instrument platforms.

Our plan for expanding our business includes developing and acquiring additional tests that can be transferred into our current lab footprint in the US and/or onto molecular testing instrument platforms for distribution in ex-US markets. Due to differences in the hardware and software platforms available at different laboratories for running molecular tests, we may need to make adjustments to the configuration of the reagents that make up our LDTs in our US labs or as we convert them to kits, and there may be changes to the related software in order for the tests to be performed on particular hardware platforms. Making any such adjustments could take a considerable amount of time and expense, and there will be no assurance that we will succeed in running our tests on the hardware and software that we may encounter in different laboratories. To manage this issue and to attain uniformity among our laboratory locations, we may license or acquire our own instrument system and software from another company that has a platform that will be compatible with our tests. In addition to acquisition costs, operationally we will have to build out infrastructure for installing a new testing platform across multiple laboratory locations as well as support functions to help maintain these instrument systems in new customer labs, and we may also encounter unexpected technology issues in the process.

If our laboratory facilities become damaged or inoperable, or we are required to vacate any facility, our ability to provide services and pursue our research and development and commercialization efforts may be jeopardized.

We currently have a clinical laboratory facility in Nashville, Tennessee. We also acquired a laboratory in Germany through merger with Chronix. Our facilities and equipment could be harmed or rendered inoperable by natural or man-made disasters, including fire, flooding, hurricanes, tornadoes and power outages, which may render it difficult or impossible for us to perform our tests or provide laboratory services for some period of time. The inability to perform our tests or the backlog of tests that could develop if any of our facilities is inoperable for even a short period of time may result in the loss of customers or harm to our reputation or relationships with key researchers, collaborators, and customers, and we may be unable to regain those customers or repair our reputation in the future. Furthermore, our facilities and the equipment we use to perform our research and development work could be costly and time-consuming to repair or replace.

Additionally, a key component of our research and development process involves using biological samples and the resulting data sets and medical histories, as the basis for our diagnostic test development. In some cases, these samples are difficult to obtain. If the parts of our laboratory facilities where we store these biological samples are damaged or compromised, our ability to pursue our research and development projects, commercialization of our diagnostic tests, as well as our reputation, could be jeopardized. We carry insurance for damage to our property and the disruption of our business, but this insurance may not be sufficient to cover all of our potential losses and may not continue to be available to us on acceptable terms, if at all.

Further, if our laboratories become inoperable, we may not be able to license or transfer our proprietary technology to a third-party, with established state licensure and CLIA certification under the scope of which our diagnostic tests could be performed following validation and other required procedures, to perform the tests. Even if we find a third-party with such qualifications to perform our tests, such party may not be willing to perform the tests for us on commercially reasonable terms. Moreover, we believe our tests are currently subject to enforcement discretion by the FDA because we believe the tests currently qualify as LDTs. If, however, we are required to find a third-party laboratory to conduct our testing services, we believe this would change our status and the FDA would consider such tests offered through a third-party to then be a medical device subject to active FDA regulation and enforcement under its *in vitro* diagnostic authorities. In that case, we may be required to obtain premarket clearance or approval prior to offering our tests, which would be time-consuming and costly and could result in interruptions and delays in our ability to sell or offer our tests.

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

After encountering inconsistent results using diagnostic testing equipment and reagents from one manufacturer, we switched to diagnostic testing equipment from a different manufacturer. The chemical reagents used with the diagnostic testing equipment are available only from the equipment manufacturer. If issues were to arise with the new equipment or if reagents we are using causing us to acquire different diagnostic testing equipment again, we would need to conduct validation and analytic studies to determine whether our previous test results can be reproduced using the new equipment. As a result, we could experience delays again in developing our diagnostic tests. If similar issues were to arise after commercialization of a diagnostic test, we could experience a disruption for a period of time in providing the diagnostic tests to patients and we would lose revenues and potentially market share as a result.

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

In order to facilitate the development, manufacture and commercialization of our diagnostic tests we may enter into strategic alliances with diagnostic, pharmaceutical, or medical device companies to advance our programs and enable us to maintain our financial and operational capacity. We will face significant competition in seeking appropriate alliances. We may not be able to negotiate alliances on acceptable terms, if at all. If we fail to create and maintain suitable alliances, we may have to limit the size or scope of, or delay, one or more of our product development or research programs, or we will have to increase our expenditures and will need to obtain additional funding, which may be unavailable or available only on unfavorable terms.

If we are able to enter into development and marketing arrangements with diagnostic, pharmaceutical or medical device companies for our diagnostic tests, we may license product development, manufacturing, and marketing rights to the pharmaceutical or medical device company or to a joint venture company formed with the pharmaceutical or medical device company. Under such arrangements we might receive only a royalty on sales of the diagnostic tests developed or an equity interest in a joint venture company that develops the diagnostic test. As a result, our revenues from the sale of those diagnostic tests may be substantially less than the amount of revenues and gross profits that we might receive if we were to develop, manufacture, and market the diagnostic tests ourselves.

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

We may enter into various kinds of collaborative research and development, manufacturing, and diagnostic test marketing agreements to develop and commercialize our diagnostic tests. Any future milestone payments and cost reimbursements from collaboration agreements could provide an important source of financing for our research and development programs, thereby facilitating the application of our technology to the development and commercialization of our diagnostic tests, but there are risks associated with entering into collaboration arrangements.

There is a risk that we could become dependent upon one or more collaborative arrangements for diagnostic test development or manufacturing or as a source of revenues from the sale of any diagnostic tests that may be developed by us alone or through one of the collaborative arrangements. A collaborative arrangement upon which we might depend might be terminated by our collaboration partner or they might determine not to actively pursue the development or commercialization of our diagnostic tests. A collaboration partner also may not be precluded from independently pursuing competing diagnostic tests or technologies.

There is a risk that a collaboration partner might fail to perform its obligations under the collaborative arrangements or may be slow in performing its obligations. In addition, a collaboration partner may experience financial difficulties at any time that could prevent it from having available funds to contribute to the collaboration. If a collaboration partner fails to conduct its diagnostic test development, manufacturing, commercialization, regulatory compliance, sales and marketing or distribution activities successfully and in a timely manner, or if it terminates or materially modifies its agreements with us, the development and commercialization of one or more diagnostic test candidates could be delayed, curtailed or terminated because we may not have sufficient financial resources or capabilities to continue diagnostic test development, manufacturing, and commercialization on our own.

Failure to adequately protect, or disputes relating to, trademarks, could harm our business.

We cannot be certain that the legal steps we are taking are sufficient to protect our trademark rights or that, notwithstanding legal protection, others will not infringe or misappropriate our intellectual property rights. In addition, we could come into conflict with third parties over trademark rights, which could result in disruptive and expensive litigation. Challenges to our trademarks could result in significant costs related to the prosecution or defense of the registrations of our trademarks or rebranding if we need to abandon or modify a trademark.

Our business could be adversely affected if we lose the services of the key personnel upon whom we depend.

We presently rely on a small senior management team to direct our diagnostics program and our initial commercial activities. Accordingly, the loss of the services of one or more of the members of that management team could have a material adverse effect on our business.

Our cash and cash equivalents could be adversely affected if the financial institutions in which we hold our cash and cash equivalents fail.

Actual events involving limited liquidity, defaults, non-performance or other adverse developments that affect financial institutions, transactional counterparties or other companies in the financial services industry or the financial services industry generally, or concerns or rumors about any events of these kinds or other similar risks, have in the past and may in the future lead to market-wide liquidity problems. For example, on March 10, 2023, the Federal Deposit Insurance Corporation (the “FDIC”) took control of Silicon Valley Bank (“SVB”) and created the National Bank of Santa Clara to hold the deposits of SVB after SVB was unable to continue its operations. On March 12, 2023, the FDIC, U.S. Department of the Treasury, and Board of Governors of the Federal Reserve System, issued a joint press release stating that all depositors would have access to all of their money beginning on March 13, 2023. As of March 24, 2023, we have access to our cash on deposit with SVB. If we are unable to access all or a significant portion of the amounts we have deposited at financial institutions for any extended period of time, we may not be able to pay our operational expenses or make other payments until we are able to move our funds to accounts at one or more other financial institutions, which process could cause a temporary delay in making payments to our vendors and employees and cause other operational challenges.

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

We depend on information technology and telecommunications systems, including a combination of on-site systems, managed data center systems, cloud-based systems, and the Internet, for significant elements of our operations, including processing, transmitting, and storing a wide variety of business-critical information. Despite the implementation of security measures, our internal computer systems and those of our contractors and consultants are vulnerable to damage from computer viruses, ransomware, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures. Such events could cause interruption of our operations, downtime of our information technology or telecommunications systems or those used by our third-party service providers, and have an adverse effect on our business and results of operations. For example, the loss of data for our diagnostic test candidates could result in delays in our regulatory filings and development efforts and significantly increase our costs. To the extent that any disruption or security breach results in a loss of or damage to our data, or inappropriate disclosure of confidential or proprietary information, we could incur liability under federal or state laws, be subject to litigation, and the development of our diagnostic test candidates could be delayed.

Security breaches and other disruptions could compromise our information and expose us to liability, and could cause our business and reputation to suffer.

In the ordinary course of business, we collect and store sensitive data, including intellectual property, our proprietary business information and that of our business partners, PHI, and personally identifiable information of patients and employees. We manage and maintain our applications and data utilizing a combination of on-site systems, managed data center systems and cloud-based systems. We also communicate PHI and other sensitive data through our various tools and platforms. In addition to storing and transmitting sensitive data that is subject to legal protections, these applications and data encompass a wide variety of business-critical information, including research and development information, commercial information, and business and financial information. The secure processing, maintenance, and transmission of this information is critical to our operations and business strategy.

We face a number of risks relative to protecting our information, including loss of access, inappropriate disclosure, inappropriate modification, and the risk of our being unable to adequately monitor and modify our controls over our critical information. Despite our security measures, our information technology and infrastructure are also vulnerable to attacks by hackers, viruses, ransomware or breaches due to employee error, technical error, malfeasance, or other disruptions.

These types of problems may be caused by a variety of factors, including infrastructure changes, intentional or accidental human actions or omissions, software errors, malware, security attacks, fraud, spikes in customer usage and denial of service issues. From time to time, large third-party web hosting providers have also experienced outages or other problems that have resulted in their systems being offline and inaccessible. In addition to data security risks, we also face privacy risks. Should we actually violate, or be perceived to have violated, any privacy promises we make to patients or consumers, we could be subject to a complaint from an affected individual or interested privacy regulator, such as the FTC or a state Attorney General. This risk is heightened given the sensitivity of the data we collect.

Any problems that may arise in connection with our data and systems, including those that are hosted by third-party providers, could result in interruptions to our business and operations or exposure to security vulnerabilities. Any such breach or interruption, whether of our systems or that of our third-party service providers or their subcontractors, could also compromise our networks, and the information stored there could be accessed, publicly disclosed, lost, or stolen. Any such access, disclosure, theft, or other loss of information or privacy or security compromise could result in legal claims or proceedings or liability under federal or state laws that protect the privacy or security of personal information, including HIPAA, HITECH, and state data security and data breach notification laws. Any data privacy or security event could also disrupt our operations and damage our reputation, any of which could adversely affect our business.

If a privacy or security event occurs, we may be required to comply with state breach notification laws and become subject to mandatory corrective action. Penalties for failure to comply with a requirement of HIPAA or HITECH vary significantly, and, depending on the knowledge and culpability of the HIPAA-regulated entity, may include civil monetary penalties of up to $1.5 million per calendar year for each provision of HIPAA that is violated. A person who knowingly obtains or discloses individually identifiable health information in violation of HIPAA may face a criminal penalty of up to $50,000 and up to one-year imprisonment. The criminal penalties increase if the wrongful conduct involves false pretenses or the intent to sell, transfer or use identifiable health information for commercial advantage, personal gain or malicious harm. Penalties for unfair or deceptive acts or practices under the FTC Act or state Unfair and Deceptive Acts and Practices statutes may also vary significantly.

Also, even if we do not incur an interruption of or our operations, fines, penalties, or financial liability to third parties from a security breach, we could suffer a loss of confidence in our services, which could adversely affect our business and competitive position. A security event could also result in the compromise of our trade secrets and other proprietary information, which could adversely affect our competitive position.

Failure of our internal control over financial reporting could harm our business and financial results.

Our management is responsible for establishing and maintaining adequate internal control over financial reporting. Internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting for external purposes in accordance with accounting principles generally accepted in the U.S. Internal control over financial reporting includes maintaining records that in reasonable detail accurately and fairly reflect our transactions; providing reasonable assurance that transactions are recorded as necessary for preparation of our consolidated financial statements; providing reasonable assurance that receipts and expenditures of our assets are made in accordance with management authorization; and providing reasonable assurance that unauthorized acquisition, use or disposition of our assets that could have a material effect on the consolidated financial statements would be prevented or detected on a timely basis. Because of its inherent limitations, internal control over financial reporting is not intended to provide absolute assurance that a misstatement of our consolidated financial statements would be prevented or detected. Our growth and entry into new diagnostic tests, technologies and markets will place significant additional pressure on our system of internal control over financial reporting. Any failure to maintain an effective system of internal control over financial reporting could limit our ability to report our financial results accurately and timely or to detect and prevent fraud. Because we are a smaller reporting company, we are exempt from the requirement of having our internal controls over financial reporting audited by our independent registered public accountants, which means that material weaknesses or significant deficiencies in our internal controls that might be detected by an audit may not be detected and remedied.

We are subject to laws and regulations governing corruption, which will require us to develop, maintain, and implement costly compliance programs.

We must comply with a wide range of laws and regulations to prevent corruption, bribery, and other unethical business practices, including the Foreign Corrupt Practices Act or FCPA, anti-bribery and anti-corruption laws in other countries. The creation and implementation of international business practices compliance programs is costly and such programs are difficult to enforce, particularly where reliance on third parties is required.

Anti-bribery laws prohibit us, our employees, and some of our agents or representatives from offering or providing any personal benefit to covered government officials to influence their performance of their duties or induce them to serve interests other than the missions of the public organizations in which they serve. Certain commercial bribery rules also prohibit offering or providing any personal benefit to employees and representatives of commercial companies to influence their performance of their duties or induce them to serve interests other than their employers. The FCPA also obligates companies whose securities are listed in the U.S. to comply with certain accounting provisions requiring us to maintain books and records that accurately and fairly reflect all transactions of the corporation, including international subsidiaries, and devise and maintain an adequate system of internal accounting controls for international operations. The anti-bribery provisions of the FCPA are enforced primarily by the United States Department of Justice. The SEC is involved with enforcement of the books and records provisions of the FCPA.

Compliance with these anti-bribery laws is expensive and difficult, particularly in countries in which corruption is a recognized problem. In addition, the anti-bribery laws present particular challenges in the medical industry because in many countries including China, hospitals are state-owned or operated by the government, and doctors and other hospital employees are considered foreign government officials. Furthermore, in certain countries (China in particular), hospitals and clinics are permitted to sell pharmaceuticals to their patients and are primary or significant distributors of pharmaceuticals. Certain payments to hospitals in connection with clinical studies, procurement of pharmaceuticals and other work have been deemed to be improper payments to government officials that have led to vigorous anti-bribery law enforcement actions and heavy fines in multiple jurisdictions, particularly in the U.S. and China.

It is not always possible to identify and deter violations, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations.

In the medical industry, corrupt practices include, among others, offering or accepting kickbacks, bribes or other illegal gains or benefits by the hospitals and medical practitioners from manufacturers of pharmaceutical or other products, distributors or their third-party agents in connection with the prescription of certain pharmaceuticals or sale of products. If our employees, affiliates, distributors or third-party marketing firms violate these laws or otherwise engage in illegal practices with respect to their sales or marketing of our products or other activities involving our products, we could be required to pay damages or heavy fines by multiple jurisdictions where we operate, which could materially and adversely affect our financial condition and results of operations. There have been recent occurrences in which certain hospitals have denied access to sales representatives from pharmaceutical companies because the hospitals wanted to avoid the perception of corruption. If this attitude becomes widespread among our potential customers, our ability to promote our products to hospitals may be adversely affected.

If we and our subsidiaries expand operations internationally, we will need to increase the scope of our compliance programs to address the risks relating to the potential for violations of the FCPA and other anti-bribery and anti-corruption laws and data protection laws. Our compliance programs will need to include policies addressing not only the FCPA, but also the provisions of a variety of anti-bribery and anti-corruption laws in multiple foreign jurisdictions, provisions relating to books and records that apply to us as a public company, and include effective training for our personnel throughout our organization. The creation and implementation of anti-corruption compliance programs is costly and such programs are difficult to enforce, particularly where reliance on third parties is required. Violation of the FCPA and other anti-corruption and data privacy laws can result in significant administrative and criminal penalties for us and our employees, including substantial fines, suspension or debarment from government contracting, prison sentences, or even the death penalty in extremely serious cases in certain countries. The SEC also may suspend or bar us from trading securities on U.S. exchanges for violation of the FCPA's accounting provisions. Even if we are not ultimately punished by government authorities, the costs of investigation and review, distraction of our personnel, legal defense costs, and harm to our reputation could be substantial and could limit our profitability or our ability to develop or commercialize our product candidates. In addition, if any of our competitors are not subject to the FCPA, they may engage in practices that will lead to their receipt of preferential treatment from foreign hospitals and enable them to secure business from foreign hospitals in ways that are unavailable to us.

We may in the future be subject to litigation, which could harm our stock price, business, results of operations and financial condition.

We may be subject to litigation in the future. In the past, following periods of volatility in the market price of their stock, many companies, including us, have been the subjects of securities class action litigation. Any such litigation can result in substantial costs and diversion of management's attention and resources and could harm our stock price, business results of operations and financial condition. As a result of these factors, holders of our common stock might be unable to sell their shares at or above the price they paid for such shares.

We may undertake strategic acquisitions in the future, and difficulties integrating such acquisitions could damage our ability to achieve or sustain profitability.

We may acquire businesses or assets that complement or augment our existing business. If we acquire businesses with promising products or technologies, we may not be able to realize the benefit of acquiring such businesses if we are unable to move one or more products through preclinical and/or clinical development to regulatory approval and commercialization. Integrating any newly acquired businesses or technologies could be expensive and time-consuming, resulting in the diversion of resources from our current business. We may not be able to integrate any acquired business successfully. We cannot assure that, following an acquisition, we will achieve revenues, specific net income or loss levels that justify the acquisition or that the acquisition will result in increased earnings, or reduced losses, for the combined company in any future period. Moreover, we may need to raise additional funds through public or private debt or equity financing to acquire any businesses, which would result in dilution for stockholders or the incurrence of indebtedness and may not be available on terms which would otherwise be acceptable to us. We may not be able to operate acquired businesses profitably or otherwise implement our growth strategy successfully.

We are subject to state laws in California that require gender and diversity quotas for boards of directors of public companies headquartered in California.

In September 2018, California enacted SB 826, requiring public companies headquartered in California to maintain minimum female representation on their boards of directors as follows: by December 31, 2019, public company boards must have a minimum of one female director; by December 31, 2021, public company boards with five members were required to have at least two female directors, and public company boards with six or more members were required to have at least three female directors. On May 13, 2022, the Los Angeles Superior Court declared SB 826 unconstitutional and, although the California Secretary of State has directed counsel to file an appeal of decision, the State of California is currently precluded from enforcing SB 826.

Additionally, on September 30, 2020, California enacted AB 979, requiring public companies with principal executive offices in California to each have at least one director from an underrepresented community based on ethnicity and sexual orientation by December 31, 2021. A director from an "underrepresented community" means a director who self-identifies as Black, African American, Hispanic, Latino, Asian, Pacific Islander, Native American, Native Hawaiian, Alaska Native, gay, lesbian, bisexual or transgender. By December 31,

2022, each of these companies will be required to have at least two directors from such underrepresented communities if such company has more than four but fewer than nine directors, or at least three directors from underrepresented communities if the company has nine or more directors. On April 1, 2022, the Los Angeles Superior Court declared AB 979 unconstitutional and, although the California Secretary of State has filed a notice of appeal in the case, the State of California is currently precluded from enforcing AB 979.

If the State of California successfully appeals the court decisions regarding SB 826 or AB 979, we cannot assure that we can recruit, attract and/or retain qualified members of the board and meet gender or diversity quotas as previously required by SB 826 or AB 979, and our board of directors does not currently satisfy the quota previously required under these regulations. A failure to comply with any such quota requirement could result in fines from the California Secretary of State, and our reputation may be adversely affected.

Risks Related to Our Industry

Our operations as a clinical laboratory in the United States are subject to oversight by CMS under CLIA, as well as certain state agencies, and our operation of clinical laboratories in any foreign jurisdictions are subject to similar regulatory oversight. Any failure to maintain our CLIA or applicable state or international permits and licenses may affect our ability to commercialize our diagnostic tests.

We are subject to CLIA, a federal law regulating clinical laboratories that perform testing on specimens derived from humans for the purpose of providing information for the diagnosis, prevention or treatment of disease. Our clinical laboratories must be certified under CLIA in order for us to perform testing on human specimens. CLIA is intended to ensure the quality and reliability of clinical laboratories in the United States by mandating specific standards in the areas of personnel qualifications, administration, and participation in proficiency testing, patient test management, quality control, quality assurance and inspections. We have a current certificate under CLIA to perform routine chemistry. To renew these certificates, our diagnostic laboratories are subject to survey and inspection every two years. Moreover, CLIA inspectors may make periodic inspections of our clinical laboratories outside of the renewal process.

The law also requires us to maintain a state laboratory license to conduct testing in the states in which are laboratories are located. State laws establish standards for day-to-day operation of a clinical laboratory, including the training and skills required of personnel and quality control. In addition, several states require that we hold licenses to test specimens from patients in those states. We do not have immediate plans to market our tests for commercial use in the European Union and as a result, at this time we do not believe we are subject to EU or EU member state post-market regulations related to our tests.

If we were to lose our CLIA certification or a required state license for a laboratory, whether as a result of a revocation, suspension or limitation, we would no longer be able to offer our tests from the affected laboratory, which would limit our revenue and harm our business. If we were to lose our license in other states where we are required to hold licenses, we would not be able to test specimens from those states. If we perform testing on samples originating in a state where we require a license, but do not currently have one, we could be subject to fines, sanctions, and may be denied permits or licenses in the future.

We also maintain laboratory operations in Germany and could expand our laboratory operations to other foreign jurisdictions. Therefore, we are subject to laboratory quality regulations and accreditation standards in Germany, and will be subject to such regulations and standards in any other jurisdictions where we may operate. These requirements may vary by jurisdiction and differ from those in the United States, and may require us to implement additional compliance measures. If we fail to comply with any foreign jurisdiction's applicable laboratory regulations and standards it could limit our revenue and harm or business and we could be subject to fines and other sanctions.

If the FDA takes the position that any of our tests are not within the scope of its policy on enforcement discretion for laboratory-developed tests, or otherwise determines that it will seek to actively regulate one or more of our diagnostic tests, responding to such a regulatory position could lead to delays in commercialization, or (if encountered after commercialization) requirements to halt the commercial provision of our tests until FDA marketing authorization is obtained.

Although the FDA has historically exercised enforcement discretion over most LDTs, it does not consider tests to be subject to this enforcement discretion if they were or are designed or manufactured completely, or partly, outside of the laboratory that offers and uses them, or if they are offered "over-the-counter" (as opposed to being available to patients only when prescribed by a health care provider). In recent years, however, the FDA has stated it intends to end its policy of general enforcement discretion and regulate certain LDTs as medical devices. To this end, on October 3, 2014, the FDA issued two draft guidance documents, entitled "Framework for Regulatory Oversight of Laboratory Developed Tests (LDTs)" and "FDA Notification and Medical Device Reporting for Laboratory Developed Tests (LDTs)," respectively, that set forth a proposed risk-based regulatory framework that would apply varying levels of FDA oversight to LDTs. Subsequently, on January 13, 2017, the FDA published a "discussion paper" in which it outlined a substantially revised "possible approach" to the oversight of LDTs.

In August 2020, the U.S. Department of Health and Human Services, the parent agency for FDA, announced that the FDA "will not require premarket review of LDTs absent notice-and-comment rulemaking, as opposed to through guidance documents, compliance manuals, website statements, or other informal issuances." It is unclear at this time whether this policy will be retained the Biden Administration, and if so, when the FDA might seek to begin the notice and comment rulemaking process.

Legislative proposals addressing the FDA's oversight of LDTs have been introduced in previous Congresses, and we expect that new legislative proposals may 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 certain LDTs as medical devices is difficult to predict at this time.

In March 2020, a bill titled the "Verifying Accurate Leading-edge IVCT Development Act of 2020," or VALID Act, was officially introduced in Congress. The bill proposes a risk-based approach to regulate LDTs and creates a new in vitro clinical test, or IVCT, category of regulated products, which includes LDTs, and a regulatory structure under the FDA. As proposed, the bill grandfathers many existing tests from the proposed premarket approval, quality systems, and labeling requirements, respectively, but would require such tests to comply with other regulatory requirements (e.g., registration and listing, adverse event reporting). Later that month, Senator Paul introduced the Verified Innovative Testing in American Laboratories Act of 2020, or VITAL Act, which proposes that all aspects of "laboratory-developed testing procedures" be subject to regulation under CLIA, and that no aspects of such procedures be subject to regulation by the FDA. We cannot predict if either of these bills will be enacted in their current (or any other) form and cannot quantify the effect of these bills on our business.

If the FDA were to determine that our tests are not within the policy for LDTs for any reason, including new rules, policies, or guidance, or due to new legislation such as the proposed VALID Act, our tests may become subject to FDA requirements, including pre-market review. If required, the regulatory marketing authorization process may involve, among other things, successfully completing additional clinical trials and submitting a pre-market clearance (510(k)) submission or filing a *de novo* or pre-market approval application with the FDA. If pre-market review and approval is required by the FDA, we may need to incur additional expenses or require additional time to seek it, or we may be unable to satisfy FDA standards, and our tests may not be cleared or approved on a timely basis, if at all, and the labeling claims permitted by the FDA may not be consistent with our currently planned claims or adequate to support adoption of and reimbursement for our tests. Ongoing compliance with FDA regulations would increase the cost of conducting our business, and subject us to inspection by and the regulatory requirements of the FDA, for example registration and listing, adherence to good manufacturing practices under the Quality System Regulation, and medical device reporting, and enforcement action in the event we fail to comply with these requirements. Our laboratories are operating under CLIA and are not currently operating as device manufacturing facilities following FDA's Quality System Regulation. Because these standards differ, we may face challenges establishing FDA-compliant quality systems or be unable to do so. If after commercialization under the LDT framework our tests are allowed to remain on the market but there is uncertainty about the regulatory status of our tests, including questions that may be raised if competitors object to our regulatory positioning as an LDT, we may encounter ongoing regulatory and legal challenges and related costs. Such challenges or related developments (for example if the labeling claims the FDA allows us to make are more limited than the claims we currently plan to make) may impact our commercialization efforts as orders or reimbursement may be less than anticipated. Any of these regulatory developments may cause our business to suffer.

We will also need to obtain FDA and other regulatory approvals for any IVDs that we may develop, in order to market those IVD tests.

If we decide to develop IVDs, we will need to obtain regulatory clearance or approval to market each new IVD test. This means that:

- The IVDs that we may develop cannot be sold until the CMS or the FDA, and corresponding foreign regulatory authorities approve or authorize the laboratory tests or the IVDs for medical use.
- We will have to conduct expensive and time-consuming clinical trials of new diagnostic tests. The full cost of conducting and completing clinical trials necessary to obtain FDA clearance or approval of IVD tests or for gaining reimbursement from health insurance companies, health maintenance organizations, Medicare, and other third-party payers cannot be presently determined but could exceed our financial resources.
- Data obtained from preclinical and clinical studies is susceptible to varying interpretations that could delay, limit or prevent regulatory agency clearances or approvals. Delays or denials of the regulatory clearances or approvals may be encountered as a result of changes in regulatory agency policy, regulations, or laws.
- A diagnostic test that is cleared or approved for marketing may be subject to restrictions on use.
- The FDA can withdraw approval of an FDA regulated product if problems arise.

Clinical trial failures can occur at any stage of the testing and we may experience numerous unforeseen events during, or as a result of, the clinical trial process that could delay or prevent commercialization of our current or future diagnostic tests.

Clinical trial failures or delays can occur at any stage of the trials, and may be directly or indirectly caused by a variety of factors, including but not limited to:

- Delays in securing clinical investigators or trial sites for our clinical trials;
- Delays in obtaining Institutional Review Board and other regulatory approvals to commence a clinical trial;
- Slower than anticipated rates of patient recruitment and enrollment, or failing to reach the targeted number of patients due to competition for patients from other trials;
- Limited or no availability of coverage, reimbursement and adequate payment from health maintenance organizations and other third-party payers for the use of our diagnostic test candidates in our clinical trials;
- Negative or inconclusive results from clinical trials;
- Approval and introduction of new diagnostic or changes in standards of practice or regulatory guidance that render our clinical trial endpoints or the targeting of our proposed indications obsolete;
- Inability to monitor patients adequately during or after treatment or problems with investigator or patient compliance with the trial protocols;
- Inability to replicate in large controlled studies safety and efficacy data obtained from a limited number of patients in uncontrolled trials; and
- Inability or unwillingness of medical investigators to follow our clinical protocols.

The commercial success of our diagnostic tests depends on the availability and sufficiency of third-party payer coverage and reimbursement, which may be limited or unavailable.

Our ability to successfully commercialize our diagnostic tests will depend, in significant part, on the extent to which appropriate reimbursement levels can be obtained for patients. Physicians will be hesitant to order a diagnostic test for a patient when they may be left with a large out-of-pocket fee through co-payments or co-insurance or unreimbursed balances. Third-party payers, including Medicare, Medicaid and private insurers, are increasingly challenging the prices charged for healthcare products and services. In addition, legislative proposals to reform health care or reduce government insurance programs may result in lower prices or the actual inability of prospective customers to purchase our tests. Furthermore, even if reimbursement is available, it may not be available at price levels sufficient for us to realize a positive return on our investment. We have never successfully obtained reimbursement for any test and may never be able to obtain reimbursement from any third-party payer; without such coverage and reimbursement, we may not achieve market acceptance of our test and may never be profitable.

The United States government and state legislatures have shown significant interest in implementing cost containment programs to limit the growth of government-paid healthcare costs, including price controls, restrictions on reimbursement and coverage. Adoption of government controls and measures, and tightening of restrictive policies in jurisdictions with existing controls and measures, could exclude or limit one or more of our diagnostic tests from coverage. Even if a diagnostic test receives coverage and reimbursement from third-party payers, such coverage policies and reimbursement rates may change at any time, might not be adequate, or less favorable coverage policies and reimbursement rates may be implemented in the future. If we are unable to obtain and maintain sufficient third-party coverage and adequate reimbursement for a diagnostic test, its commercial success may be greatly hindered, and our financial condition and results of operations may be materially and adversely affected.

We may need to conduct additional studies in order to demonstrate the cost-effectiveness of our diagnostic tests to the satisfaction of our target customers and their third-party payers. Such studies might require us to commit a significant amount of management time and financial and other resources

Changes in healthcare laws and policies may have a material adverse effect on our financial condition, results of operations and cash flows.

We cannot predict whether future healthcare initiatives will be implemented at the federal or state level, or how any future legislation or regulation may affect us. For instance, the payment reductions imposed by the Affordable Care Act ("ACA") and the expansion of the federal and state governments' role in the U.S. healthcare industry as well as changes to the reimbursement amounts paid by payers for our tests and future tests and products may reduce our profits and have a materially adverse effect on our business, financial condition, results of operations and cash flows. Notably, Congress enacted legislation in 2017 that eliminated the ACA's "individual mandate" beginning in 2019, which may significantly impact the number of covered lives participating in exchange plans. The U.S. Supreme Court is currently reviewing the constitutionality of the ACA, although it is unclear when a decision will be made. Further, it is possible that additional governmental action be taken in response to the recent COVID-19 public health emergency.

PAMA significantly altered the payment methodology under the Clinical Laboratory Fee Schedule that determines Medicare coverage for laboratory tests. Under PAMA (as amended by the Further Consolidated Appropriations Act, 2020 and the Coronavirus Aid, Relief, and Economic Security Act, respectively) and its implementing regulations, clinical laboratories must report to CMS private payer rates for clinical diagnostic laboratory tests. Laboratories that fail to timely report the required payment information may be subject to substantial civil money penalties. Medicare payments for clinical diagnostic laboratory tests are paid based upon these reported private payer rates. For certain clinical diagnostic laboratory tests that are not designated as advanced diagnostic laboratory tests, initial payment rates will be assigned by the cross-walk or gap-fill methodology. For laboratory tests that are designated as new advanced diagnostic laboratory tests initial payment rates will be based on the actual list charge for the laboratory test. On December 10, 2021 CMS reported that the payment rates calculated under PAMA will be held at 2020 levels during 2022, and then, where applicable based upon median private payer rates reported, reduced by up to 15% per test year in each of 2023 through 2025, with a second round of private payer rate reporting between January 1, 2022 and March 31, 2022 to establish the 2023 through 2025 rates. Thereafter, additional data collection and reporting obligations are scheduled to continue on an every third subsequent calendar year cycle to establish the payment rates.

Because of certain Medicare billing policies, we may not receive complete reimbursement for tests provided to Medicare patients.

Medicare has coverage policies that can be national or regional in scope. Coverage means that the test or assay is approved as a benefit for Medicare beneficiaries. If there is no coverage, neither the supplier nor any other party, such as a diagnostic laboratory, may receive reimbursement from Medicare for the service. Regional policies are directed by Medicare's regional MACs. Reimbursement for our diagnostic testing may be negatively impacted by California MAC policies.

Long payment cycles of Medicare, Medicaid and other third-party payers, or other payment delays, could hurt our cash flows and increase our need for working capital.

Medicare and Medicaid have complex billing and documentation requirements that we will have to satisfy in order to receive payment. Failure to comply with these requirements and other laws applicable to billing may result in, among other things, non-payment, refunds, exclusion from government healthcare programs, and civil or criminal liabilities, any of which may have a material adverse effect on our revenues and earnings. Similarly, the failure of private health insurers or other private third-party payers to properly process our payment claims in a timely manner could delay our receipt of payment for our diagnostic tests and services, which may have a material adverse effect on our cash flows.

Private health insurance company policies may deny coverage or limit the amount they will reimburse us for the performance of our diagnostic tests.

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

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

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

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

If we are successful in commercializing our diagnostic tests, we will be obligated to comply with numerous additional federal and state statutes and regulations pertaining to our business and be subject to government oversight and scrutiny for our compliance with such laws. Laboratory and health care regulatory compliance efforts are expensive and time-consuming, and failure to maintain compliance with applicable laws could result in enforcement action which could be detrimental to our business.

If we are successful in commercializing any of our diagnostic tests, and particularly if payment becomes available from government or commercial payers for a test, we will be subject to extensive and frequently changing federal and state laws governing various aspects of our business. We will be subject to ongoing compliance with laws addressing our laboratory licensure and certification at the federal and state level; advertising and promotion (including laws enforced by the Federal Trade Commission); and laws intended to prevent fraud, waste, and abuse in healthcare programs (including among others the Anti-Kickback Statute, False Claims Act, the Eliminating Kickbacks in Recovery Act (EKRA), the Stark Law, and applicable state law equivalents).

These laws and regulations are complex and are subject to interpretation by the courts and by government agencies. If one or more such agencies alleges that we may be in violation of any of these requirements, regardless of the outcome, it could damage our reputation and adversely affect important business relationships with third parties. Any action brought against us for violation of these or other laws or regulations, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management's attention from the operation of our business. If our operations are found to be in violation of any of these laws and regulations, we may be subject to any applicable penalty associated with the violation, including civil and criminal penalties, damages and fines, and in some circumstances we could be required to refund payments received by us from payers, or even be excluded from participation in healthcare programs. Any of the foregoing consequences could seriously harm our business and our financial results.

We plan to adopt policies and procedures designed to comply with applicable laws and regulations. Developing a compliance infrastructure is costly and time-consuming, and even a well-designed and implemented compliance program cannot necessarily prevent all violations of relevant laws. We may be subject to enforcement action based on the actions or omissions of employees or contractors, including our anticipated sales force.

Risks Related to Intellectual Property

We rely on patents and trade secrets, and our financial success will depend, in part, on our ability to obtain commercially valuable patent claims, protect our intellectual property rights and operate without infringing upon the proprietary rights of others.

We rely primarily on patents and contractual obligations with employees and third parties to protect our proprietary rights. We have sought, and intend to continue to seek, appropriate patent protection for important and strategic components of our proprietary technologies by filing patent applications in the United States and certain foreign countries. We may also use license agreements both to access technologies developed by other companies and universities and to convey certain intellectual property rights to others. Our financial success will depend, in part, on our ability to obtain commercially valuable patent claims, protect our intellectual property rights and operate without infringing upon the proprietary rights of others.

We may not be able to obtain patent protection for our diagnostic test if our pending U.S. patent applications are found to be directed to unpatentable subject matter.

The U.S. Supreme Court has ruled on several patent cases in recent years, either narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations. For example, recent cases have held that diagnostic methods merely reciting a correlation between a naturally occurring event and a diagnostic outcome associated with that event is not patentable subject matter. If our pending U.S. patent applications are found to be directed to unpatentable subject matter by the USPTO, or any patents issuing from our pending patent applications are invalidated based on these decisions, we may be unable to prevent competitors from using the biomarkers or other subject matter disclosed in the patent applications to develop similar diagnostic tests that would compete with our tests. Additionally, there have been recent proposals for additional changes to the patent laws of the United States and other countries that, if adopted, could impact our ability to enforce our proprietary technology. Depending on future actions by the U.S. Congress, U.S. courts, the USPTO and the relevant law-making bodies in other countries, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce our existing patents and patents that we might obtain in the future.

Changes to the patent laws in the United States and other jurisdictions could diminish the value of patents in general, thereby impairing our ability to protect our diagnostic tests.

Our success is heavily dependent on intellectual property, particularly patents. Obtaining and enforcing patents in the biopharmaceutical industry involves both technological and legal complexity and is costly, time-consuming and inherently uncertain. Patent reform legislation in the United States and other countries, including the Leahy-Smith America Invents Act, or the Leahy-Smith Act, signed into law in September 2011, could increase those uncertainties and costs. The Leahy-Smith Act includes a number of significant changes to U.S. patent law. These include provisions that affect the way patent applications are prosecuted, redefine prior art and provide more efficient and cost-effective avenues for competitors to challenge the validity of patents. In addition, the Leahy-Smith Act has transformed the U.S. patent system into a “first to file” system. The first-to-file provisions, however, only became effective in March 2013. Accordingly, it is not yet clear what, if any, impact the Leahy-Smith Act will have on the operation of our business. However, the Leahy-Smith Act and its implementation could make it more difficult to obtain patent protection for our inventions and increase the uncertainties and costs surrounding the prosecution of our or our collaboration partners’ patent applications and the enforcement or defense of our or our collaboration partners’ issued patents, all of which could harm our business, results of operations and financial condition.

Other companies or organizations may challenge our patent rights or may assert patent rights that prevent us from developing and commercializing our diagnostic tests.

Any patent applications that we file and any patents that we hold or later obtain could be challenged by third parties and declared invalid or infringing of third-party claims. A patent interference proceeding may be instituted with the USPTO when more than one person files a patent application covering the same technology, or if someone wishes to challenge the validity of an issued patent filed before March 16, 2013. At the completion of the interference proceeding, the USPTO will determine which competing applicant is entitled to the patent, or whether an issued patent is valid. Patent interference proceedings are complex, highly contested legal proceedings, and the USPTO's decision is subject to appeal. This means that if an interference proceeding arises with respect to any of our patent applications, we may experience significant expenses and delay in obtaining a patent, and if the outcome of the proceeding is unfavorable to us, the patent could be issued to a competitor rather than to us. In addition to interference proceedings, the USPTO can review issued patents at the request of a third party seeking to have the patent invalidated. An *inter partes* review proceeding allows third parties to challenge the validity of an issued patent where there is a reasonable likelihood of invalidity. This means that patents owned or licensed by us may be subject to administrative review and may be lost if the outcome of the review is unfavorable to us.

Post Grant Review under the Leahy-Smith Act makes available opposition-like proceedings in the United States. As with the USPTO interference proceedings, Post Grant Review proceedings will be very expensive to contest and can result in significant delays in obtaining patent protection or can result in a denial of a patent application. Further, a derivation proceeding may be instituted by the USPTO or an inventor alleging that a patent or application was derived from the work of another inventor.

Oppositions to the issuance of patents may be filed under European patent law and the patent laws of certain other countries. As with the USPTO interference proceedings, these foreign proceedings can be very expensive to contest and can result in significant delays in obtaining a patent or can result in a denial of a patent application.

The enforcement of patent rights often requires litigation against third party infringers, and such litigation can be costly to pursue. Even if we succeed in having new patents issued or in defending any challenge to issued patents, our patents may not be comprehensive enough to provide us with meaningful patent protection against our competitors.

If we are unable to protect the confidentiality of our trade secrets, the value of our technology could be materially adversely affected, and our business would be harmed.

In addition to patents, we rely on trade secrets, know-how, and continuing technological advancement to maintain our competitive position. The molecular diagnostics that we are developing use gene expression classifiers or algorithms, which are mathematical models that weight the biomarkers to produce a score. We will treat the mathematical models as trade secrets. We have entered into intellectual property, invention, and non-disclosure agreements with our employees, and it is our practice to enter into confidentiality agreements with our consultants. These measures, however, may not prevent the unauthorized disclosure or use of our trade secrets and know-how, or that others may not independently develop similar trade secrets and know-how or obtain access to our trade secrets, know-how, or proprietary technology.

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

Competitors may infringe our patents, trademarks, copyrights or other intellectual property. To counter infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time-consuming and divert the time and attention of our management and scientific personnel. Any claims we assert against perceived infringers could provoke these parties to assert counterclaims against us alleging that we infringe their patents, in addition to counterclaims asserting that our patents are invalid or unenforceable, or both. In any patent infringement proceeding, a court may decide that a patent of ours is invalid or unenforceable, in whole or in part, and that we do not have the right to stop the other party from using the invention at issue. Even if the validity of such patents is upheld, the court may construe the patent's claims narrowly or decide that we do not have the right to stop the other party from using the invention at issue on the grounds that our patent claims do not cover the invention. An adverse outcome in a litigation or proceeding involving our patents could limit our ability to assert our patents against those parties or other competitors, and may curtail or preclude our ability to exclude third parties from making and selling similar or competitive products. Any of these occurrences could adversely affect our competitive business position, business prospects and financial condition. Similarly, if we assert trademark infringement claims, a court may determine that the marks we have asserted are invalid or unenforceable, or that the party against whom we have asserted trademark infringement has superior rights to the marks in question, in which case, we could ultimately be forced to cease use of such trademarks.

Even if we establish infringement, the court may decide not to grant an injunction against further infringing activity and instead award only monetary damages, which may or may not be an adequate remedy. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, some of our confidential information could be compromised by disclosure during litigation. There could also be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a material adverse effect on the price of shares of our common stock. Moreover, we may not have sufficient financial or other resources to file and pursue such infringement claims, which typically last for years before they are concluded. Even if we ultimately prevail in such claims, the monetary cost of such litigation and the diversion of the attention of our management and scientific personnel could outweigh any benefit we receive as a result of the proceedings.

We may not be able to enforce our intellectual property rights throughout the world.

Filing, prosecuting and defending patents, if issued, on our diagnostic test candidate in all countries throughout the world would be prohibitively expensive. The requirements for patentability may differ in certain countries, particularly in developing countries. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and, further, may export otherwise infringing products to territories where we may obtain patent protection, but where patent enforcement is not as strong as that in the United States. These products may compete with our diagnostic tests in jurisdictions where we do not have any issued or licensed patents or where any future patent claims or other intellectual property rights may not be effective or sufficient to prevent them from competing with us.

Moreover, our ability to protect and enforce our intellectual property rights may be adversely affected by unforeseen changes in foreign intellectual property laws. Additionally, laws of some countries outside of the United States and Europe do not afford intellectual property protection to the same extent as the laws of the United States and Europe. Many companies have encountered significant problems in protecting and defending intellectual property rights in certain foreign jurisdictions. The legal systems of some countries, including India, China and certain developing countries, do not favor the enforcement of patents and other intellectual property rights. This could make it difficult for us to stop the infringement of our patents or the misappropriation of our other intellectual property rights. For example, many foreign countries have compulsory licensing laws under which a patent owner must grant licenses to third parties. Consequently, we may not be able to prevent third parties from practicing our inventions in certain countries outside the United States and Europe. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and, further, may export otherwise infringing products to territories where we have patent protection, if our ability to enforce our patents to stop infringing activities is inadequate. These products may compete with our diagnostic test, and our patents, if issued, or other intellectual property rights may not be effective or sufficient to prevent them from competing.

Proceedings to enforce our patent rights in foreign jurisdictions, whether or not successful, could result in substantial costs and divert our efforts and resources from other aspects of our business. Furthermore, while we intend to protect our intellectual property rights in major markets for our diagnostic test, we cannot ensure that we will be able to initiate or maintain similar efforts in all jurisdictions in which we may wish to market our diagnostic tests. Accordingly, our efforts to protect our intellectual property rights in such countries may be inadequate.

If we are sued for infringing intellectual property rights of third parties, such litigation could be costly and time consuming and could prevent or delay us from developing or commercializing our diagnostic tests.

There is a substantial amount of intellectual property litigation in the biotechnology and pharmaceutical industries, and we may become party to, or threatened with, litigation or other adversarial proceedings regarding intellectual property rights with respect to our current or future diagnostic test, including interference proceedings before the USPTO, misappropriation claims, or other allegations. The outcome of intellectual property litigation is subject to uncertainties that cannot be adequately quantified in advance. For example, the biotechnology and pharmaceutical industries have produced a significant number of patents, and it may not always be clear to industry participants, including us, which patents cover various types of products or methods of use. The coverage of patents is subject to interpretation by the courts, and the interpretation is not always uniform. If we were sued for patent infringement, we would need to demonstrate that our diagnostic tests or methods either do not infringe the patent claims of the relevant patent or that the patent claims are invalid or unenforceable, and we may not be able to do this. Proving invalidity is difficult. For example, in the United States, proving invalidity requires a showing of clear and convincing evidence to overcome the presumption of validity enjoyed by issued patents.

In addition, several of our employees have executed proprietary rights, non-disclosure and non-competition agreements, or similar agreements with their previous employers, who may allege these employees have used or disclosed intellectual property, including trade secrets or other proprietary information. Even if we are successful in these proceedings, we may incur substantial costs, and the time and attention of our management and scientific personnel could be diverted in pursuing these proceedings, which could significantly harm our business and operating results. We may also not have sufficient resources to bring these actions to a successful conclusion.

If we are found to infringe a third party's intellectual property rights, we may have to pay monetary damages, lose valuable intellectual property rights or personnel, or be forced to cease developing, manufacturing or commercializing the infringing diagnostic test. Alternatively, we may be required to obtain a license from such third party in order to use the infringing technology and continue developing, manufacturing or marketing the infringing diagnostic test. However, we may not be able to obtain any required license on commercially reasonable terms or at all. Even if we were able to obtain a license, it could be non-exclusive, thereby giving our competitors access to the same technologies licensed to us. In addition, we could be found liable for monetary damages, including treble damages and attorneys' fees if we are found to have willfully infringed a patent. A finding of infringement could prevent us from commercializing our diagnostic tests or force us to cease some of our business operations, which could materially harm our business. Claims that we have misappropriated the confidential information or trade secrets of third parties could have a similar negative impact on our business.

Patent terms may be inadequate to protect our competitive position on our diagnostic tests for an adequate amount of time.

Given the amount of time required for the development, testing and regulatory review of new diagnostic tests, patents protecting such candidates might expire before or shortly after such candidates are commercialized. We expect to seek extensions of patent terms in the United States and, if available, in other countries where we are prosecuting patents. In the United States, the Drug Price Competition and Patent Term Restoration Act of 1984 permits a patent term extension of up to five years beyond the normal expiration of the patent, which is limited to the approved indication or any additional indications approved during the period of extension. However, the applicable authorities, including the FDA and the USPTO in the United States, and any equivalent regulatory authorities in other countries, may not agree with our assessment of whether such extensions are available, and may refuse to grant extensions to our patents, or may grant more limited extensions than we request. If this occurs, our competitors may be able to take advantage of our investment in development and clinical trials by referencing our clinical and preclinical data and launch their product earlier than might otherwise be the case.

Risks Related to the Covid-19 Pandemic

The recent COVID-19 global pandemic and the worldwide attempts to contain it could harm our business and our results of operations and financial condition could be adversely impacted by such pandemic.

The recent global outbreak of the coronavirus COVID-19, and the various attempts throughout the world to contain it, have created significant volatility, uncertainty and disruption. The COVID-19 pandemic has had, and actions taken in response thereto may continue to have, significant effects on our operations, ability to generate revenues, and financing activities. In response to government directives and guidelines, health care advisories and employee and other concerns, we have altered certain aspects of our operations. A number of our employees have had to work remotely from home and those on site have had to follow our social distance guidelines, which could impact their productivity.

The pandemic is affecting our revenue-generating activities. During the COVID-19 pandemic, we have not been able, and may continue to not be able, to maintain our preferred level of physician or customer outreach and marketing of our diagnostic testing and Pharma Services, which may have negatively impacted, and may continue to negatively impact, our potential new customers' interest in our tests and services. Because of COVID-19, travel, visits, and in-person meetings related to our business have been severely curtailed or canceled and we have instead used on-line or virtual meetings to meet with potential customers and others.

The consequences of the COVID-19 pandemic have led to uncertainties related to our business growth and our ability to forecast the demand for our diagnostic testing and Pharma Services and resulting revenues. Although we have experienced limited COVID-19 related supply chain disruptions which to date did not impact our testing capacity, if the vendors of equipment and reagents used in our diagnostic laboratories experience supply, operational, or financial disruptions due to the COVID-19 pandemic, we could experience supply constraints in the future that could cause increased costs or delays in performing Pharma Services and in continuing the development of our diagnostic tests, including DetermaIO, DetermaCNI and VitaGraft.

Additionally, the continuing economic consequences of the COVID-19 pandemic have adversely impacted, and may continue to, adversely impact financial markets, resulting in high share price volatility, reduced market liquidity, and substantial declines in the market prices of the securities of some publicly traded companies. Volatile or declining markets for equities could adversely affect our ability to raise capital when needed through the sale of shares of common stock or other securities. Accordingly, we cannot assure that adequate financing will be available on favorable terms, if at all. If we are not able to raise the capital we need, we could be forced to modify, curtail, delay, or suspend some or all aspects of planned operations. Sales of additional equity securities could result in significant dilution of the interests of our shareholders.

It is possible that impacts of COVID-19 on Oncocyte's operations or revenues or its access to capital could prevent Oncocyte from complying, or could result in a material noncompliance, with one or more obligations or covenants under material agreements to which Oncocyte is a party, with the result that Oncocyte would be in material breach of the applicable obligation, covenant, or agreement. Any such material breach could cause Oncocyte to incur material financial liabilities or an acceleration of the date for paying a financial obligation to the other party to the applicable agreement, or could cause Oncocyte to lose material contractual rights, such as rights to use leased equipment or laboratory or office space, or rights to use licensed patents or other intellectual property the use of which is material to Oncocyte's business. Similarly, it is possible that impacts of COVID-19 on the business, operations, or financial condition of any third party with whom Oncocyte has a contractual relationship could cause the third party to be unable to perform its contractual obligations to Oncocyte, resulting in Oncocyte's loss of the benefits of a contract that could be material to Oncocyte's business.

The full extent to which the COVID-19 pandemic and the various responses might impact our business, operations and financial results will depend on numerous evolving factors that we will not be able to accurately predict, including: the development and spread of new strains, such as Delta and Omicron; governmental, business and individuals' actions that have been and continue to be taken in response to the pandemic; the difficulty or delay in clinical site initiation; the diversion of healthcare resources away from the conduct of clinical trials; delays or difficulties in enrolling patients in clinical trials; interruption of key clinical trial activities; interruption or delays in the operations of regulatory agencies, which may impact review and approval times; the availability and cost to access COVID-19 tests, vaccines and therapies; the effect on our potential customers and their demand for our diagnostic testing and Pharma Services; the effects on delays in development programs; and the effect on our suppliers and their ability to provide the necessary equipment and materials to support our tests and services and the general global supply chain disruptions that may have lasting impacts and consequences that are difficult to predict. In addition to the direct impacts to our business operations, the global economy is likely to continue to be significantly weakened as a result of actions taken in response to the COVID-19 pandemic and to the extent that such a weakened global economy impacts customers' ability or willingness to purchase and pay for our tests, our business and results of operation could be negatively impacted. Due to the uncertain scope and duration of the COVID-19 pandemic and uncertain timing of any recovery or normalization, we are currently unable to estimate the resulting impacts on our operations and financial results. We will continue to actively monitor the issues raised by the COVID-19 pandemic and may take further actions that alter our operations, as may be required by federal, state, local or foreign authorities, or that we determine are in the best interests of our employees, any customers and stockholders. It is not clear what the potential effects any such alterations or modifications may have on our business, including the effects on our financial results.

The COVID-19 pandemic has affected and continues to affect our ability to conduct clinical trial activities, causing delays in clinical site initiations and patient screening and enrollment in our clinical trials, and may delay and disrupt regulatory activities and our manufacturing and supply chain and have other adverse effects on our business and operations.

Like many other biopharmaceutical and diagnostic companies, we have experienced and continue to experience delays in clinical site initiations, as well as patient screening and enrollment in our clinical trials due to the COVID-19 pandemic. At the beginning of 2020, the pace of site opening and patient screening and enrollment was in line with our expectations. However, in the spring of 2020, the COVID-19 pandemic began to rapidly affect clinical trial sites around the world. The delays continued throughout 2021 due to new variant surges in the US and EU where all of our trials are executed. Many of our clinical sites established self-imposed holds on site initiations and enrollment during this period out of concern for patient exposure to COVID-19 and due to lack of available staff. As a result, we experienced significant delays in site initiations, as well as patient screening and enrollment. During the summer of 2020, as the number of COVID-19 cases declined due to public health safety measures, some clinical sites removed their self-imposed holds on site initiations and enrollment, which improved the momentum of patient enrollment. However, beginning in November 2020, another steep rise in COVID-19 cases again negatively impacted the pace of enrollment. The emergence of COVID-19 variants also continued throughout 2021, causing further unpredictability and uncertainty about the pace at which patients and healthcare workers would be able to return to clinical sites.

Since vaccine distribution has commenced in many countries, and we have begun to see the number of COVID-19 cases declining, we currently believe our clinical trial operations may normalize over the next several months. However, the pace at which any normalization may occur remains uncertain and unpredictable. Given the above factors, we expect there may continue to be delays in our clinical trials, in addition to delays and disruptions in regulatory activities as well as delays in manufacturing and supply chain that may continue to have adverse effects on our business.

Risks Related to Our Common Stock

Ownership of our common stock will entail certain risks associated with the limited history of the trading of our common stock, volatility of prices for our shares, and the fact that we do not pay dividends.

We have identified a material weakness in our internal control over financial reporting. If we are unable to remediate the material weakness and otherwise maintain an effective system of internal control over financial reporting, it could result in us not preventing or detecting on a timely basis a material misstatement of the Company's financial statements.

A material weakness is a deficiency, or combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of the company's annual or interim financial statements will not be prevented or detected on a timely basis. As further disclosed in "Item 9A. Controls and Procedures" of this Annual Report on Form 10-K, management had identified a material weakness specifically relating to deficiencies in its internal controls over the review process relating to third-party valuations. Outside of this subjective review process relating to valuations, no other deficiencies in internal controls were identified. The Company has taken actions to remediate the material weakness related to our internal control process of review contributing to financial reporting. We have made improvements to the design of the related controls, including standardized review procedures over third-party valuations. While these control deficiencies did not result in a misstatement to the consolidated financial statements, the material weakness could have resulted in a misstatement impacting account balances or disclosures that would have resulted in a material misstatement to the consolidated financial statements that would not have been prevented or detected on a timely basis.

Although we are implementing plans to remediate this material weakness, we cannot be certain of the success of the plans. If our remedial measures are insufficient to address the material weakness, or if one or more additional material weaknesses or significant deficiencies in our internal control over financial reporting are discovered or occur in the future, or our disclosure controls and procedures are again determined to be ineffective, we may not be able to prevent or identify irregularities or ensure the fair and accurate presentation of our financial statements included in our periodic reports filed with the U.S. Securities and Exchange Commission. Additionally, the occurrence of, or failure to remediate, a material weakness and any future material weaknesses in our internal control over financial reporting or determination that our disclosure controls and procedures are ineffective may have other consequences that could materially and adversely affect our business, including an adverse impact on the market price of our common stock, potential actions or investigations by the U.S. Securities and Exchange Commission or other regulatory authorities, shareholder lawsuits, a loss of investor confidence and damage to our reputation.

Our common stock may be delisted from The Nasdaq Capital Market which could negatively impact the price of our common stock, liquidity and our ability to access the capital markets.

Although our common stock is currently listed on The Nasdaq Capital Market, we may not be able to continue to meet the minimum listing requirements of The Nasdaq Capital Market or those of any other national exchange. On August 9, 2022, the Company received a letter (the "Nasdaq Notice") from The Nasdaq Stock Market LLC ("Nasdaq") indicating that Nasdaq has determined that the Company no longer meets the minimum bid price requirement of Nasdaq Listing Rule 5450(a)(1), as the minimum closing bid price for the Company's common stock was less than $1.00 for the previous 30 consecutive business days. The Notice provided that the Company may consider applying to transfer the listing of the Company's common stock to The Nasdaq Capital Market, subject to the Company submitting an online transfer application, paying the requisite fee, satisfying such market's continued listing requirement for the market value of publicly held shares and all other initial listing standards, with the exception of the bid price requirement, and providing written notice of its intention to cure the deficiency period during the additional compliance period. Following a transfer to The Nasdaq Capital Market, under Nasdaq Listing Rule 5810(c)(3)(A)(ii), the Company may be eligible for an additional 180 calendar day compliance period.

The Company applied on January 24, 2023 to transfer the listing of its common stock, no par value, from The Nasdaq Global Market to The Nasdaq Capital Market (the “Transfer”). Upon receiving confirmation that Nasdaq had approved the Transfer, the Company’s common stock began trading on The Nasdaq Capital Market effective with the open of trading on February 7, 2023. The Company’s common stock continues to trade under the symbol “OCX”. The Nasdaq Capital Market operates in substantially the same manner as The Nasdaq Global Market, with issuers listed on The Nasdaq Capital Market tier required to meet certain financial and corporate governance requirements to qualify for continued listing.

On February 7, 2023, the Company received confirmation that Nasdaq has determined that the Company is eligible for an additional 180-calendar day period to regain compliance by meeting the minimum bid price requirement. The minimum bid price requirement would be met if the Company's common stock has a minimum closing bid price of at least $1.00 per share for a minimum of 10 consecutive business days during the 180-calendar day period.

If we are unable to maintain listing on The Nasdaq Capital Market or if a liquid market for our common stock does not develop or is not sustained, our common stock may remain thinly traded. If, for any reason, Nasdaq should delist our securities from trading on its exchange and we are unable to obtain listing on another national securities exchange, a reduction in some or all of the following may occur, each of which could have a material adverse effect on our shareholders:

- The liquidity of our common stock;
- The market price of our common stock;
- Our ability to obtain financing for the continuation of our operations;
- The number of investors that will consider investing in our common stock;
- The number of market makers in our common stock;
- The availability of information concerning the trading prices and volume of our common stock; and
- The number of broker-dealers willing to execute trades in our common stock.

The price of our stock may rise and fall rapidly.

The market price of our common stock, like that of the shares of many biotechnology companies, may be highly volatile. The price of our common stock may rise or fall rapidly as a result of a number of factors, including:

- Sales or potential sales of substantial amounts of our common stock;
- Results of or delays in preclinical testing or clinical trials of our diagnostic test candidates;
- Announcements about us or about our competitors, including clinical trial results, regulatory approvals, new diagnostic test introductions and commercial results;
- The cost of our development programs;
- The success of competitive diagnostic tests or technologies;
- Litigation and other developments relating to our issued patents or patent applications or other proprietary rights or those of our competitors;
- Conditions in the diagnostic, pharmaceutical or biotechnology industries;
- Actual or anticipated changes in estimates as to financial results, development timelines or recommendations by securities analysts;
- Variations in our financial results or those of companies that are perceived to be similar to us, including the failure of our earnings to meet analysts' expectations;
- General economic, industry and market conditions; and
- Changes in payer coverage and or reimbursement.

Many of these factors are beyond our control. The stock markets in general, and the market for pharmaceutical and biotechnological companies in particular, have been experiencing extreme price and volume fluctuations which have affected the market price of the equity securities without regard to the operating performance of the issuing companies. Broad market fluctuations, as well as industry factors and general economic and political conditions, may adversely affect the market price of our common stock.

Because we do not pay dividends, our stock may not be a suitable investment for anyone who needs to earn dividend income.

We do not pay cash dividends on our common stock. For the foreseeable future we anticipate that any earnings generated in our business will be used to finance the growth of our business and will not be paid out as dividends to our shareholders.

Securities analysts may not initiate coverage or continue to cover our common stock, and this may have a negative impact on the market price of our shares.

The market for our common stock will depend, in part, on the research and reports that securities analysts publish about our business and our common stock. We do not have any control over these analysts. Certain securities analysts cover our shares and they could issue reports or recommendations that are unfavorable to the price of our shares, and they could downgrade a previously favorable report or recommendation, and in either case our share price could decline as a result of the report. If one or more of these analysts ceases to cover our shares or fails to publish regular reports on our business, we could lose visibility in the financial markets, which could cause our share price or trading volume to decline.

You may experience dilution of your ownership interests if we issue additional shares of common stock or preferred stock.

In the future, we may issue our authorized but previously unissued equity securities, resulting in the dilution of the ownership interests of our present shareholders. We are currently authorized to issue an aggregate of 235,000,000 shares of capital stock consisting of 230,000,000 shares of common stock and 5,000,000 “blank check” shares of preferred stock. At December 31, 2022, there were 118,643,821 shares of common stock outstanding, 16,395,343 shares of common stock reserved for exercise of warrants and 9,167,688 shares of common stock reserved for issuance upon the exercise of options under our employee stock option plans. No shares of preferred stock are presently outstanding.

We may issue additional common stock or other securities that are convertible into or exercisable for common stock in order to raise additional capital, or in connection with hiring or retaining employees, directors, or consultants, or in connection with future acquisitions of licenses to technology or diagnostic tests in connection with future business acquisitions, or for other business purposes. The future issuance of any such additional common stock or other securities may create downward pressure on the trading price of our common stock.

We may also issue preferred stock having rights, preferences, and privileges senior to the rights of our common stock with respect to dividends, rights to share in distributions of our assets if we liquidate our company, or voting rights. Any preferred stock may also be convertible into common stock on terms that would be dilutive to holders of common stock.

Our former parent company may sell its Oncocyte shares to raise capital to finance its operations.

Prior to February 17, 2017, Oncocyte was a consolidated subsidiary of its former parent company Lineage Cell Therapeutics, Inc., formerly known as BioTime, Inc. ("Lineage"). Based on its most recent report of beneficial ownership on Schedule 13D, as of January 8, 2021 Lineage held 3,297,401 shares of Oncocyte common stock. Lineage has been periodically selling shares of Oncocyte common stock from its holdings and has announced its intention to continue to sell Oncocyte shares. The sale of such shares could have a depressing effect on the market value of Oncocyte common stock and the prices at which we can sell our own shares of common stock to raise capital to support our operations.

Item 1B. Unresolved Staff Comments

Not applicable.

Item 2. Properties

Our principal executive and administrative offices are located in an office and laboratory facility of leased space in Irvine, California. The Irvine lease expires in September 2027.

We also operate a CLIA-certified laboratory in Nashville, Tennessee and sublease laboratory space in Brisbane, California. The lease of the Nashville, Tennessee CLIA laboratory space will expire in April 2024, and our subleased Brisbane CLIA laboratory space sublease will expire in March 2023.

Item 3. Legal Proceedings

From time to time, we may be involved in routine litigation incidental to the conduct of our business. We are not presently involved in any material litigation or proceedings.

Item 4. Mine Safety Disclosures

Not applicable

PART II

Item 5. Market for Registrant's Common Equity, Related Stockholder Matters, and Issuer Purchases of Equity Securities

Market Information

On February 7, 2023, our common stock began trading on The Nasdaq Capital Market under the symbol "OCX." Previously, as of March 8, 2021, our common stock was trading on The Nasdaq Global Market, and prior to that date, our common stock was traded on The New York Stock Exchange ("NYSE") American, both previously under the same symbol.

Dividends

We have not declared or paid any cash dividends on our common stock. Any future decision to declare or pay dividends will be at the sole discretion of our Board of Directors.

Holders

As of March 22, 2023, we had approximately 309 holders of record of our common stock. This number does not include shareholders whose shares of Oncocyte common stock are held in "street name" in accounts with securities broker-dealers or other financial institutions or fiduciaries.

Securities Authorized for Issuance under Equity Compensation Plans

The following table shows certain information concerning the options outstanding and available for issuance under all of our compensation plans and agreements as of December 31, 2022 (in thousands, except weighted average exercise price):

Plan Category	Number of Shares to be Issued upon Exercise of Outstanding Options, Warrants and Rights [1]	Weighted Average Exercise Price of the Outstanding Options, Warrants and Rights [1]	Number of Shares Remaining Available for Future Issuance under Equity Compensation Plans [2]
Oncocyte Stock Option Plans Approved by Shareholders	9,168	$ 2.96	10,804

(1) Includes both our 2010 Employee Stock Option Plan and our 2018 Equity Incentive Plan, as amended.

(2) All shares remaining available for future issuance are under our 2018 Equity Incentive Plan, as amended.

Additional information concerning our 2010 Employee Stock Option Plan and our 2018 Equity Incentive Plan (as amended), and stock options may be found in Note 6 to the consolidated financial statements found elsewhere in this Report.

Recent Sales of Unregistered Securities

None.

Repurchases

None.

Item 6. [RESERVED.]

Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations

The following Management's Discussion and Analysis of Financial Condition and Results of Operations is intended to provide information necessary to understand our audited consolidated financial statements for the years ended December 31, 2022 and 2021, and highlight certain other information which, in the opinion of management, will enhance a reader's understanding of our financial condition, changes in financial condition and results of operations. These historical consolidated financial statements may not be indicative of our future performance. This Management's Discussion and Analysis of Financial Condition and Results of Operations contains a number of forward-looking statements, all of which are based on our current expectations and could be affected by the uncertainties and risks described throughout this filing, particularly in "Risk Factors."

Management's Discussion and Analysis of Financial Condition and Results of Operations.

We are a precision diagnostics company focused on developing and commercializing proprietary tests in three areas: DetermaIO is a gene expression test that assesses the tumor microenvironment to predict response to immunotherapies, VitaGraft is a blood-based solid organ transplantation monitoring test and DetermaCNI is a blood-based monitoring tool for monitoring therapeutic efficacy in cancer patients.

We are currently developing DetermaIO, a test with promising data supporting its potential to help identify patients likely to respond to checkpoint inhibitor drugs. This new class of drugs modulate the immune response and show activity in multiple solid tumor types including non-small cell lung cancer (NSCLC), and triple negative breast cancer (TNBC). DetermaIO is presently available for research use through our Pharma Services operations but one of our goals is to complete development of that assay and to make it available for clinical use later this year. We also perform other assay development and clinical testing services for pharmaceutical and biotechnology companies through our Pharma Services operations.

We have added to our diagnostic test pipeline VitaGraft, a blood-based solid organ transplantation monitoring test, and DetermaCNI, a patented, blood-based test from Chronix for immunotherapy monitoring.

The inherent uncertainties of developing and commercializing new diagnostic tests for medical use make it impossible to predict the amount of time and expense that will be required to complete the development and commercialization of those tests. There is no assurance that we will be successful in developing new technology or diagnostic tests, or that any technology or diagnostic tests that we may develop will be proven safe and effective in diagnosis of cancer in humans or will be successfully commercialized.

We believe we have sufficient cash, cash equivalents, and marketable equity securities to carry out our current operations through at least twelve months from the issuance date of our consolidated financial statements included elsewhere in this Report. We expect that our operating expenses will continue to increase if we successfully complete the development of DetermaIO and commercialize this test. We have hired a sales and marketing team. We also acquired a laboratory in Germany through our completed merger with Chronix and we will incur additional expenses resulting from our continued investment in Chronix. We are continuing to seek other opportunities to acquire ownership of or marketing rights to additional cancer tests. Because of the expected time frame to apply for and receive Medicare reimbursement approval for our tests, our pre-Medicare approval revenues from commercialization of our tests and revenues from services we perform for pharmaceutical companies are not expected to cover our operating expenses. We will need to obtain additional financing for our operations until such time as we generate sufficient revenues from the commercialization of our tests to cover our operating expenses. Our determination as to when we will seek new financing and the amount of financing that we will need will be based on our evaluation of the progress we make in our research and development programs, any changes to or the expansion of the scope and focus of our research, progress and results of commercializing our tests after completion of development, progress in receiving Medicare and other payor reimbursement approval, and our projection of future costs. See "Liquidity and Capital Resources" for a discussion of our available capital resources, our need for future financing, and possible sources of capital.

Recent Developments

Nasdaq Notice

On August 9, 2022, the Company received the Nasdaq Notice indicating that Nasdaq has determined that the Company no longer meets the minimum bid price requirement of Nasdaq Listing Rule 5450(a)(1), as the minimum closing bid price for the Company's common stock was less than $1.00 for the previous 30 consecutive business days. The Notice provided that the Company may consider applying to transfer the listing of the Company's common stock to The Nasdaq Capital Market, subject to the Company submitting an online transfer application, paying the requisite fee, satisfying such market's continued listing requirement for the market value of publicly held shares and all other initial listing standards, with the exception of the bid price requirement, and providing written notice of its intention to cure the deficiency period during the additional compliance period. Following a transfer to The Nasdaq Capital Market, under Nasdaq Listing Rule 5810(c)(3)(A)(ii), the Company may be eligible for an additional 180 calendar day compliance period.

The Company applied on January 24, 2023 to transfer the listing of its common stock, no par value, from The Nasdaq Global Market to The Nasdaq Capital Market. Upon receiving confirmation that Nasdaq had approved the Transfer, the Company's common stock began trading on The Nasdaq Capital Market effective with the open of trading on February 7, 2023. The Company's common stock continues to trade under the symbol "OCX". The Nasdaq Capital Market operates in substantially the same manner as The Nasdaq Global Market, with issuers listed on The Nasdaq Capital Market tier required to meet certain financial and corporate governance requirements to qualify for continued listing.

On February 7, 2023, the Company received confirmation that Nasdaq has determined that the Company is eligible for an additional 180-calendar day period to regain compliance by meeting the minimum bid price requirement. The minimum bid price requirement would be met if the Company's common stock has a minimum closing bid price of at least $1.00 per share for a minimum of 10 consecutive business days during the 180-calendar day period.

Workforce Reduction Plan

In August 2022, the Company initiated a workforce reduction plan to strategically realign its operations and implement cost reduction programs to prioritize near term revenue generators and to manage and preserve cash. In connection with the reduction, the Company eliminated 14 positions, implemented tighter expense controls, and ceased non-core activities.

Further, on December 16, 2022, Oncocyte initiated an additional reduction in work force involving over 40% of its full-time employees. The transition began on December 16, 2022 and was completed in February 2023. As of December 31, 2022, the Company incurred an aggregate of $1.9 million related to employee severance and benefits costs in connection with its reductions in force during fiscal year 2022.

Razor Genomics Purchase Agreement

On December 15, 2022, Oncocyte Corporation, a California corporation ("Oncocyte" or the "Company"), entered into a Stock Purchase Agreement (the "Razor Stock Purchase Agreement") with Dragon Scientific, LLC, a Delaware limited liability company ("Dragon"), and Razor Genomics Inc., a Delaware corporation and wholly-owned subsidiary of Oncocyte ("Razor"). Pursuant to the Razor Stock Purchase Agreement Oncocyte agreed to sell to Dragon, 3,188,181 shares of common stock of Razor, which constitutes approximately 70% of the issued and outstanding equity interests of Razor on a fully-diluted basis, and transfer to Razor all of the assets and liabilities related to DetermaRx (the "Razor Sale Transaction"). The Razor Stock Purchase Agreement provides that following the closing of the transaction (the "Razor Closing"), Oncocyte will own 1,366,364 shares of common stock of Razor, which will constitute approximately 30% of the issued and outstanding equity interests of Razor on a fully-diluted basis. On February 16, 2023, Oncocyte completed the Razor Sale Transaction.

While no monetary consideration was received for the sale of 70% of the equity interests of Razor, the transaction allows the Company to eliminate all development and commercialization costs with respect to DetermaRx. Following the Razor Closing, Oncocyte continues to own 1,366,364 shares of common stock of Razor.

Critical Accounting Estimates

The preparation of financial statements in conformity with accounting principles generally accepted in the United States ("GAAP"), requires management to make estimates and assumptions that affect the reported amounts in our consolidated financial statements and related notes. Our significant accounting policies are described in Note 2 to our consolidated financial statements included elsewhere in this Report. We have identified below our critical accounting policies and estimates that we believe require the greatest amount of judgment. On an ongoing basis, we evaluate estimates which are subject to significant judgment, including those related to the going concern assessments of our consolidated financial statements, revenue recognition, allowance for doubtful accounts, business combination valuation, contingent consideration valuation, allocation of direct and indirect expenses, useful lives associated with long-lived intangible assets, machinery and equipment, loss contingencies, valuation allowances related to deferred income taxes, and assumptions used to value stock-based awards, debt or other equity instruments. Actual results could differ materially from those estimates. On an ongoing basis, we evaluate our estimates compared to historical experience and trends, which form the basis for making judgments about the carrying value of assets and liabilities. To the extent that there are material differences between our estimates and our actual results, our future financial statement presentation, financial condition, results of operations and cash flows will be affected.

We believe the assumptions and estimates associated with the following have the greatest potential impact on our consolidated financial statements.

Assets held for sale and discontinued operations

Assets classified as held for sale are reported at the lower of their carrying value or fair value less costs to sell. Depreciation and amortization of assets ceases upon designation as held for sale. Discontinued operations comprise activities that were disposed of, discontinued or held for sale at the end of the period, represent a separate major line of business that can be clearly distinguished for operational and financial reporting purposes and represent a strategic business shift having a major effect on the Company's operations and financial results according to Accounting Standard Codification ("ASC") Topic 205, *Presentation of Financial Statements*. We have included all of our revenues and expenses for Razor Genomics, Inc. as discontinued operations and all assets and liabilities as held for sale.

Going concern assessment

With the implementation of FASB's standard on going concern, ASU No. 2014-15, we assess going concern uncertainty in our consolidated financial statements to determine if we have sufficient cash and cash equivalents on hand and working capital, including available loans or lines of credit, if any, to operate for a period of at least one year from the date our consolidated financial statements are issued, which is referred to as the "look-forward period" as defined by ASU No. 2014-15. As part of this assessment, based on conditions that are known and reasonably knowable to us, we consider various scenarios, forecasts, projections, and estimates, and we make certain key assumptions, including the timing and nature of projected cash expenditures or programs, and our ability to delay or curtail those expenditures or programs, if necessary, among other factors. Based on this assessment, as necessary or applicable, we make certain assumptions around implementing curtailments or delays in the nature and timing of programs and expenditures to the extent we deem probable those implementations can be achieved and we have the proper authority to execute them within the look-forward period in accordance with ASU No. 2014-15.

Business combinations

We account for business combinations in accordance with Accounting Standards Codification ("ASC") Topic 805, *Business Combinations*, which requires the purchase price to be measured at fair value. When the purchase consideration consists, in part or entirely of our common shares, we calculate the purchase price by determining the fair value, as of the acquisition date, of shares issued in connection with the closing of the acquisition. We recognize estimated fair values of the tangible assets and intangible assets acquired, including in-process research and development ("IPR&D"), and liabilities assumed as of the acquisition date, and we record as goodwill any amount of the fair value of the tangible and intangible assets acquired and liabilities assumed in excess of the purchase price.

Contingent consideration liabilities

ASC 805 requires that contingent consideration be estimated and recorded at fair value as of the acquisition date as part of the total consideration transferred. Contingent consideration is an obligation of the acquirer to transfer additional assets or equity interests to the selling shareholders in the future if certain future events occur or conditions are met, such as the attainment of product development milestones. Contingent consideration also includes additional future payments to selling shareholders based on achievement of components of earnings, such as "earn-out" provisions or percentage of future revenues, including royalties paid to the selling shareholders based on a percentage of revenues generated over their respective useful life.

The fair value of milestone-based contingent consideration was determined using a scenario analysis valuation method which incorporates our assumptions with respect to the likelihood of achievement of the milestones, as defined in the merger agreements, credit risk, timing of the contingent consideration payments and a risk-adjusted discount rate to estimate the present value of the expected payments, all of which require significant management judgment and assumptions. Since the contingent consideration payments are based on nonfinancial, binary events, management believes the use of the scenario analysis method is appropriate.

The fair value of royalty or revenue share-based contingent consideration was determined using a single scenario analysis method to value those payments. The single scenario method incorporates our assumptions with respect to specified future revenues generated over their respective useful lives, credit risk, and a risk-adjusted discount rate to estimate the present value of the expected royalty payments, all of which require significant management judgment and assumptions. Since the royalty-based contingent consideration payments are based on future revenues and linear payouts, management believes the use of the single scenario method is appropriate.

The fair value of all contingent consideration after the acquisition date is reassessed by us as changes in circumstances and conditions occur, with the subsequent change in fair value recorded in our consolidated statements of operations. Changes in key assumptions can materially affect the estimated fair value of contingent consideration liabilities and, accordingly, the resulting gain or loss that we record in our consolidated financial statements. See Note 3 to our consolidated financial statements included elsewhere in this Report.

Goodwill and intangible assets

In accordance with ASC 350, *Intangibles – Goodwill and Other*, IPR&D projects acquired in a business combination that are not complete as of the acquisition date are capitalized and accounted for as indefinite-lived intangible assets until completion or abandonment of the related research and development efforts. Upon successful completion of the project, the capitalized amount is amortized over its estimated useful life. If a project is abandoned, all remaining capitalized amounts are written off immediately. We consider various factors and risks for potential impairment of IPR&D assets, including the current legal and regulatory environment, uncertainties posed by the recent COVID-19 pandemic and the competitive landscape. Adverse clinical trial results, significant delays or inability to obtain local determination coverage (“LCD”) from the Centers for Medicare and Medicaid Services (“CMS”) for Medicare reimbursement for a diagnostic test, the inability to bring a diagnostic test to market and the introduction or advancement of competitors’ diagnostic tests could result in partial or full impairment of the related intangible assets. Consequently, the eventual realized value of the IPR&D project may vary from its fair value at the date of acquisition, and IPR&D impairment charges may occur in future periods. During the period between completion or abandonment, the IPR&D assets will not be amortized but will be tested for impairment on an annual basis and between annual tests if we become aware of any events occurring or changes in circumstances that would indicate a reduction in the fair value of the IPR&D projects below their respective carrying amounts.

Goodwill represents the excess of the purchase price over the fair value of net identifiable assets and liabilities. Goodwill, similar to IPR&D, is not amortized but is tested for impairment at least annually, or if circumstances indicate its value may no longer be recoverable. Qualitative factors considered in this assessment include industry and market conditions, overall financial performance, and other relevant events and factors affecting our business. Based on the qualitative assessment, if it is determined that the fair value of goodwill is more likely than not to be less than its carrying amount, the fair value of a reporting unit will be calculated and compared with its carrying amount and an impairment charge will be recognized for the amount that the carrying value exceeds the fair value. We continue to operate in one segment and considered to be the sole reporting unit and, therefore, goodwill is tested for impairment at the enterprise level.

Goodwill is not amortized but instead qualitatively or quantitively tested for impairment at least annually should an event or circumstances indicate that a reduction in fair value of the reporting unit may have occurred during the year, goodwill would also be tested at such occasion. We perform the goodwill test at the reporting unit level. If necessary, the goodwill quantitative impairment test is performed on October 1 every year.

We use a two-step process to assess the realizability of goodwill. The first step (generally referred to as a “step 0” analysis) is a qualitative assessment that analyzes current economic indicators associated with a particular reporting unit. For example, we analyze changes in economic, market and industry conditions, business strategy, cost factors, and financial performance, among others, to determine if there are indicators of a significant decline in the fair value of a particular reporting unit. If the qualitative assessment indicates a stable or improved fair value, no further testing is required. If a qualitative assessment indicates it is more likely than not that the fair value of a reporting unit is less than its carrying amount, we will proceed to the quantitative second step (generally referred to as a “step 1” analysis) where the fair value of a reporting unit is calculated based on weighted income and market-based approaches. If the fair value of a reporting unit is lower than its carrying value, an impairment to goodwill is recorded, not to exceed the carrying amount of goodwill in the reporting unit.

Step 1 of the quantitative test requires comparison of the fair value of each of the reporting units to the respective carrying value. If the carrying value of the reporting unit is less than the fair value, no impairment exists. Otherwise, we would recognize an impairment charge for the amount by which the carrying amount of a reporting unit exceeds its fair value up to the amount of goodwill allocated to that reporting unit.

Accounting for warrants

We determine the accounting classification of warrants we issue, as either liability or equity classified, by first assessing whether the warrants meet liability classification in accordance with ASC 480-10, *Accounting for Certain Financial Instruments with*

Characteristics of both Liabilities and Equity, then in accordance with ASC 815-40, *Accounting for Derivative Financial Instruments Indexed to, and Potentially Settled in, a Company's Own Stock*. Under ASC 480, warrants are considered liability classified if the warrants are mandatorily redeemable, obligate us to settle the warrants or the underlying shares by paying cash or other assets, and warrants that must or may require settlement by issuing variable number of shares. If warrants do not meet the liability classification under ASC 480-10, we assess the requirements under ASC 815-40, which states that contracts that require or may require the issuer to settle the contract for cash are liabilities recorded at fair value, irrespective of the likelihood of the transaction occurring that triggers the net cash settlement feature. If the warrants do not require liability classification under ASC 815-40, in order to conclude equity classification, we also assess whether the warrants are indexed to our common stock and whether the warrants are classified as equity under ASC 815-40 or other GAAP. After all such assessments, we conclude whether the warrants are classified as liability or equity. Liability classified warrants require fair value accounting at issuance and subsequent to initial issuance with all changes in fair value after the issuance date recorded in the statements of operations. Equity classified warrants only require fair value accounting at issuance with no changes recognized subsequent to the issuance date. We do not have any liability classified warrants as of any period presented. See Note 5 to our consolidated financial statements included elsewhere in this Report.

Stock-based compensation

We recognize compensation expense related to share-based payments in accordance with ASC 718, *Compensation - Stock Compensation* ("ASC 718"), which requires the measurement and recognition of compensation expense for share-based payment awards made to directors and employees based on estimated fair values. We estimate the fair value of employee stock-based payment awards on the grant-date and recognize the resulting fair value over the requisite service period on a straight-line basis. For stock-based awards that vest only upon the attainment of one or more performance goals, compensation cost is recognized if and when we determine that it is probable that the performance condition or conditions will be, or have been, achieved. We utilize the Black-Scholes option pricing model for determining the fair value of stock options. Our determination of fair value of share-based payment awards on the date of grant using an option-pricing model is affected by our stock price as well as assumptions regarding a number of complex and subjective variables. These variables include, but are not limited to, expected stock price volatility over the term of the awards, and actual and projected employee stock option exercise behaviors. For the years ended December 31, 2022 and 2021, we estimated the expected volatility using our own stock price volatility to the extent applicable or a combination of our stock price volatility and the stock price volatility of stock of peer companies, for a period equal to the expected term of the options. The expected term of options granted is based on our own experience and, in part, based upon the "simplified method" provided under *Staff Accounting Bulletin, Topic 14*, or SAB Topic 14, as necessary. The risk-free rate is based on the U.S. Treasury rates in effect during the corresponding period of grant. Although the fair value of employee stock options is determined in accordance with FASB guidance, the key inputs and assumptions may change as we develop our own company estimates, experience and key inputs including our expected term, and stock price volatility based on the trading history of our stock in the public market. Changes in these subjective assumptions can materially affect the estimated value of equity grants and the stock-based compensation that we record in our consolidated financial statements.

Leases

We account for leases in accordance with ASC 842, *Leases*. We determine if an arrangement is a lease at inception. Leases are classified as either financing or operating, with classification affecting the pattern of expense recognition in the consolidated statements of operations. Under the available practical expedients for the adoption of ASC 842, we account for the lease and non-lease components as a single lease component. We recognize right-of-use ("ROU") assets and lease liabilities for leases with terms greater than twelve months in the consolidated balance sheet. ROU assets represent the right to use an underlying asset during the lease term and lease liabilities represent the obligation to make lease payments arising from the lease. Operating lease ROU assets and liabilities are recognized at commencement date based on the present value of lease payments over the lease term. As most leases do not provide an implicit rate, we use an incremental borrowing rate based on the information available at commencement date in determining the present value of lease payments. We use the implicit rate when it is readily determinable. The operating lease ROU asset also includes any lease payments made and excludes lease incentives. Lease terms may include options to extend or terminate the lease when it is reasonably certain that we will exercise that option. Lease expense for lease payments is recognized on a straight-line basis over the lease term. Operating leases are included as right-of-use assets in machinery and equipment, and ROU lease liabilities, current and long-term, in the consolidated balance sheets. Financing leases are included in machinery and equipment, and in financing lease liabilities, current and long-term, in the consolidated balance sheets. We disclose the amortization of our ROU assets and operating lease payments as a net amount, "Amortization of right-of-use assets and liabilities", on the consolidated statements of cash flows.

During the years ended December 31, 2022 and 2021, we entered into various operating leases in accordance with ASC 842 discussed in Notes 9 and 10 to the consolidated financial statements included elsewhere in this Report. Our accounting for financing leases (previously referred to as “capital leases”) remained substantially unchanged.

Impairment of long-lived assets

We assess the impairment of long-lived assets, which consists primarily of long-lived intangible assets, machinery and equipment, whenever events or changes in circumstances indicate that such assets might be impaired and the carrying value may not be recoverable. If events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable and the expected undiscounted future cash flows attributable to the asset are less than the carrying amount of the asset, an impairment loss equal to the excess of the asset’s carrying value over its fair value is recorded.

Certain events or changes in circumstances may indicate that the recoverability of the carrying amount of long lived assets should be assessed. When such events or changes in circumstances are present, we estimate the future cash flows expected to result from the use of the asset (or asset group) and its eventual disposition. If the sum of the expected undiscounted future cash flows is less than the carrying amount, we recognize an impairment based on the fair value of such assets.

Income taxes

We account for income taxes in accordance with ASC 740, *Income Taxes*, which prescribes the use of the asset and liability method, whereby deferred tax asset or liability account balances are calculated at the balance sheet date using current tax laws and rates in effect. Valuation allowances are established when necessary to reduce deferred tax assets when it is more likely than not that a portion or all of the deferred tax assets will not be realized. Our judgments regarding future taxable income may change over time due to changes in market conditions, changes in tax laws, tax planning strategies or other factors. If our assumptions and consequently our estimates change in the future, the valuation allowance may be increased or decreased, which may have a material impact on our statements of operations.

The guidance also prescribes a recognition threshold and a measurement attribute for the financial statement recognition and measurement of tax positions taken or expected to be taken in a tax return. For those benefits to be recognized, a tax position must be more-likely-than-not sustainable upon examination by taxing authorities. We will recognize accrued interest and penalties, if any, related to unrecognized tax benefits as income tax expense. No amounts were accrued for the payment of interest and penalties as of the financial statement periods presented herein. We account for uncertain tax positions by assessing all material positions taken in any assessment or challenge by relevant taxing authorities. We are currently unaware of any tax issues under review. See Note 8 to our consolidated financial statements included elsewhere in this Report.

Revenue recognition

Effective on January 1, 2021, we adopted the revenue recognition standard ASC Topic 606, *Revenue from Contracts with Customers* (ASC) 606. Pursuant to ASC 606, revenues are recognized when control of services performed is transferred to customers, in an amount that reflects the consideration we expect to be entitled to in exchange for those services. ASC 606 provides for a five-step model that includes:

(i) identifying the contract with a customer,
(ii) identifying the performance obligations in the contract,
(iii) determining the transaction price,
(iv) allocating the transaction price to the performance obligations, and
(v) recognizing revenue when, or as, an entity satisfies a performance obligation.

DetermaRx testing revenue

As of December 31, 2022, Oncocyte performed tests on clinical samples through orders received from physicians, hospitals, and other healthcare providers. In determining whether all the revenue recognition criteria (i) through (v) above are met with respect to DetermaRx tests, each test result is considered a single performance obligation and is generally considered complete when the test result is delivered or made available to the prescribing physician electronically, and, as such, there are no shipping or handling fees incurred by Oncocyte or billed to customers. Although Oncocyte bills a list price for all tests ordered and completed for all payer types, Oncocyte considers constraints on the variable consideration when recognizing revenue for DetermaRx. Because DetermaRx is a novel test and there are no current reimbursement arrangements with third-party payers other than Medicare, the transaction price represents variable consideration. Application of the constraint for variable consideration is an area that requires significant judgment. For all payers other than Medicare and payers subscribed to Medicare Advantage, Oncocyte must consider the novelty of the test, the uncertainty of receiving payment, or being subject to claims for a refund, from payers with whom it does not have a sufficient payment collection history or contractual reimbursement agreements. Accordingly, for those payers, Oncocyte expects to continue to recognize revenue upon payment until it has a sufficient history to reliably estimate payment patterns or has contractual reimbursement arrangements, or both, in place.

We maintain an allowance for doubtful accounts at an amount we estimate to be sufficient to provide adequate protection against losses resulting from extending credit to our customers. We base this allowance, in the aggregate, on historical collection experience, age of receivables and general economic conditions. Our bad debts have not been material and have been within management expectations.

Pharma Services revenue

Through our Insight subsidiary we provide a range of molecular diagnostic services to pharmaceutical customers referred to as “Pharma Services” including testing for biomarker discovery, assay design and development, clinical trial support, and a broad spectrum of biomarker tests in Insight’s CLIA-certified laboratory. These Pharma Services are generally performed under individual scope of work (“SOW”) arrangements with specific deliverables defined by the customer. Pharma Services are generally performed on a time and materials basis. Upon completion of the service to the customer in accordance with the SOW, we have the right to bill the customer for the agreed upon price (either on a per test or per deliverable basis) and we recognize the pharma service revenue at that time. We generally identify each sale of its pharma service offering as a single performance obligation.

Completion of the service and satisfaction of the performance obligation under a SOW is typically evidenced by access to the report or test made available to the customer or any other form or applicable manner of delivery defined in the SOW. However, for certain SOWs under which work is performed pursuant to the customer’s highly customized specifications, we have the enforceable right to bill the customer for work completed, rather than upon completion of the SOW. For those SOWs, we recognize revenue over a period of time during which the work is performed using a formula that accounts for expended efforts, generally measured in labor hours, as a percentage of total estimated efforts for the completion of the SOW. As the performance obligation under the SOW is satisfied, any amounts earned as revenue and billed to the customer are included in accounts receivable. Any revenues earned but not yet billed to the customer as of the date of our consolidated financial statements are issued are recorded as contract assets and are included in prepaids and other current assets as of the financial statement date. Amounts recorded in contract assets are reclassified to accounts receivable in our consolidated financial statements when the customer is invoiced according to the billing schedule in the contract.

We establish an allowance for doubtful accounts based on the evaluation of the collectability of Pharma Services accounts receivables after considering a variety of factors, including the length of time receivables are past due, significant events that may impair the customer’s ability to pay, such as a bankruptcy filing or deterioration in the customer’s operating results or financial position, and historical experience. If circumstances related to customers change, estimates of the recoverability of receivables would be further adjusted. The Company has significant cash balances at financial institutions which throughout the year regularly exceed the federally insured limit of $250,000. Any loss incurred or a lack of access to such funds could have a significant adverse impact on the Company’s financial condition, results of operations, and cash flows. Amounts determined to be uncollectible are written off against the allowance for doubtful accounts. As of December 31, 2022, we have not recorded any losses or allowance for doubtful accounts on accounts receivables from Pharma Services.

Licensing revenue

Revenues recognized includes licensing revenue derived from agreements with customers for exclusive rights to market Oncocyte's proprietary testing technology. Under the agreements, Oncocyte grants exclusive rights to certain trademarks and technology of Oncocyte for the purpose of marketing Oncocyte's tests within a defined geographic territory. A license agreement may specify milestone deliverables or performance obligations, for which Oncocyte recognizes revenue when its licensee confirms the completion of Oncocyte's performance obligation. A licensing agreement may also include ongoing sales support from Oncocyte and typically includes non-refundable licensing fees and per-test Pharma Services revenues discussed above, for which Oncocyte treats the licensing of the technology, trademarks, and ongoing support as a single performance obligation satisfied by the passage of time over the term of the agreement.

Cost of revenues

Cost of revenues generally consists of cost of materials, direct labor including benefits, bonus and stock-based compensation, equipment and infrastructure expenses, clinical sample related costs associated with performing Pharma Services and DetermaRx tests, and license fees due to third parties, and also includes amortization of acquired customer relationship intangible assets. Infrastructure expenses include depreciation of laboratory equipment, allocated rent costs, leasehold improvements and allocated information technology costs for operations at our CLIA laboratories. Costs associated with performing diagnostic tests and Pharma Services are recorded as the tests or services are performed regardless of whether revenue was recognized with respect to that test or pharma service. Royalties or revenue share payments for licensed technology calculated as a percentage of revenues or determined based on achieving certain aggregated amounts of revenues generated using the associated technology are recorded as expenses at the time the related revenues are recognized.

Research and development expenses

Research and development expenses are comprised of costs incurred to develop technology and include salaries and benefits (including stock-based compensation), laboratory expenses (including reagents and supplies used in research and development laboratory work), infrastructure expenses (including allocated facility occupancy costs), and contract services and other outside costs. Indirect research and development expenses are allocated primarily based on headcount, as applicable, and include rent and utilities, common area maintenance, telecommunications, property taxes, and insurance. Research and development costs are expensed as incurred.

Sales and marketing expenses

Sales and marketing expenses consist primarily of personnel costs and related benefits, including stock-based compensation, trade show expenses, branding and positioning expenses, and consulting fees. Sales and marketing expenses also include indirect expenses for applicable overhead allocated based on headcount, and include allocated costs for rent and utilities, common area maintenance, telecommunications, property taxes, and insurance.

General and administrative expenses

General and administrative expenses consist primarily of compensation and related benefits (including stock-based compensation) for executive and corporate personnel, professional and consulting fees, rent and utilities, common area maintenance, telecommunications, property taxes, and insurance.

Results of Operations

The recent global outbreak of COVID-19, and the various attempts throughout the world to contain it, have created significant financial volatility, economic uncertainty, and changes to the way Oncocyte conducts certain aspects of its operations. The COVID-19 pandemic has had, and may continue to have, significant effects on our operations, ability to generate revenues, and financing activities. In response to government directives and guidelines, health care advisories and employee and other concerns, a number of our employees have had to work remotely from home and those on site have had to follow our social distance guidelines, which could impact their productivity. Although employee absenteeism due to COVID-19 illness has not had an adverse impact on our operations as of the date of this Report, we face the risk of losing, at least temporarily, the services of employees if they become ill.

The consequences of the COVID-19 pandemic have led to uncertainties related to our growth and our ability to forecast the demand for our diagnostic testing and Pharma Services and resulting revenues, as we have not had time to establish a base of customers, revenues or other relevant trends prior to the outbreak of COVID-19. We had no commercial revenues until the first quarter of 2020 when we launched our first commercial diagnostic test, DetermaRx, and acquired the Pharma Services business of Insight. We had expected that initial DetermaRx revenues would be constrained by the lack of Medicare coverage. CMS Medicare reimbursement pricing approval for DetermaRx did not become effective until September 2020. Deferrals in lung cancer surgeries due to COVID-19 may have reduced demand for DetermaRx, but because of the lack of historical DetermaRx revenues, with and without Medicare reimbursement, we are unable to determine the extent to which the deferral of those surgeries impacted our DetermaRx revenues. Resurgences in COVID-19 cases could cause additional deferrals of lung cancer surgeries during the course of the pandemic. The lack of in-person interaction with healthcare providers for our promotion of the use of DetermaRx has also placed a constraint on our ability to market that test, but we cannot determine the extent to which that has impacted our revenues due to the absence of historical revenues. Similarly, our Pharma Services revenues commenced with our acquisition of Insight during the first quarter of 2020, and because we do not have a prior history of Pharma Services revenues we cannot assess how COVID-19 may have impacted those revenues, although we are aware that certain planned clinical trials of new pharmaceuticals for which we had expected to provide Pharma Services were delayed due to the pandemic.

During the COVID-19 pandemic, we have not been, and may not be, able to maintain our preferred level of physician or customer outreach and marketing of our diagnostic testing and Pharma Services, which could negatively impact our potential new customers' interest in our tests and services. Even if government and other COVID-19 related restrictions are relaxed and lung cancer surgeries are performed at or close to pre-pandemic levels, any growth and anticipated adoption of our diagnostic tests may not occur. Although we have not yet experienced COVID-19 related supply chain disruptions impacting our testing capacity, if the vendors of equipment and reagents used in our diagnostic laboratories experience supply, operational, or financial disruptions due to the COVID-19 pandemic, we could experience supply constraints in the future that could cause increased costs or delays in performing DetermaRx tests and Pharma Services and in continuing the development of new diagnostic tests.

The full extent to which the COVID-19 pandemic and the various responses might impact our business, operations and financial results will depend on numerous evolving factors that we will not be able to accurately predict, including: the duration and scope of the pandemic; governmental, business and individuals' actions that have been and continue to be taken in response to the pandemic; the availability and cost to access COVID-19 tests, vaccines and therapies; the effect on our potential customers and their demand for our diagnostic testing and Pharma Services; the effect on our suppliers and their ability to provide the necessary equipment and materials to support our tests and services; disruptions or restrictions on our employees' ability to work and travel; interruptions or restrictions related to the distribution of our tests in foreign markets, including impacts on logistics of shipping and receiving patient samples; and any stoppages, disruptions or increased costs associated with development, production and marketing of our diagnostic tests. In addition to the direct impacts to our business operations, the global economy is likely to continue to be significantly weakened as a result of actions taken in response to the COVID-19 pandemic and to the extent that such a weakened global economy impacts customers' ability or willingness to purchase and pay for our tests, our business and results of operation could be negatively impacted. Due to the uncertain scope and duration of the COVID-19 pandemic and uncertain timing of any recovery or normalization, we are currently unable to estimate the resulting impacts on our operations and financial results. We will continue to actively monitor the issues raised by the COVID-19 pandemic and may take further actions that alter our operations, as may be required by federal, state, local or foreign authorities, or that we determine are in the best interests of our employees, our customers, and our shareholders.

Revenues for the Year Ended December 31, 2022

As a result of the classification of the Company's Razor's operations to discontinued operations, all revenue derived from DetermaRx has been classified as discontinued operations. The remaining revenue is derived from VitaGraft technology, and from Pharma Services generated by our wholly owned subsidiary, Insight.

The following table shows our revenues for the years ended December 31, 2022 and 2021 (in thousands, except percentage change values).

	2022	2021	*$ Change*	*% Change*
Revenues from continuing operations	$ 958	$ 2,198	*(1,240)*	*-56%*
Revenues from discontinued operations	$ 4,673	$ 5,529	*(856)*	*-15%*
Total	$ 5,631	$ 7,727	*(2,096)*	*-27%*

Pharma Services are generally performed on a time and materials basis. Upon our completion of the service to the customer in accordance with the contract, we have the right to bill the customer for the agreed upon price (either on a per test or per deliverable basis) and recognize the Pharma Services revenue at that time, on an accrual basis.

Licensing revenues are generally recognized upon transfer of promised technology information and other contractual performance obligations to licensees in an amount that reflects the consideration we expect to receive in exchange. Licensing revenue is recognized at the point in time when the applicable performance obligations are satisfied, and all other revenue recognition criteria have been met.

Pharma Services revenues are generated under discrete agreements for particular customer projects that generally expire with the completion or termination of the customer's project. Accordingly, different customers may account for greater or lesser portions of Pharma Services during different accounting periods, and Pharma Services revenues may exhibit a larger variance from accounting period to accounting period than other revenues such as DetermaRx testing revenues.

Licensing revenues for the twelve months ended December 31, 2022 included in discontinued operations primarily reflect the revenue recognition of $1.0 million in relation to the Initial Milestone Payments related to the Exclusive Sublicense Agreement in the PRC Territory (the "Sublicense Agreement") with Burning Rock Biotech Limited ("Burning Rock"). Like Pharma Services revenues, licensing revenues may vary significantly between accounting periods reflecting the attainment of additional licensing agreement milestones that trigger license fees payable to Oncocyte or reflecting the beginning or end of a revenue stream upon the commencement or termination of a license agreement related to a particular customer project.

The following table presents the percentage of consolidated revenues by products or services classes:

	Year Ended December 31,			
	2022	2021	2022	2021
Pharma Services	958	1,460	100%	66%
Licensing	-	738	-%	34%
Total	$ 958	$ 2,198	100%	100%

The following table presents the percentage of consolidated revenues received from unaffiliated customers that individually represent greater than ten percent of consolidated revenues:

	Year Ended December 31,	
	2022	2021
Pharma services - Company A	43%	
Pharma services - Company B	14%	
Pharma services - Company C	11%	
Pharma services Other	31%	
Licensing - Company A	*%	
Total	100%	

**Less than 10%*

Operating Summary

The following table shows our operating net loss for the years ended December 31, 2022 and 2021 (in thousands).

	Year Ended December 31,	
	2022	2021
Revenues	$ 958	$ 2,198
Cost of revenues	976	778
Research and development expenses	7,301	5,035
Sales and marketing expenses	1,132	552
General and administrative expenses	21,881	22,292
Change in fair value of contingent consideration	(31,019)	27,266
Loss from goodwill impairment	18,684	-
Loss from operations	(17,997)	(53,725)
Other income (expense)	(615)	854
Loss before income taxes	(18,612)	(52,871)
Income tax benefit	-	9,261
Loss from continuing operations	(18,612)	(43,610)
Loss from discontinued operations	(54,290)	(20,487)
Net loss	$ (72,902)	$ (64,097)

Cost of revenues

Cost of revenues generally consists of cost of materials; direct labor including payroll, payroll taxes, bonus, benefit and stock-based compensation; equipment and infrastructure expenses; clinical sample costs associated with performing Pharma Services; license fees due to third parties, and amortization of acquired intangible assets. Infrastructure expenses include depreciation of laboratory equipment; allocated rent costs; and leasehold improvements.

Cost of revenues for Pharma Services and licensing revenue varies depending on the nature, timing, and scope of customer projects.

Research and development expenses

A summary of the main drivers of the change in research and development expenses for the periods presented, is as follows:

	Year Ended December 31,			
	2022	**2021**	***$ Change***	***% Change***
Personnel-related expenses	$ 2,931	$ 1,918	*$ 1,013*	*53 %*
Professional fees, legal, and outside services	*1,334*	*1,129*	*205*	*18 %*
Laboratory supplies and expenses	*1,369*	*746*	*623*	*84 %*
Clinical trials	*9*	*96*	*(87)*	*-91 %*
Share-based compensation	*773*	*473*	*300*	*63 %*
Severance	*21*	*233*	*(212)*	*-91 %*
Depreciation	*315*	*228*	*87*	*38 %*
Facilities and insurance	*334*	*12*	*322*	*2683 %*
Other	*215*	*200*	*15*	*8 %*
Total	$ 7,301	$ 5,035	*$ 2,266*	*45 %*
% of Net Revenue	762 %	229 %		533 %

We expect to continue to incur a significant amount of research and development expenses during the foreseeable future. As of December 31, 2022, we will continue development of DetermaIO and VitaGraft. Our future research and development efforts and expenses will also depend on the amount of capital that we are able to raise to finance those activities and whether we acquire rights to any new diagnostic tests. A portion of our costs for leasing and operating our CLIA laboratories in California and Tennessee, and in Germany with Chronix, will also be included in research and development expenses to the extent allocated to the development of our diagnostic tests.

The COVID-19 global pandemic has negatively impacted, and is expected to continue to negatively impact, clinical trials of immunotherapies by pharma companies that may use DetermaIO in selecting patients for their trials. We may also commence our own clinical trials of DetermaIO if we develop that diagnostic test to the point where we determine that its use as a clinical diagnostic appears to be feasible.

Sales and marketing expenses

A summary of the main drivers of the change in sales and marketing expenses for the periods presented, is as follows:

	Year Ended December 31,			
	2022	**2021**	***$ Change***	***% Change***
Personnel-related expenses	$ 592	$ 147	$ 445	*303%*
Share-based compensation	261	114	147	*129%*
Professional fees, legal, and outside services	219	286	(67)	*-23%*
Facilities and insurance	43	-	43	*100%*
Other	17	5	12	*240%*
Total	$ 1,132	$ 552	*$ 580*	*105%*
% of Net Revenue	118%	25%		93%

We expect to continue to incur sales and marketing expenses during the foreseeable future as we complete product development and begin commercialization efforts for DetermaIO as a clinical test. Sales and marketing expenses will also increase if we successfully develop and begin commercializing DetermaCNI, and VitaGraft, or if we acquire and commercialize other diagnostic tests. Our commercialization efforts and expenses will also depend on the amount of capital that we are able to raise to finance commercialization of our tests. Our future expenditures on sales and marketing will also depend on the amount of revenue that those efforts are likely to generate. Because physicians are more likely to prescribe a test for their patients if the cost is covered by Medicare or health insurance, demand for our diagnostic and other tests and our expenditures on sales and marketing are likely to increase if our diagnostic or other tests qualify for reimbursement by Medicare or private health insurance companies.

General and administrative expenses

A summary of the main drivers of the change in general and administrative expenses for the periods presented, is as follows:

	Year Ended December 31,			
	2022	**2021**	***$ Change***	***% Change***
Personnel-related expenses and board fees	$ 7,155	$ 6,137	*$ 1,018*	*17%*
Share-based compensation	5,435	3,657	*1,778*	*49%*
Professional fees, legal, and outside services	4,299	6,214	*(1,915)*	*-31%*
Facilities and insurance	2,696	3,197	*(501)*	*-16%*
Severance – Chronix acquisition	-	2,452	*(2,452)*	*-100%*
Severance	1,480	-	*(1,480)*	*-%*
Other	816	635	*181*	*29%*
Total	$ 21,881	$ 22,292	*$ (411)*	*-2%*
% of Net Revenue	2,284%	1,014%		1,270%

Change in fair value of contingent consideration

We will pay contingent consideration if various payment milestones are triggered under the merger agreements through which we acquired Insight and Chronix. See Note 3 to our consolidated financial statements included in this Report. Changes in the fair value of the contingent consideration will be based on our reassessment of the key assumptions underlying the determination of this liability as changes in circumstances and conditions occur from the Insight acquisition date to the reporting period being presented, with the subsequent change in fair value recorded as part of our consolidated loss from operations for that period. For the year ended December 31, 2022 and December 31, 2021, we recorded an unrealized gain of approximately $31.0 million and an unrealized loss of approximately $27.3 million, respectively, related to the change in the fair value of contingent consideration primarily attributable to a revised estimate on the timing of the possible future payouts, respectively.

Loss from goodwill impairment

Goodwill represents the excess of the purchase price over the fair value of net identifiable assets and liabilities. Goodwill, similar to IPR&D, is not amortized but is tested for impairment at least annually, or if circumstances indicate its value may no longer be recoverable. Qualitative factors considered in this assessment include industry and market conditions, overall financial performance, and other relevant events and factors affecting Oncocyte's business. Based on the qualitative assessment, if it is determined that the fair value of goodwill is more likely than not to be less than its carrying amount, the fair value of a reporting unit will be calculated and compared with its carrying amount and an impairment charge will be recognized for the amount that the carrying value exceeds the fair value. Oncocyte continues to operate in one segment and considered to be the sole reporting unit and, therefore, goodwill is tested for impairment at the enterprise level.

Oncocyte does not have intangible assets with indefinite useful lives other than goodwill and the acquired IPR&D discussed in Notes 3 and 4. During December 2022, the Company assessed its current environment and after taking into consideration the Stock Purchase Agreement to Sale Razor Genomics, management concluded that it was more likely than not that the fair value of the goodwill was less than the carrying value. As such, the Company performed a quantitative test to estimate the fair value of the enterprise. Using the discounted cash flow method and taking into consideration the loss of Razor's future cash flows, the calculated enterprise fair value was lower than carrying value. As a result, the Company recorded a goodwill impairment of $18.7 million as part of its operating expenses; as of December 31, 2022. No impairment was noted for IPR&D assets.

Other income and expenses, net

Other income and expenses, net, is primarily comprised of interest income and interest expenses, net, unrealized gains and losses on Lineage and AgeX marketable equity securities we hold, and change in fair value of Series A redeemable convertible preferred stock second closing tranche obligation. Interest income is earned from money market funds we hold for capital preservation. Interest expense was incurred under our loan payable to the Silicon Valley Bank, and under financing lease obligations. Interest expense, net, reflects the interest expense incurred on our loans and financing obligations in excess of interest income earned from money market accounts.

For the years ended December 31, 2022 and December 31, 2021, we recorded interest expense, net, of $77,000 and $0.2 million, respectively, from our loans and financing leases. For the year ended December 31, 2022, we recorded $0.5 million of unrealized loss from the fair market value decrease of the marketable equity securities we hold in shares of Lineage and AgeX common stock. We did not sell any marketable securities during any of the periods presented. As of December 31, 2022 and 2021, we held marketable equity securities with a total fair market value of $0.4 million and $0.9 million, respectively.

Income taxes

A summary of the income taxes and tax rates for the periods presented, is as follows:

	2022	2021
Income taxes (in thousands)	$ -	$ 9,261
Effective tax rate	%	-13%

In connection with the Chronix and Razor acquisitions discussed in Note 3 to our consolidated financial statements included else wherein this Report, a change in the acquirer's valuation allowance that stems from the purchase of assets should be recognized as an element of the acquirer's income tax benefit in the period of the acquisition. Accordingly, for the year ended December 31, 2021, we recorded a $9.3 million partial release of our valuation allowance and a corresponding income tax benefit stemming from the deferred tax liability generated by the Chronix and Razor intangible assets we acquired no similar amount was recorded during 2022.

A valuation allowance is provided when it is more likely than not that some portion of the deferred tax assets will not be realized. Other than the partial release discussed above for the years ended December 31, 2022 and 2021, we established a full valuation allowance for all periods presented due to the uncertainty of realizing future tax benefits from our net operating loss carryforwards and other deferred tax assets. Accordingly, due to losses incurred for all periods presented, we did not record any provision or benefit for income taxes except for the tax benefit recorded in connection with the acquisitions discussed above.

Liquidity and Capital Resources

Since formation, we have financed our operations primarily through the sale of our common stock, preferred stock and warrants. We have incurred operating losses and negative cash flows since inception and had an accumulated deficit of $260.7 million at December 31, 2022. We expect to continue to incur operating losses and negative cash flows for the near future.

At December 31, 2022, we had $20.0 million of cash and cash equivalents, and held shares of Lineage and AgeX common stock as marketable equity securities valued at $0.4 million. During the year ended December 31, 2022, we raised approximately $30,000 in net cash proceeds through sales of shares of our common stock through the ATM Offering. On June 1, 2022, Oncocyte received net proceeds of approximately $4.8 million from the Series A Preferred Stock issued from the first tranche of the Series A Preferred Stock Offering. On April 19, 2022, Oncocyte received net proceeds of approximately $32.4 million from the Underwritten Offering of 26,266,417 shares of common stock and 26,266,417 shares of April 2022 Warrants to purchase up to 13,133,208.5 shares of common stock. See Notes 1 and 15 for additional information about the April 2022 Offerings.

As reflected in the consolidated financial statements, the Company had an accumulated deficit at December 31, 2022, a net loss and net cash used in operating activities for the reporting period then ended.

On April 3, 2023 the Company entered into an agreement with certain members of the Company's board of directors, and several institutional and accredited investors, including Broadwood Capital, L.P., the Company's largest shareholder, relating to their purchase of an aggregate of up to 45,562,425 shares of its common stock at an offering price of $0.3544 per share to board members and $0.30168 per share to the other investors participating in the offering. The offering is intended to be priced 'at-the market' for purposes of complying with applicable NASDAQ Listing Rules. The aggregate gross proceeds from the offering were approximately $13.9 million before deducting offering expenses payable by the Company.

Although it is difficult to predict the Company's liquidity requirements, based upon the Company's current operating plan, management believe that it will have sufficient cash to meet its projected operating requirements for at least the next 12 months following the issuance of the consolidated financial statements. The Company anticipates that it will continue to incur net losses for the foreseeable future as it continues the development its various programs and incurs additional costs associated with being a public company.

We expect that our operating expenses will remain flat as we continue to manage our available cash. Although we intend to market our diagnostic tests in the United States through our own sales force, we are also beginning to make marketing arrangements with distributors in other countries. We may also explore a range of other commercialization options in order to enter overseas markets and to reduce our capital needs and expenditures, and the risks associated the timelines and uncertainty for attaining the Medicare reimbursement approvals that will be essential for the successful commercialization of additional cancer diagnostic tests. Those alternative arrangements could include marketing arrangements with other diagnostic companies through which we might receive a licensing fee and royalty on sales, or through which we might form a joint venture to market one or more tests and share in net revenues, in the United States or abroad.

In addition to sales and marketing expenses, we will incur expenses from leasing and improving our new office and laboratory facilities in Nashville, Tennessee.

We may need to meet significant cash payment or stock obligations to former Insight and Chronix shareholders in connection with our acquisition of those companies, as disclosed in Note 3 to the consolidated financial statements included elsewhere in this Report. To meet the future cash payment obligations, we may have to utilize cash on hand that would otherwise be available to us for other business and operational purposes, which could cause us to delay or reduce activities in the development and commercialization of our cancer tests.

We will need to continue to raise additional capital to finance our operations, including the development and commercialization of our diagnostic tests, and making payments that may become due under our obligations to former Chronix shareholders and former Insight shareholders, until such time as we are able to generate sufficient revenues to cover our operating expenses. Delays in the development of DetermaIO, or obtaining reimbursement coverage from Medicare for that diagnostic test and for the other diagnostic tests that we may develop or acquire, could prevent us from raising sufficient additional capital to finance the completion of development and commercial launch of those tests. Investors may be reluctant to provide us with capital until our tests are approved for reimbursement by Medicare or reimbursement by private healthcare insurers or healthcare providers, or until we begin generating significant amounts of revenue from performing those tests. The unavailability or inadequacy of financing or revenues to meet future capital needs could force us to modify, curtail, delay, or suspend some or all aspects of our planned operations. Sales of additional equity securities could result in the dilution of the interests of our shareholders. We cannot assure that adequate financing will be available on favorable terms, if at all.

Cash used in operating activities

During the years ended December 31, 2022 and 2021, our total research and development expenses were $7.3 million and $5.0 million, respectively, our general and administrative expenses were $21.9 million and $22.2 million, respectively, and our sales and marketing expenses were $1.1 million and $0.6 million, respectively. We also incurred $1.0 million in cost of revenues, including $96,000 amortization of intangible expenses, in the year ended 2022. Net loss for the years ended December 31, 2022 and 2021 amounted to $72.9 million and $64.1 million, respectively. Net cash used in operating activities for the years ended December 31, 2022 and 2021 amounted to $45.6 million and $35.9 million, respectively, of which $18.6 million and $43.6 million represent loss from continuing operations respectively and $54.3 million and $20.5 million from discontinued operations respectively. Our cash used in operating activities during 2022 does not include the following noncash items: $10.0 million in stock-based compensation; $31.0 million in gain from change in fair value of contingent consideration; $5.2 million in depreciation and amortization expenses; $18.7 million loss from goodwill impairment, $25.9 million loss from held for sale asset impairment, and $0.5 million in unrealized loss on marketable equity securities. Changes in operating assets and liabilities were approximately $2.0 million as an additional use of cash.

Cash used in investing activities

During the 2022, net cash used in investing activities from operations was $4.3 million, due to cash paid for construction in progress and purchase of furniture and equipment.

Cash provided by financing activities

During 2022, net cash provided in financing activities was $35.8 million, primarily attributable to $32.4 million of net cash proceeds from the sale of shares of common stock, including $30,000 of net cash proceeds from at-the-market transactions, and $4.8 million of net cash proceeds from the sale of redeemable convertible Series A preferred shares, offset by repayments of principal on loans payable and financing lease obligations of $1.3 million.

Off-Balance Sheet Arrangements

As of December 31, 2022, we did not have any off-balance sheet arrangements, as defined in Item 303(a)(4)(ii) of SEC Regulation S-K.

Item 7A. Quantitative and Qualitative Disclosures about Market Risk

Under SEC rules and regulations, as a smaller reporting company, we are not required to provide the information required by this item.

Item 8. Financial Statements and Supplementary Data

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

Report of Independent Registered Public Accounting Firm

To the Shareholders and Board of Directors
Oncocyte Corporation

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Oncocyte Corporation (the "Company") as of December 31, 2022 and 2021, and the related consolidated statements of operations, comprehensive loss, shareholders' equity, and cash flows for the years then ended, and the related notes (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company at December 31, 2022 and 2021, and the results of its operations and its cash flows for the years then ended, in conformity with accounting principles generally accepted in the United States of America.

Basis for Opinion

These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) ("PCAOB") and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits we are required to obtain an understanding of internal control over financial reporting, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the consolidated financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the consolidated financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements. We believe that our audits provide a reasonable basis for our opinion.

Critical Audit Matters

The critical audit matters communicated below are matters arising from the current period audit of the consolidated financial statements that were communicated or required to be communicated to the Audit Committee and that: (1) relate to accounts or disclosures that are material to the consolidated financial statements; and (2) involved our especially challenging, subjective, or complex judgments. The communication of a critical audit matter does not alter in any way our opinion on the consolidated financial statements, taken as a whole, and we are not, by communicating the critical audit matters below, providing separate opinions on the critical audit matters or on the accounts or disclosures to which they relate.

Valuation of Contingent Consideration Liabilities - Refer to Notes 3 to the consolidated financial statements

Description of the Matter

The Company recognized contingent consideration liabilities at the estimated fair value on the acquisition date in connection with applying the acquisition method of accounting for business combinations. Subsequent changes to the fair value of the contingent consideration liabilities were recorded within the consolidated statement of operations in the period of change. At December 31, 2022, the Company had $5.4 million and $40.3 million in contingent consideration liabilities, for the Company's DetermaIO™ and TheraSure™ tests, respectively, which were associated with business combinations. These amounts represented a 'Level 3' fair value measurement in the fair value hierarchy due to the significant unobservable inputs used in determining the fair value and the use of management judgment about the assumptions market participants would use in pricing the liabilities.

Auditing the valuation of contingent consideration liabilities, consisting of milestone and royalty consideration, was complex and required significant auditor judgment due to the use of a scenario analysis valuation method and the high degree of subjectivity in evaluating certain assumptions required to estimate the fair value of the milestone contingent consideration and royalty contingent consideration. In particular, the royalty contingent consideration fair value measurement is based on future revenues, revenues for current services, and discount rates. The milestone contingent consideration fair value measurement is based on nonfinancial, binary events, therefore is reassessed as changes in circumstances and conditions occur. Management utilized its expertise within the industry, including commercial dynamics, trends and utilization, as well as knowledge of clinical development and regulatory approval processes to determine certain of these assumptions.

How We Addressed the Matter in Our Audit

To test the estimated fair value of contingent consideration liabilities, our audit procedures included, among others, inspecting the terms of the executed agreement, assessing the scenario analysis valuation method used and testing the key contractual inputs and significant assumptions discussed above. We evaluated the assumptions and judgments considering observable industry and economic trends and standards, external data sources and regulatory factors. Estimated amounts of future sales were evaluated for reasonableness in relation to internal and external analyses, clinical development progress and timelines, probability of success benchmarks, and regulatory notices. Our procedures included evaluating the data sources used by management in determining its assumptions and, where necessary, included an evaluation of available information that either corroborated or contradicted management's conclusions. We involved our valuation specialists to assess the Company's scenario analysis valuation and to perform corroborative fair value calculations.

Assessment of Held for Sale and Discontinued Operations Classification and Impairment Charge - Refer to Notes 16 to the consolidated financial statements

Description of the Matter

On December 15, 2022, the Company entered into a Stock Purchase Agreement to sell 3,188,181 shares of common stock of Razor Genomics Inc., a wholly-owned subsidiary of the Company ("Razor"), which constitutes approximately 70% of the issued and outstanding equity interests of Razor on a fully-diluted basis. As a result, Razor was classified as held for sale and reported as discontinued operations and impairment charges of $25.9 million were recorded to reduce the carrying amount of the assets to zero as there were minimal considerations received.

We identified the assessment of held for sale and discontinued operations classification and associated impairment charges as a critical audit matter because of the extensive effort required to audit the subjective and complex judgments associated with those matters, including:

- The assessment of whether the sale meets the criteria for held for sale;
- The assessment of whether the sale of Razor represents a discontinued operation; and
- The determination of the impairment charges.

How We Addressed the Matter in Our Audit

The primary procedures we performed to address this critical audit matter included the following. We obtained an understanding and evaluated the design of the Company's internal control over accounting for significant unusual transactions. We assessed management's judgments in determining whether the sale of Razor meets the held for sale and discontinued operations classification criteria through procedures performed, including, but not limited to, reviewing relevant supporting documentation, and inquiring of management regarding specific assumptions made. We tested the recognition and classifications of the Company's segregation of assets, liabilities and the results of operations that are classified as discontinued operations by inspecting the Company's accounting data and related adjustments. We also reviewed the accuracy and completeness of the Company's disclosures as they relate to discontinued operations.

/s/ WithumSmith+Brown, PC

We have served as the Company's auditor since 2015.

East Brunswick, New Jersey

April 12, 2023

PCAOB ID Number 100

ONCOCYTE CORPORATION
CONSOLIDATED BALANCE SHEETS
(*In thousands*)

	December 31,	
	2022	**2021**
ASSETS		
CURRENT ASSETS		
Cash and cash equivalents	$ 19,993	$ 32,948
Accounts receivable, net of allowance of $154 and $-, respectively	2,012	1,437
Marketable equity securities	433	904
Prepaid expenses and other current assets	977	901
Current assets of discontinuing operations	2,121	2,953
Total current assets	25,536	39,143
NONCURRENT ASSETS		
Right-of-use and financing lease assets, net	2,088	2,779
Machinery and equipment, net, and construction in progress	8,763	5,590
Goodwill	-	18,684
Intangible assets, net	61,633	61,721
Restricted cash	1,700	1,700
Other noncurrent assets	371	264
Other noncurrent assets of discontinuing operations	-	29,682
TOTAL ASSETS	$ 100,091	$ 159,563
LIABILITIES AND SHAREHOLDERS' EQUITY		
CURRENT LIABILITIES		
Accounts payable	$ 1,253	$ 1,810
Accrued compensation	1,771	2,827
Accrued expenses and other current liabilities	3,839	2,085
Accrued severance from acquisition	2,314	2,352
Accrued liabilities from acquisition	109	1,388
Loans payable, net of deferred financing costs	-	1,313
Right-of-use and financing lease liabilities, current	815	819
Current liabilities of discontinuing operations	2,005	1,526
Total current liabilities	12,106	14,120
NONCURRENT LIABILITIES		
Right-of-use and financing lease liabilities, noncurrent	2,729	3,545
Contingent consideration liabilities	45,662	76,681
TOTAL LIABILITIES	60,497	94,346
COMMITMENTS AND CONTINGENCIES		
Series A Redeemable Convertible Preferred Stock, no par value; stated value $1,000 per share; 6 shares and - shares issued and outstanding at December 31, 2022 and December 31, 2021, respectively; aggregate liquidation preference of $6,091 and $- as of December 31, 2022 and December 31, 2021, respectively	5,302	-

SHAREHOLDERS' EQUITY		
Preferred stock, no par value, 5,000 shares authorized; no shares issued and outstanding	-	-
Common stock, no par value, 230,000 shares authorized; 118,644 and 92,232 shares issued and outstanding at December 31, 2022 and December 31, 2021, respectively	294,929	252,954
Accumulated other comprehensive income	39	37
Accumulated deficit	(260,676)	(187,774)
Total shareholders' equity	34,292	65,217
TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY	$ 100,091	$ 159,563

The accompanying notes are an integral part of these consolidated financial statements.

ONCOCYTE CORPORATION
CONSOLIDATED STATEMENTS OF OPERATIONS
(In thousands, except per share data)

	Year Ended December 31,	
	2022	**2021**
Net revenue	$ 958	$ 2,198
Cost of revenues	880	697
Cost of revenues – amortization of acquired intangibles	96	81
Gross margin	(18)	1,420
Operating expenses:		
Research and development	7,301	5,035
Sales and marketing	1,132	552
General and administrative	21,881	22,292
Change in fair value of contingent consideration	(31,019)	27,266
Loss from goodwill impairment	18,684	-
Total operating expenses	17,979	55,145
Loss from operations	(17,997)	(53,725)
OTHER INCOME (EXPENSES), NET		
Interest expense, net	(77)	(209)
Unrealized gain (loss) on marketable equity securities	(471)	229
Pro rata loss from equity method investment in Razor	-	(270)
Gain on extinguishment of debt (PPP loan)	-	1,141
Other expenses, net	(67)	(37)
Total other income (expenses), net	(615)	854
LOSS BEFORE INCOME TAXES	(18,612)	(52,871)
Income tax benefit	-	9,261
Loss from continuing operations	(18,612)	(43,610)
Loss from discontinuing operations	(54,290)	(20,487)
NET LOSS	(72,902)	(64,097)
Accretion of Series A redeemable convertible preferred stock	(520)	-
NET LOSS ATTRIBUTABLE TO COMMON STOCKHOLDERS: BASIC AND DILUTED	(73,422)	(64,097)
Net loss per share from continuing operations, basic and diluted	$ (0.17)	$ (0.49)
Net loss per share from discontinuing operations, basic and diluted	$ (0.49)	$ (0.23)
Net loss per share: basic and diluted	$ (0.66)	$ (0.72)
Weighted average shares outstanding: basic and diluted	110,800	88,920

ONCOCYTE CORPORATION
CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS
(In thousands)

	Year Ended December 31,	
	2022	**2021**
NET LOSS	$ (72,902)	$ (64,097)
Foreign currency translation adjustments	2	37
COMPREHENSIVE LOSS	$ (72,900)	$ (64,060)

The accompanying notes are an integral part of these consolidated financial statements.

ONCOCYTE CORPORATION
CONSOLIDATED STATEMENTS OF SHAREHOLDERS' EQUITY
(In thousands)

	Series A Redeemable Convertible Preferred Stock		Common Stock		Accumulated Other Comprehensive	Accumulated	Total Stockholders'
	Shares	Amount	Shares	Amount	Income	Deficit	Equity
Balance at December 31, 2020	**-**	**$ -**	**69,117**	**$ 157,160**	**$ -**	**$ (123,677)**	**$ 33,483**
Net Loss	-	-	-	-	-	(64,097)	(64,097)
Foreign currency translation adjustment	-	-	-	-	37	-	37
Stock-based compensation	-	-	-	6,841	-	-	6,841
Sale of common shares, including at-the-market transactions	-	-	19,536	77,987	-	-	77,987
Financing costs paid to issue common shares, including at-the-market transactions	-	-	-	(3,065)	-	-	(3,065)
Stock options exercised	-	-	924	2,584	-	-	2,584
Warrants exercised	-	-	872	2,631	-	-	2,631
Shares issued upon vesting of RSU, net of shares retired to pay employees' taxes	-	-	153	(239)	-	-	(239)
Issuance of common stock to Razor Genomics	-	-	982	5,756	-	-	5,756
Issuance of common stock to Chronix Biomedical	-	-	648	3,299	-	-	3,299

Balance at December 31, 2021	**-**	**$ -**	**92,232**	**$ 252,954**	**$ 37**	**$ (187,774)**	**$ 65,217**
Net Loss	-	-	-	-	-	(72,902)	(72,902)
Foreign currency translation adjustment	-	-	-	-	2	-	2
Stock-based compensation	-	-	-	10,042	-	-	10,042
Issuance of common shares, including at-the-market transactions, net of financing costs and underwriting discounts	-	-	26,281	32,453	-	-	32,453
Shares issued upon vesting of RSU, net of shares retired to pay employees' taxes	-	-	131	-	-	-	-
Issuance of Series A redeemable convertible preferred stock, net of financing costs	5,882	4,782	-	-	-	-	-
Accretion of Series A convertible preferred stock to redemption value	-	520	-	(520)	-	-	(520)
Balance at December 31, 2022	**5,882**	**$ 5,302**	**118,644**	**$ 294,929**	**$ 39**	**$ (260,676)**	**$ 34,292**

The accompanying notes are an integral part of these consolidated financial statements.

ONCOCYTE CORPORATION
CONSOLIDATED STATEMENTS OF CASH FLOWS
(In thousands)

	Year Ended December 31,	
	2022	**2021**
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	$ (72,902)	$ (64,097)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation expense	1,528	844
Amortization of intangible assets	3,692	3,361
Pro rata loss from equity method investment in Razor	-	270
Stock-based compensation	10,042	6,841
Unrealized (gain) loss on marketable equity securities	471	(229)
Amortization of debt issuance costs	12	56
Change in fair value of contingent consideration	(31,019)	27,266
Deferred income tax benefit	-	(9,261)
Gain on extinguishment of debt (PPP loan)	-	(1,141)
Loss from goodwill impairment	18,684	-
Impairment loss from held for sale assets	25,866	-
Changes in operating assets and liabilities:		
Accounts receivable	(575)	(1,229)
Lease liabilities	(116)	147
Prepaid expenses and other assets	(231)	227
Accounts payable and accrued liabilities	297	(1,348)
Accrued severance and liabilities from Chronix Biomedical acquisition	(1,317)	2,352
Net cash used in operating activities	(45,568)	(35,941)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Acquisition of Insight Genetics, net of cash acquired	-	(607)
Acquisition of Razor Genomics asset, net of cash acquired	-	(6,648)
Acquisition of Chronix Biomedical, net of cash acquired	-	(4,459)
Construction in progress and purchases of equipment	(4,340)	(2,247)
Net cash used in investing activities	(4,340)	(13,961)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from exercise of stock options	-	2,584
Proceeds from sale of common shares	32,812	65,263
Financing costs to issue common shares	(389)	(2,675)
Proceeds from sale of redeemable convertible Series A preferred shares	4,875	-
Financing costs to issue redeemable convertible Series A preferred shares	(93)	-
Proceeds from sale of common shares under at-the-market transactions	31	12,724
Financing costs for at-the-market sales	(1)	(390)
Proceeds from exercise of warrants	-	2,631
Common shares received and retired for employee taxes paid	-	(239)
Repayment of loan payable	(1,325)	(1,500)
Repayment of financing lease obligations	(104)	(34)

Net cash provided by financing activities	35,806	78,364
NET (DECREASE) INCREASE IN CASH, CASH EQUIVALENTS AND RESTRICTED CASH	(14,102)	28,462
CASH, CASH EQUIVALENTS AND RESTRICTED CASH, BEGINNING	37,305	8,843
CASH, CASH EQUIVALENTS AND RESTRICTED CASH, ENDING	23,203	37,305
SUPPLEMENTAL DISCLOSURE OF CASH FLOW INFORMATION		
Cash paid for interest	24	114
SUPPLEMENTAL SCHEDULE OF NONCASH FINANCING AND INVESTING ACTIVITIES		
Common stock issued for acquisition of Razor Genomics asset	-	5,756
Deferred tax liability generated from the acquisition of Razor Genomics asset	-	7,077
Common stock issued for acquisition of Chronix Biomedical	-	3,299
Deferred tax liability generated from the acquisition of Chronix	-	2,183
Initial fair value of contingent consideration at acquisition date	-	42,295
Assumed liability from Chronix Acquisition	-	3,352
Construction in progress, machinery and equipment purchases included in accounts payable, accrued liabilities and landlord liability	323	1,083
See Note 10 for additional disclosures around leases		

The accompanying notes are an integral part of these consolidated financial statements.

ONCOCYTE CORPORATION
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

1. Organization, Description of the Business and Liquidity

Oncocyte Corporation ("Oncocyte" or the "Company"), incorporated in 2009 in the state of California, is a precision diagnostics company focused on developing and commercializing proprietary tests in three areas: DetermaIO is a gene expression test that assesses the tumor microenvironment to predict response to immunotherapies, VitaGraft is a blood-based solid organ transplantation monitoring test and DetermaCNI is a blood-based monitoring tool for monitoring therapeutic efficacy in cancer patients.

Oncocyte's first product for commercial release was a proprietary treatment stratification test called DetermaRx that identifies which patients with early-stage non-small cell lung cancer may benefit from chemotherapy, resulting in a significantly higher, five-year survival rate. Beginning in September 2019 through February 23, 2021, Oncocyte held a 25% equity interest in Razor Genomics, Inc. ("Razor"), a privately held company, that has developed and licensed to Oncocyte the lung cancer treatment stratification laboratory test that Oncocyte is commercializing as DetermaRx. On February 24, 2021, Oncocyte completed the purchase of all the remaining issued and outstanding shares of common stock of Razor and paid the selling shareholders in total $10 million in cash and issued them Oncocyte common stock having a market value of $5.7 million on that date. As a result of the purchase of the Razor common stock, Oncocyte is now the sole shareholder of Razor. The acquisition of the remaining equity interests has been accounted for as an asset acquisition in accordance with Accounting Standards Codification ("ASC") Topic 805-50, *Business Combinations*. See Note 3 for a full discussion of the Razor asset acquisition.

On December 15, 2022, the Company, entered into a Stock Purchase Agreement (the "Razor Stock Purchase Agreement") with Dragon Scientific, LLC, a Delaware limited liability company ("Dragon") and Razor. Pursuant to the Razor Stock Purchase Agreement, Oncocyte agreed to sell to Dragon, 3,188,181 shares of common stock of Razor, which constitutes approximately 70% of the issued and outstanding equity interests of Razor on a fully-diluted basis, and transfer to Razor all of the assets and liabilities related to DetermaRx (the "Razor Sale Transaction"). Following the closing of the Razor Sale Transaction (the "Razor Closing"), Oncocyte will own approximately 30% of the issued and outstanding equity interests of Razor on a fully-diluted basis. See Notes 16 and 17 for a full discussion of the Razor Sale Transaction.

Oncocyte completed its acquisition of Insight Genetics, Inc. ("Insight") on January 31, 2020 (the "Insight Merger Date") through a merger with a newly incorporated wholly owned subsidiary of Oncocyte (the "Insight Merger") under the terms of an Agreement and Plan of Merger (the "Insight Merger Agreement"). Prior to the Insight Merger, Insight was a privately held company specializing in the discovery and development of the multi-gene molecular, laboratory-developed diagnostic tests that Oncocyte has branded as DetermaIO. DetermaIO is a proprietary gene expression assay with promising data supporting its potential to help identify patients likely to respond to checkpoint inhibitor drugs. Insight has a CLIA-certified diagnostic laboratory with the capacity to support clinical trials or assay design on certain commercially available analytic platforms that may be used to develop additional diagnostic tests. Insight also performs Pharma Services in its CLIA-certified laboratory for pharmaceutical and biotechnology companies, including testing for biomarker discovery, assay design and development, clinical trial support, and a broad spectrum of biomarker tests ("Pharma Services"). The Insight Merger has been accounted for using the acquisition method of accounting in accordance with ASC 805, which requires, among other things, that the assets and liabilities assumed be recognized at their fair values as of the acquisition date. See Note 3 for a full discussion of the Insight Merger.

On April 15, 2021 (the "Chronix Merger Date"), Oncocyte completed its acquisition of Chronix Biomedical, Inc. ("Chronix") pursuant to an Agreement and Plan of Merger dated February 2, 2021, amended February 23, 2021, and amended and restated as of April 15, 2021 (as amended and restated, the "Chronix Merger Agreement"), by and among Oncocyte, CNI Monitor Sub, Inc., a Delaware corporation and wholly-owned subsidiary of Oncocyte ("Merger Sub"), Chronix, the stockholders party to the Chronix Merger Agreement and a party named as equity holder representative. Pursuant to the Chronix Merger Agreement, Merger Sub merged with and into Chronix, with Chronix surviving as a wholly owned subsidiary of Oncocyte (the "Chronix Merger"). Prior to the Chronix Merger, Chronix was a privately held molecular diagnostics company, developing blood tests for use in cancer treatment and organ transplantation. Through the Chronix Merger, Oncocyte has added to its LDT development pipeline the VitaGraft-CNI Monitor, a patented, blood-based test for immunotherapy monitoring which Oncocyte expects to market as DetermaCNI in the United States, and VitaGraft Transplant Monitor, a solid organ transplantation monitoring test. See Note 3 for additional information about the Chronix Merger.

Certain amounts in prior periods have been reclassified to reflect the impact of the discontinued operations treatment of Razor in order to conform to the current period presentation.

As a result of the divestiture of Razor, the Company has retrospectively revised the consolidated statements of operations for the year ended December 31, 2021 and the consolidated balance sheet as of December 31, 2021, to reflect the operations and cash flows of Razor as discontinued operations and the related assets and liabilities as held for sale. See Note 16 for additional information about assets held for sale and discontinued operations.

Liquidity

In accordance with Accounting Standards Update ("ASU") No. 2014-15, Presentation of Financial Statements – Going Concern (Subtopic 205-40), the Company's management evaluates whether there are conditions or events, considered in the aggregate, that raise substantial doubt about the Company's ability to continue as a going concern within one year after the date that the financial statements are issued.

Oncocyte has incurred operating losses and negative cash flows since inception and had an accumulated deficit of $260.7 million as of December 31, 2022. Oncocyte expects to continue to incur operating losses and negative cash flows for the foreseeable future. Oncocyte revenues during 2022 were not sufficient to cover Oncocyte's operating expenses for that period. Since its formation, Oncocyte has financed its operations primarily through the sale of shares of its common stock, convertible preferred stock and warrants to acquire common stock.

As of December 31, 2022, Oncocyte had $20.0 million of cash and cash equivalents, and held shares of Lineage Cell Therapeutics, Inc. ("Lineage") and AgeX Therapeutics, Inc. ("AgeX") common stock as marketable equity securities with a combined fair market value of $0.4 million.

On June 11, 2021, Oncocyte entered into an at-the-market sales agreement with BTIG, LLC as sales agent and/or principal (the "Agent") pursuant to which Oncocyte may sell up to an aggregate of $50,000,000 of shares of Oncocyte common stock from time to time through the Agent (the "ATM Offering").

Between July 1, 2021 and December 31, 2022, Oncocyte sold 1,123,337 shares of common stock at an average offering price of $5.58 per share, for gross proceeds of approximately $6.27 million through the ATM Offering. Oncocyte will need to raise additional capital to finance its operations, including the development and commercialization of its cancer diagnostic and other tests, until such time as it is able to generate sufficient revenues from the commercialization of one or more of its laboratory tests and other tests and performing Pharma Services to cover its operating expenses.

On April 13, 2022, Oncocyte entered into a securities purchase agreement (the "Securities Purchase Agreement") with institutional accredited investors (the "Investors"), including Broadwood Partners, L.P. ("Broadwood"), Oncocyte's largest shareholder, in a registered direct offering of 11,765 shares of Series A Convertible Preferred Stock (the "Series A Preferred Stock"), which are convertible into a total of 7,689,542 shares of common stock, at a conversion price of $1.53 (the "Series A Preferred Stock Offering"). The purchase price of each share of Series A Preferred Stock was $850, which included an original issue discount to the stated value of $1,000 per share. The Securities Purchase Agreement provides that the closing of the Series A Preferred Stock Offering will occur, subject to the satisfactory of certain closing conditions, in two equal tranches of $5,000,000 each for aggregate gross proceeds from both closings of $10,000,000. The first closing occurred on June 1, 2022, and Oncocyte received net proceeds of approximately $4.9 million from the Series A Preferred Stock issued from the first tranche. The second closing would occur, subject to the satisfactory of certain closing conditions (including but not limited to a requirement that the Company has not received, in the 12 months preceding the second closing, a notice from The Nasdaq Stock Market LLC ("Nasdaq") that the Company is not in compliance with the listing and maintenance and listing requirements of Nasdaq), on the earlier of (a) the second trading day following the date that Oncocyte receives notice from an Investor to accelerate the second closing and (b) a date selected by Oncocyte on or after October 8, 2022 and on or prior to March 8, 2023. On August 9, 2022, Oncocyte received a letter from Nasdaq indicating that the Company no longer meets the minimum bid price requirement of Nasdaq Listing Rule 5450(a)(1) of the Nasdaq continued listing requirements. Accordingly as of December 31, 2022, no additional proceeds are expected from the second closing of the Security Purchase Agreement. See Note 15 for additional information about the Series A Preferred Stock Offering.

Further, on April 13, 2022, Oncocyte entered into an underwriting agreement (the "Underwriting Agreement") with BTIG, LLC, as representative of the underwriters named therein (the "Underwriters"), pursuant to which Oncocyte agreed to issue and sell to the Underwriters an aggregate of 26,266,417 shares of common stock, and 26,266,417 warrants to purchase up to 13,133,208.5 shares of common stock ("April 2022 Warrants") (the "Underwritten Offering," and collectively with the Series A Preferred Stock Offering, the "April 2022 Offerings"). The Underwritten Offering closed on April 19, 2022. Pursuant to the Underwritten Offering, Broadwood acquired from us (i) 5,220,654 shares of common stock, and (ii) 6,003,752 April 2022 Warrants to purchase up to 3,001,876 shares of common stock at an exercise price of $1.53 per share. Pura Vida acquired from us (i) 4,984,093 shares of common stock, and (ii) 5,731,707 April 2022 Warrants to purchase up to 2,865,853 shares of common stock. On April 19, 2022, Oncocyte received net proceeds of approximately $32.4 million from the Underwritten Offering of 26,266,417 shares of common stock and 26,266,417 April 2022 Warrants to purchase up to 13,133,208.5 shares of common stock. See Note 15 for additional information about the Underwritten Offering.

As of December 31, 2022, Oncocyte devoted substantially all of its efforts on initial commercialization efforts for DetermaRx, completing clinical development and planning commercialization of DetermaIO, although DetermaIO is currently available for biopharma diagnostic development and research use only as a companion test in immunotherapy drug development to select patients for clinical trials; and the clinical launch of VitaGraft. While Oncocyte plans to primarily market its laboratory tests in the United States through its own sales force, it is also beginning to make marketing arrangements with distributors in other countries. In order to reduce capital needs and to expedite the commercialization of any new laboratory tests that may become available for clinical use, Oncocyte may also pursue marketing arrangements with other diagnostic companies through which Oncocyte might receive licensing fees and royalty on sales, or through which it might form a joint venture to market its tests and share in net revenues, in the United States or abroad.

In addition to general economic and capital market trends and conditions, Oncocyte's ability to raise sufficient additional capital to finance its operations from time to time will depend on a number of factors specific to Oncocyte's operations such as operating revenues and expenses, progress in development of, or in obtaining reimbursement coverage from Medicare for, DetermaIO and other future laboratory tests that Oncocyte may develop or acquire.

The unavailability or inadequacy of financing or revenues to meet future capital needs could force Oncocyte to modify, curtail, delay, or suspend some or all aspects of planned operations. Sales of additional equity securities could result in the dilution of the interests of its shareholders. Oncocyte cannot assure that adequate financing will be available on favorable terms, if at all.

The Company applied on January 24, 2023 to transfer the listing of its common stock, no par value, from The Nasdaq Global Market to The Nasdaq Capital Market (the "Transfer"). Upon receiving confirmation that Nasdaq had approved the Transfer, the Company's common stock began trading on The Nasdaq Capital Market effective with the open of trading on February 7, 2023. The Company's common stock continues to trade under the symbol "OCX". The Nasdaq Capital Market operates in substantially the same manner as The Nasdaq Global Market, with issuers listed on The Nasdaq Capital Market tier required to meet certain financial and corporate governance requirements to qualify for continued listing.

On February 7, 2023, the Company received confirmation that Nasdaq has determined that the Company is eligible for an additional 180-calendar day period to regain compliance by meeting the minimum bid price requirement. The minimum bid price requirement would be met if the Company's common stock has a minimum closing bid price of at least $1.00 per share for a minimum of 10 consecutive business days during the 180-calendar day period.

On April 3, 2023 the Company entered into an agreement with certain members of the Company's board of directors, and several institutional and accredited investors, including Broadwood Capital, L.P., the Company's largest shareholder, relating to their purchase of an aggregate of up to 45,562,425 shares of its common stock at an offering price of $0.3544 per share to board members and $0.30168 per share to the other investors participating in the offering. The offering is intended to be priced 'at-the market' for purposes of complying with applicable NASDAQ Listing Rules. The aggregate gross proceeds from the offering were approximately $13.9 million before deducting offering expenses payable by the Company.

Although it is difficult to predict the Company's liquidity requirements, management believe that it will have sufficient cash to meet its projected operating requirements for at least the next 12 months following the issuance of the consolidated financial statements. The Company anticipates that it will continue to incur net losses for the foreseeable future as it continues the development of its various programs and incurs additional costs associated with being a public company.

2. Basis of Presentation and Summary of Significant Accounting Policies

Basis of presentation

The consolidated financial statements presented herein, and discussed below, have been prepared in accordance with accounting principles generally accepted in the United States of America ("GAAP").

Principles of consolidation

On January 31, 2020, with the consummation of the Insight Merger, Insight became a wholly owned subsidiary of Oncocyte, and on that date Oncocyte began consolidating Insight's operations and results with Oncocyte's operations and results (see Note 3). On February 24, 2021, with the acquisition of the remaining equity interests in Razor, Razor became a wholly owned subsidiary of Oncocyte, and on that date Oncocyte began consolidating Razor's results with Oncocyte's operations and results (see Note 3). On April 15, 2021, with the acquisition of Chronix, Chronix became a wholly owned subsidiary of Oncocyte, and on that date Oncocyte began consolidating Chronix's operations and results with Oncocyte's operations and results (see Note 3).

All material intercompany accounts and transactions have been eliminated in consolidation.

Use of estimates

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, and contingent assets and liabilities, at the date of the consolidated financial statements, and the reported amounts of revenues and expenses during the reporting period. On an ongoing basis, management evaluates estimates which are subject to significant judgment, including, but not limited to, valuation methods used, assumptions requiring the use of judgment to prepare financial projections, timing of potential commercialization of acquired in-process intangible assets, applicable discount rates, probabilities of the likelihood of multiple outcomes of certain events related to contingent consideration, comparable companies or transactions, determination of fair value of the assets acquired and liabilities assumed including those relating to contingent consideration, assumptions related to the going concern assessments, allocation of direct and indirect expenses, useful lives associated with long-lived intangible assets, key assumptions in operating and financing leases including incremental borrowing rates, loss contingencies, valuation allowances related to deferred income taxes, and assumptions used to value debt and stock-based awards and other equity instruments. Actual results may differ materially from those estimates.

Similarly, Oncocyte assessed certain accounting matters that generally require consideration of forecasted financial information. The accounting matters assessed included, but were not limited to, Oncocyte's equity investments, the carrying value of goodwill, acquired in-process intangible assets and other long-lived assets. Those assessments as well as other estimates referenced above were made in the context of information reasonably available to Oncocyte.

Going concern assessment

In accordance with the Financial Accounting Standards Board's ("FASB") standard on going concern, Accounting Standard Update, or ASU No. 2014-15, Oncocyte assesses going concern uncertainty in its consolidated financial statements to determine if it has sufficient cash, cash equivalents and working capital on hand, including marketable equity securities, and any available borrowings on loans, to operate for a period of at least one year from the date the consolidated financial statements are issued, which is referred to as the "look-forward period" as defined by ASU No. 2014-15. As part of this assessment, based on conditions that are known and reasonably knowable to Oncocyte, it will consider various scenarios, forecasts, projections, estimates and will make certain key assumptions, including the timing and nature of projected cash expenditures or programs, and its ability to delay or curtail expenditures or programs, if necessary, among other factors. Based on this assessment, as necessary or applicable, Oncocyte makes certain assumptions around implementing curtailments or delays in the nature and timing of programs and expenditures to the extent Oncocyte deems probable those implementations can be achieved and it has the proper authority to execute them within the look-forward period in accordance with ASU No. 2014-15.

Business combinations and fair value measurements

Oncocyte accounts for business combinations in accordance with ASC 805, which requires the purchase consideration transferred to be measured at fair value on the acquisition date in accordance with ASC 820, *Fair Value Measurement*. ASC 820 establishes a single authoritative definition of fair value, sets out a framework for measuring fair value and expands on required disclosures about fair value measurement. Fair value is defined as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. Valuation techniques used to measure fair value must maximize the use of observable inputs and minimize the use of unobservable inputs to the extent possible. ASC 820 describes a fair value hierarchy based on three levels of inputs, of which the first two are considered observable and the last unobservable, that may be used to measure fair value, which are the following:

- *Level 1* – Quoted prices in active markets for identical assets and liabilities.
- *Level 2* – Inputs other than Level 1 that are observable, either directly or indirectly, such as quoted market prices for similar assets or liabilities; quoted prices in markets that are not active; or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities.
- *Level 3* – Unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities.

When a part of the purchase consideration consists of shares of Oncocyte common stock, Oncocyte calculates the purchase price attributable to those shares, a Level 1 security, by determining the fair value of those shares quoted on the NYSE American as of the acquisition date. Oncocyte recognizes estimated fair values of the tangible assets and identifiable intangible assets acquired, including IPR&D, and liabilities assumed, including any contingent consideration, as of the acquisition date. Goodwill is recognized as any amount of the fair value of the tangible and identifiable intangible assets acquired and liabilities assumed in excess of the consideration transferred. ASC 805 precludes the recognition of an assembled workforce as an asset, effectively subsuming any assembled workforce value into goodwill.

In determining fair value, Oncocyte utilizes valuation techniques that maximize the use of observable inputs and minimize the use of unobservable inputs to the extent possible, and also considers counterparty credit risk in its assessment of fair value. For the periods presented, Oncocyte has no financial assets or liabilities recorded at fair value on a recurring basis, except for cash and cash equivalents consisting of money market funds and marketable equity securities of Lineage and AgeX common stock held by Oncocyte described below. These assets are measured at fair value using the period-end quoted market prices as a Level 1 input. Oncocyte also has certain contingent consideration liabilities which are carried at fair value based on Level 3 inputs (see Note 3).

The following table presents the Company's assets and liabilities, measured and recognized at fair value on a recurring basis, classified under the appropriate level of the fair value hierarchy as of December 31, 2022 (in thousands):

	As of December 31, 2022			
	Total carrying and estimated fair value	**Quoted prices in active markets (Level 1)**	**Significant other observable inputs (Level 2)**	**Significant other observable inputs (Level 3)**
Assets:				
Marketable equity securities	$ 433	$ 433	$ -	$ -
Total	$ 433	$ 433	$ -	$ -
Liabilities:				
Contingent consideration liabilities	$ 45,662	$ -	$ -	$ 45,662

Total	$ 45,662	$ -	$ -	$ 45,662

74

The following table presents the Company's assets and liabilities, measured and recognized at fair value on a recurring basis, classified under the appropriate level of the fair value hierarchy as of December 31, 2021 (in thousands):

	As of December 31, 2021			
	Total carrying and estimated fair value	Quoted prices in active markets (Level 1)	Significant other observable inputs (Level 2)	Significant other observable inputs (Level 3)
Assets:				
Marketable equity securities	$ 904	$ 904	$ -	$ -
Total	$ 904	$ 904	$ -	$ -
Liabilities:				
Contingent consideration liabilities	$ 76,681	$ -	$ -	$ 76,681
Total	$ 76,681	$ -	$ -	$ 76,681

The carrying amounts of prepaid expenses and other current assets, accounts payable, accrued expenses and other current liabilities approximate fair values because of the short-term nature of these items.

Cash and cash equivalents

The Company's reconciliation of cash and cash equivalents, and restricted cash reported within the audited consolidated balance sheets that sum to the total of the same amounts shown in the audited consolidated statements of cash flows were as follows (in thousands):

	December 31,	
	2022	2021
Cash and cash equivalents	$ 19,993	$ 32,948
Restricted cash	1,700	1,700
Cash from discontinued operations	1,510	2,657
Cash, cash equivalents and restricted cash shown in the statements of cash flows	$ 23,203	$ 37,305

Assets Held for Sale and Discontinued Operations

On December 16, 2022 the Company entered into the Razor Stock Purchase Agreement with Dragon and Razor, pursuant to which Oncocyte agreed to transfer to Dragon 70% of its ownership of Razor and all of the assets and liabilities related to DetermaRx to Razor. The Razor Stock Purchase Agreement provides that Oncocyte will retain 30% stake in Razor.

Assets and liabilities are classified as held for sale when all of the following criteria for a plan of sale have been met: (1)management, having the authority to approve the action, commits to a plan to sell the assets; (2) the assets are available for immediate sale, in their present condition, subject only to terms that are usual and customary for sales of such assets; (3) an active program to locate a buyer and other actions required to complete the plan to sell the assets have been initiated; (4) the sale of the assets is probable and is expected to be completed within one year; (5) the assets are being actively marketed for a price that is reasonable in relation to their current fair value; and (6) actions required to complete the plan indicate that it is unlikely that significant changes to the plan will be made or the plan will be withdrawn. When all of these criteria have been met, the assets and liabilities are classified as held for sale in the consolidated balance sheet. Assets classified as held for sale are reported at the lower of their carrying value or fair value less costs to sell. Depreciation and amortization of assets ceases upon designation as held for sale.

Discontinued operations comprise activities that were disposed of, discontinued or held for sale at the end of the period, represent a separate major line of business that can be clearly distinguished for operational and financial reporting purposes and represent a strategic business shift having a major effect on the Company's operations and financial results according to Accounting Standard Codification ("ASC") Topic 205, *Presentation of Financial Statements*.

Additional details surrounding the Company's assets and liabilities held for sale and discontinued operations are included in Note 16.

Goodwill and intangible assets

In accordance with ASC 350, *Intangibles – Goodwill and Other*, IPR&D projects acquired in a business combination that are not complete as of the acquisition date are capitalized and accounted for as indefinite-lived intangible assets until completion or abandonment of the related research and development efforts. Upon successful completion of the project, the capitalized amount is amortized over its estimated useful life. If a project is abandoned, all remaining capitalized amounts are written off immediately. Oncocyte considers various factors and risks for potential impairment of IPR&D assets, including the current legal and regulatory environment and the competitive landscape. Adverse clinical trial results, significant delays or inability to obtain local determination coverage ("LCD") from the Centers for Medicare and Medicaid Services ("CMS") for Medicare reimbursement for a diagnostic test, the inability to bring a diagnostic test to market and the introduction or advancement of competitors' diagnostic tests could result in partial or full impairment of the related intangible assets. Consequently, the eventual realized value of the IPR&D project may vary from its fair value at the date of acquisition, and IPR&D impairment charges may occur in future periods. During the period between completion or abandonment, the IPR&D assets will not be amortized but will be tested for impairment on an annual basis and between annual tests if Oncocyte becomes aware of any events occurring or changes in circumstances that would indicate a reduction in the fair value of the IPR&D projects below their respective carrying amounts (see Notes 3 and 4).

Goodwill represents the excess of the purchase price over the fair value of net identifiable assets and liabilities. Goodwill, similar to IPR&D, is not amortized but is tested for impairment at least annually, or if circumstances indicate its value may no longer be recoverable. Qualitative factors considered in this assessment include industry and market conditions, overall financial performance, and other relevant events and factors affecting Oncocyte's business. Based on the qualitative assessment, if it is determined that the fair value of goodwill is more likely than not to be less than its carrying amount, the fair value of a reporting unit will be calculated and compared with its carrying amount and an impairment charge will be recognized for the amount that the carrying value exceeds the fair value. Oncocyte continues to operate in one segment and considered to be the sole reporting unit and, therefore, goodwill is tested for impairment at the enterprise level.

Oncocyte does not have intangible assets with indefinite useful lives other than goodwill and the acquired IPR&D discussed in Notes 3 and 4. As of December 31, 2022, goodwill has been fully impaired and a loss was recorded, IPR&D assets are not impaired.

Contingent consideration liabilities

Certain of Oncocyte's asset and business acquisitions involve the potential for future payment of consideration to third-parties and former selling shareholders in amounts determined as a percentage of future net revenues generated, or upon attainment of revenue milestones, from Pharma Services or diagnostic tests, as applicable, or annual minimum royalties to certain licensors, as provided in the applicable agreements. The fair value of such liabilities is determined using unobservable inputs. These inputs include the estimated amount and timing of projected cash flows and the risk-adjusted discount rate used to present value the cash flows. These obligations are referred to as contingent consideration.

ASC 805 requires that contingent consideration be estimated and recorded at fair value as of the acquisition date as part of the total consideration transferred. Contingent consideration is an obligation of the acquirer to transfer additional assets or equity interests to the selling shareholders in the future if certain future events occur or conditions are met, such as the attainment of product development milestones. Contingent consideration also includes additional future payments to selling shareholders based on achievement of components of earnings, such as "earn-out" provisions or percentage of future revenues, including royalties paid to the selling shareholders based on a percentage of certain revenues generated.

The fair value of contingent consideration after the acquisition date is reassessed by Oncocyte as changes in circumstances and conditions occur, with the subsequent change in fair value recorded in the consolidated statements of operations. Changes in key assumptions can materially affect the estimated fair value of contingent consideration liabilities and, accordingly, the resulting gain or loss that Oncocyte records in its consolidated financial statements. See Note 3 for a full discussion of these liabilities.

Investments in capital stock of privately held companies

Oncocyte evaluates whether investments held in common stock of other companies require consolidation of the company under, first, the variable interest entity ("VIE") model, and then under the voting interest model in accordance with accounting guidance for consolidations under Accounting Standards Codification ("ASC") 810-10. If consolidation of the entity is not required under either the VIE model or the voting interest model, Oncocyte determines whether the equity method of accounting should be applied in accordance with ASC 323, *Investments – Equity Method and Joint Ventures*. The equity method applies to investments in common stock or in-substance common stock if Oncocyte exercises significant influence over, but does not control, the entity, where significant influence is typically represented by ownership of 20% or more, but less than majority ownership, of the voting interests of a company.

Oncocyte initially records equity method investments at fair value on the date of the acquisition with subsequent adjustments to the investment balance based on Oncocyte's pro rata share of earnings or losses from the investment.

Since February 24, 2021, the date of Oncocyte's acquisition of the remaining interests in Razor, the Razor entity's financial statements have been consolidated with Oncocyte (see Notes 3 and 4).

Leases

Oncocyte accounts for leases in accordance with ASC 842, *Leases*. Oncocyte determines if an arrangement is a lease at inception. Leases are classified as either financing or operating, with classification affecting the pattern of expense recognition in the consolidated statements of operations. Under the available practical expedients for the adoption of ASC 842, Oncocyte accounts for the lease and non-lease components as a single lease component. Oncocyte recognizes right-of-use ("ROU") assets and lease liabilities for leases with terms greater than twelve months in the consolidated balance sheet. ROU assets represent the right to use an underlying asset during the lease term and lease liabilities represent the obligation to make lease payments arising from the lease. Operating lease ROU assets and liabilities are recognized at commencement date based on the present value of lease payments over the lease term. As most leases do not provide an implicit rate, Oncocyte uses an incremental borrowing rate based on the information available at commencement date in determining the present value of lease payments. Oncocyte uses the implicit rate when it is readily determinable. The operating lease ROU asset also includes any lease payments made and excludes lease incentives. Lease terms may include options to extend or terminate the lease when it is reasonably certain that Oncocyte will exercise that option. Lease expense for lease payments is recognized on a straight-line basis over the lease term. Operating leases are included as right-of-use assets in machinery and equipment, and ROU lease liabilities, current and long-term, in the consolidated balance sheets. Financing leases are included in machinery and equipment, and in financing lease liabilities, current and long-term, in the consolidated balance sheets. Oncocyte discloses the amortization of our ROU assets and operating lease payments as a net amount, "Amortization of right-of-use assets and liabilities", on the consolidated statements of cash flows. Based on the available practical expedients under the standard, Oncocyte elected not to capitalize leases that have terms of twelve months or less.

During 2022 and 2021, Oncocyte entered into various operating leases and an embedded operating lease in accordance with ASC 842 discussed in Note 10. Oncocyte's accounting for financing leases remained substantially unchanged.

Accounting for Lineage and AgeX shares of common stock

Oncocyte accounts for the shares of Lineage and AgeX common stock it holds as marketable equity securities in accordance with ASC 320-10-25, *Investments – Debt and Equity Securities*, as amended by Accounting Standards Update ("ASU") 2016-01, *Financial Instruments–Overall: Recognition and Measurement of Financial Assets and Financial Liabilities*, as the shares have a readily determinable fair value quoted on the NYSE American and are held principally to meet future working capital purposes, as necessary. The securities are measured at fair value, with related gains and losses in the value of such securities recorded in the consolidated statements of operations in other income (expense) and are reported as current assets on the consolidated balance sheets based on the closing trading price of the security as of the date being presented.

As of December 31, 2022, Oncocyte held 353,264 and 35,326 shares of common stock of Lineage and AgeX, respectively, as marketable equity securities with a fair market value of $0.4 million and $19thousand, respectively.

Machinery and equipment, construction in progress

Machinery and equipment are stated at cost, less accumulated depreciation. Depreciation is computed using the straight-line method over the estimated useful lives of the assets, generally over a period of 3 to 10 years. For equipment purchased under financing leases, Oncocyte depreciates the equipment based on the shorter of the useful life of the equipment or the term of the lease, ranging from 3 to 5 years, depending on the nature and classification of the financing lease. Maintenance and repairs are expensed as incurred whereas significant renewals and betterments are capitalized. When assets are retired or otherwise disposed of, the cost and the related accumulated depreciation are removed from the respective accounts and any resulting gain or loss is reflected in Oncocyte's results of operations.

Construction in progress, comprised primarily of leasehold improvements under construction, is not depreciated until the underlying asset is placed into service.

Long-lived intangible assets

Long-lived intangible assets, consisting of acquired Razor asset and customer relationships, are stated at acquired cost, less accumulated amortization. Amortization expense is computed using the straight-line method over the estimated useful life of 5 years (see Note 3).

Impairment of long-lived assets

Oncocyte assesses the impairment of long-lived assets, which consist primarily of right-of-use assets for operating leases, customer relationships and machinery and equipment, whenever events or changes in circumstances indicate that such assets might be impaired and the carrying value may not be recoverable. If events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable and the expected undiscounted future cash flows attributable to the asset are less than the carrying amount of the asset, an impairment loss equal to the excess of the asset's carrying value of the asset over its fair value is recorded.

As of December 31, 2022 and 2021, there has been no other impairment of long-lived assets from continuing operations.

Accounting for warrants

Oncocyte determines the accounting classification of warrants it issues, as either liability or equity classified, by first assessing whether the warrants meet liability classification in accordance with ASC 480-10, *Accounting for Certain Financial Instruments with Characteristics of both Liabilities and Equity*, then in accordance with ASC 815-40, *Accounting for Derivative Financial Instruments Indexed to, and Potentially Settled in, a Company's Own Stock*. Under ASC 480, warrants are considered liability classified if the warrants are mandatorily redeemable, obligate Oncocyte to settle the warrants or the underlying shares by paying cash or other assets or warrants that must or may require settlement by issuing variable number of shares. If warrants do not meet liability classification under ASC 480-10, Oncocyte assesses the requirements under ASC 815-40, which states that contracts that require or may require the issuer to settle the contract for cash are liabilities recorded at fair value, irrespective of the likelihood of the transaction occurring that triggers the net cash settlement feature. If the warrants do not require liability classification under ASC 815-40, and in order to conclude equity classification, Oncocyte also assesses whether the warrants are indexed to its common stock and whether the warrants are classified as equity under ASC 815-40 or other applicable GAAP. After all relevant assessments, Oncocyte concludes whether the warrants are classified as liability or equity. Liability classified warrants require fair value accounting at issuance and subsequent to initial issuance with all changes in fair value after the issuance date recorded in the statements of operations. Equity classified warrants only require fair value accounting at issuance with no changes recognized subsequent to the issuance date. Oncocyte does not have any liability classified warrants as of any period presented (see Note 5).

Income taxes

Oncocyte and its subsidiaries file a consolidated U.S. federal income tax return and combined California state return for the years ended December 31, 2022 and 2021. Oncocyte accounts for income taxes in accordance with ASC 740, *Income Taxes*, which prescribes the use of the asset and liability method, whereby deferred tax asset or liability account balances are calculated at the balance sheet date using current tax laws and rates in effect. Valuation allowances are established when necessary to reduce deferred tax assets when it is more likely than not that a portion or all of the deferred tax assets will not be realized. Oncocyte's judgments regarding future taxable income may change over time due to changes in market conditions, changes in tax laws, tax planning strategies or other factors. If Oncocyte's assumptions and consequently its estimates change in the future, the valuation allowance may be increased or decreased, which may have a material impact on Oncocyte's statements of operations.

The guidance also prescribes a recognition threshold and a measurement attribute for the financial statement recognition and measurement of tax positions taken or expected to be taken in a tax return. For those benefits to be recognized, a tax position must be more-likely-than-not sustainable upon examination by taxing authorities. Oncocyte will recognize accrued interest and penalties related to unrecognized tax benefits as income tax expense. No amounts were accrued for the payment of interest and penalties as of December 31, 2022 and 2021. Oncocyte is not aware of any uncertain tax positions that could result in significant additional payments, accruals, or other material deviation for the years ended December 31, 2022 and 2021. Oncocyte is currently unaware of any tax issues under review.

On December 21, 2020, the U.S. president signed into law the "Consolidated Appropriations Act, 2021" which includes further COVID-19 economic relief and extension of certain expiring tax provisions. The relief package includes a tax provision clarifying that businesses with forgiven PPP loans can deduct regular business expenses that are paid for with the loan proceeds for federal tax purposes. Additional pandemic relief tax measures include an expansion of the employee retention credit, enhanced charitable contribution deductions, and a temporary full deduction for business expenses for food and beverages provided by a restaurant (see Note 12).

In accordance with the 2017 Tax Act, research and experimental (R&E) expenses under Internal Revenue Code Section 174 are required to be capitalized beginning in 2022. R&E expenses are required to be amortized over a period of 5 years for domestic expenses and 15 years for foreign expenses.

The Inflation Reduction Act of 2022 specifically introduces the topic of corporate alternative minimum tax ("CAMT") on adjusted financial statement income on applicable corporations for taxable years beginning after December 31, 2022. There is no impact to our current tax provision.

Revenue recognition

Pursuant to ASC 606, revenues are recognized when control of services performed is transferred to customers, in an amount that reflects the consideration Oncocyte expects to be entitled to in exchange for those services. ASC 606 provides for a five-step model that includes:

(i) identifying the contract with a customer,
(ii) identifying the performance obligations in the contract,
(iii) determining the transaction price,
(iv) allocating the transaction price to the performance obligations, and
(v) recognizing revenue when, or as, an entity satisfies a performance obligation.

Oncocyte determines transaction prices based on the amount of consideration we expect to receive for transferring the promised goods or services in the contract. Consideration may be fixed, variable, or a combination of both. The Company considers any constraints on the variable consideration and includes in the transaction price variable consideration to the extent it is deemed probable that a significant reversal in the amount of cumulative revenue recognized will not occur when the uncertainty associated with the variable consideration is subsequently resolved.

DetermaRx testing revenue

Oncocyte generates revenue from performing DetermaRx tests on clinical samples through orders received from physicians, hospitals, and other healthcare providers. In determining whether all the revenue recognition criteria (i) through (v) above are met with respect to DetermaRx tests, each test result is considered a single performance obligation and is generally considered complete when the test result is delivered or made available to the prescribing physician electronically, and, as such, there are no shipping or handling fees incurred by Oncocyte or billed to customers. Although Oncocyte bills a list price for all tests ordered and completed for all payer types, Oncocyte considers constraints on the variable consideration when recognizing revenue for DetermaRx. Because DetermaRx is a novel test and there are no current reimbursement arrangements with third-party payers other than Medicare, the transaction price represents variable consideration. Application of the constraint for variable consideration is an area that requires significant judgment. For all payers other than Medicare, Oncocyte must consider the novelty of the test, the uncertainty of receiving payment, or being subject to claims for a refund, from payers with whom it does not have a sufficient payment collection history or contractual reimbursement agreements. Accordingly, for those payers, Oncocyte expects to continue to recognize revenue upon payment until it has a sufficient history to reliably estimate payment patterns or has contractual reimbursement arrangements, or both, in place.

As of December 31, 2022, Oncocyte had accounts receivable of $1.8 million from Medicare and Medicare Advantage covered DetermaRx test. As of December 31, 2021, Oncocyte had accounts receivable of $1.1 million from Medicare covered DetermaRx tests. DetermaRx accounts receivable balance has been included in the current assets from discontinued operations. (see Notes 16 and 17).

We maintain an allowance for doubtful accounts at an amount we estimate to be sufficient to provide adequate protection against losses resulting from extending credit to our customers. We base this allowance, in the aggregate, on historical collection experience, age of receivables and general economic conditions. Our bad debts have not been material and have been within management expectations. As of December 31, 2022, we had a bad debt allowance of $0.2 million. As of December 31, 2021, we had no bad debt allowance.

Pharma services revenue

Revenues recognized include Pharma Services performed by Oncocyte's Insight and Chronix subsidiaries for its pharmaceutical customers, including testing for biomarker discovery, assay design and development, clinical trial support, and a broad spectrum of biomarker tests. These Pharma Services are generally performed under individual scope of work ("SOW") arrangements or license agreements (together with SOW the "Pharma Services Agreements") with specific deliverables defined by the customer. Pharma Services are performed on a (i) time and materials basis or (ii) per test completed basis. Upon completion of the service to the customer in accordance with a Pharma Services Agreement, Oncocyte has the right to bill the customer for the agreed upon price (either on a per test or per deliverable basis) and recognizes Pharma Service revenue at that time. Insight identifies each sale of its Pharma Service offering as a single performance obligation. Chronix identifies the processing of test samples as a separate performance obligation (considered a series) within license agreements with customers.

Completion of the service and satisfaction of the performance obligation is typically evidenced by access to the report or test made available to the customer or any other form or applicable manner of delivery defined in the Pharma Services Agreements. However, for certain SOWs under which work is performed pursuant to the customer's highly customized specifications, Oncocyte has the enforceable right to bill the customer for work completed, rather than upon completion of the SOW. For those SOWs, Oncocyte recognizes revenue over a period during which the work is performed using a formula that accounts for expended efforts, generally measured in labor hours, as a percentage of total estimated efforts for the completion of the SOW. As performance obligations are satisfied under the Pharma Services Agreements, any amounts earned as revenue and billed to the customer are included in accounts receivable. Any revenues earned but not yet billed to the customer as of the date of Oncocyte's consolidated financial statements are recorded as contract assets and are included in prepaids and other current assets as of the financial statement date. Amounts recorded in contract assets are reclassified to accounts receivable in Oncocyte's consolidated financial statements when the customer is invoiced according to the billing schedule in the contract.

Oncocyte establishes an allowance for doubtful accounts based on the evaluation of the collectability of its Pharma Services accounts receivables after considering a variety of factors, including the length of time receivables are past due, significant events that may impair the customer's ability to pay, such as a bankruptcy filing or deterioration in the customer's operating results or financial position, reasonable and supportable forecast that affect the collectability of the reported amount, and historical experience. If circumstances related to customers change, estimates of the recoverability of receivables would be further adjusted. Amounts determined to be uncollectible are written off against the allowance for doubtful accounts. The Company has significant cash balances at financial institutions which throughout the year regularly exceed the federally insured limit of $250,000. Any loss incurred or a lack of access to such funds could have a significant adverse impact on the Company's financial condition, results of operations, and cash flows. As of December 31, 2022 and 2021, Oncocyte has not recorded any losses or allowance for doubtful accounts on its account receivables from Pharma Services.

As of December 31, 2022, Oncocyte had accounts receivable from Pharma Services customers of $0.3 million, as compared to $0.4 million as of December 31, 2021 (see Note 7).

Licensing revenue

Revenues recognized includes licensing revenue derived from agreements with customers for exclusive rights to market Oncocyte's proprietary testing technology. Under the agreements, Oncocyte grants exclusive rights to certain trademarks and technology of Oncocyte for the purpose of marketing Oncocyte's tests within a defined geographic territory. A license agreement may specify milestone deliverables or performance obligations, for which Oncocyte recognizes revenue when its licensee confirms the completion of Oncocyte's performance obligation. A licensing agreement may also include ongoing sales support from Oncocyte and typically includes non-refundable licensing fees and per-test Pharma Services revenues discussed above, for which Oncocyte treats the licensing of the technology, trademarks, and ongoing support as a single performance obligation satisfied by the passage of time over the term of the agreement.

Cost of revenues

Cost of revenues generally consists of cost of materials, direct labor including benefits, bonus and stock-based compensation, equipment and infrastructure expenses, clinical sample related costs associated with performing DetermaRx tests and Pharma Services, providing deliverables according to our licensing agreements, license fees due to third parties, and amortization of acquired intangible assets. Infrastructure expenses include depreciation of laboratory equipment, allocated rent costs, leasehold improvements, and allocated information technology costs for operations at Oncocyte's CLIA laboratories in California and Tennessee. Costs associated with generating the revenues are recorded as the tests or services are performed regardless of whether revenue was recognized.

Research and development expenses

Research and development expenses are comprised of costs incurred to develop technology, which include salaries and benefits (including stock-based compensation), laboratory expenses (including reagents and supplies used in research and development laboratory work), infrastructure expenses (including allocated facility occupancy costs), and contract services and other outside costs. Indirect research and development expenses are allocated primarily based on headcount, as applicable, and include rent and utilities, common area maintenance, telecommunications, property taxes, and insurance. Research and development costs are expensed as incurred.

Sales and marketing expenses

Sales and marketing expenses consist primarily of personnel costs and related benefits, including stock-based compensation, trade show expenses, branding and positioning expenses, and consulting fees. Sales and marketing expenses also include indirect expenses for applicable overhead allocated based on headcount, and include allocated costs for rent and utilities, common area maintenance, telecommunications, property taxes, and insurance.

General and administrative expenses

General and administrative expenses consist primarily of compensation and related benefits (including stock-based compensation) for executive and corporate personnel, professional and consulting fees, rent and utilities, common area maintenance, telecommunications, property taxes, and insurance.

Stock-based compensation

Oncocyte recognizes compensation expense related to employee option grants and restricted stock grants, if any, in accordance with FASB ASC 718, *Compensation – Stock Compensation* ("ASC 718").

All excess tax benefits and tax deficiencies from stock-based compensation awards accounted for under ASC 718 are recognized as income tax benefit or expense, respectively, in the statements of operations. An excess income tax benefit arises when the tax deduction of a share-based award for income tax purposes exceeds the compensation cost recognized for financial reporting purposes and, a tax deficiency arises when the compensation cost exceeds the tax deduction. Because Oncocyte has a full valuation allowance for all periods presented (see Note 8), there was no impact to Oncocyte statements of operations for any excess tax benefits or deficiencies, as any excess benefit or deficiency would be offset by the change in the valuation allowance. Forfeitures are accounted for as they occur.

Oncocyte estimates the fair value of employee stock-based payment awards on the grant-date and recognizes the resulting fair value over the requisite service period. For stock-based awards that vest only upon the attainment of one or more performance goals set by Oncocyte at the time of the grant (sometimes referred to as milestone vesting), compensation cost is recognized if and when Oncocyte determines that it is probable that the performance condition or conditions will be, or have been, achieved. Oncocyte uses the Black-Scholes option pricing model for estimating the fair value of options granted under Oncocyte's equity plans. The fair value of each restricted stock grant, if any, is determined based on the value of the common stock granted or sold. Oncocyte has elected to treat stock-based payment awards with graded vesting schedules and time-based service conditions as a single award and recognizes stock-based compensation on a straight-line basis over the requisite service period.

The Black-Scholes option pricing model requires Oncocyte to make certain assumptions including the expected option term, the expected volatility, the risk-free interest rate and the dividend yield (see Note 6).

The expected term of employee stock options represents the weighted-average period that the stock options are expected to remain outstanding. Oncocyte estimates the expected term of options granted based on its own experience and, in part, based on upon the "simplified method" provided under *Staff Accounting Bulletin, Topic 14*, or SAB Topic 14, as necessary. For the years ended December 31, 2022 and 2021, Oncocyte estimated the expected volatility using its own stock price volatility to the extent applicable or a combination of its stock price volatility and the stock price volatility of peer companies, for a period equal to the expected term of the options. The risk-free interest rate assumption is based upon observed interest rates on the United States government securities appropriate for the expected term of Oncocyte's stock options. The dividend yield assumption is based on Oncocyte's history and expectation of dividend payouts. Oncocyte has never declared or paid any cash dividends on its common stock, and Oncocyte does not anticipate paying any cash dividends in the foreseeable future.

Net loss per common share

Basic loss per share is computed by dividing the net loss applicable to common stockholders after deducting cumulative unpaid dividends and accretion of the preferred stock, by the weighted average number of shares of common stock outstanding during the year. Diluted loss per share is computed by dividing the net loss applicable to common stockholders after deducting cumulative unpaid dividends and accretion of the preferred stock, by the weighted average number of common shares outstanding plus the number of additional common shares that would have been outstanding if all dilutive potential common shares had been issued, using the treasury stock method or the if-converted method, or the two-class method for participating securities, whichever is more dilutive. Potential common shares are excluded from the computation if their effect is antidilutive.

All common stock equivalents are antidilutive because Oncocyte reported a net loss for all periods presented. The following table presents the calculation of basic and diluted loss per share of common stock (in thousands):

	Year Ended December 31,	
	2022	**2021**
Numerator:		
Net loss attributable to Oncocyte Corporation, from continuing operations	$ (18,612)	$ (43,610)
Net loss attributable to Oncocyte Corporation, from discontinuing operations	$ (54,290)	$ (20,487)
Accretion of Series A redeemable convertible preferred stock	(520)	-
Net loss at attributable to common stockholders - Basic and Diluted	$ (73,422)	$ (64,097)
Denominator:		
Weighted average shares used in computing net loss per share attributable to common stockholders - Basic and Diluted	110,800	88,920
Basic and diluted from continuing operations, net loss	$ (0.17)	$ (0.49)
Basic and diluted from discontinuing operations, net loss	$ (0.49)	$ (0.23)
Basic and diluted net loss per common share	$ (0.66)	$ (0.72)
Anti-dilutive potential common shares excluded from the computation of diluted net loss per common share:		
Stock options	13,665	4,579
RSUs	36	-
Warrants	16,395	2,252
Series A redeemable convertible preferred stock	3,845	-
Total	33,941	6,831

Segments

Oncocyte's executive management team, as a group, represents the entity's chief operating decision makers. To date, Oncocyte's executive management team has viewed Oncocyte's operations as one segment that includes the research, development and commercialization of diagnostic tests for the detection of cancer, including molecular diagnostic services to pharmaceutical customers. As a result, the financial information disclosed materially represents all of the financial information related to Oncocyte's sole operating segment.

Recently issued accounting pronouncements not yet adopted

The following accounting standards, which are not yet effective, are presently being evaluated by Oncocyte to determine the impact that it might have on its consolidated financial statements.

In June 2016, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") No. 2016-13, Financial Instruments-Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments and subsequent amendments to the initial guidance under ASU 2018-19, ASU 2019-04, ASU 2019-05 and ASU 2019-10, which amends the current approach to estimate credit losses on certain financial assets, including trade and other receivables. Generally, this amendment requires entities to establish a valuation allowance for the expected lifetime losses of these certain financial assets. Upon the initial recognition of such assets, which will be based on, among other things, historical information, current conditions, and reasonable supportable forecasts. Subsequent changes in the valuation allowance are recorded in current earnings and reversal of previous losses are permitted. Currently, U.S. GAAP requires entities to write down credit losses only when losses are probable and loss reversals are not permitted. This guidance will become effective for the Company beginning January 1, 2023. The Company evaluated the guidance and determined the overall impact of the adoption will have an immaterial impact on our consolidated financial statements.

In October 2021, the FASB issued ASU No. 2021-08, Business Combinations (Topic 805): *Accounting for Contract Assets and Contract Liabilities from Contracts with Customers*, to provide specific guidance to eliminate diversity in practice on how to recognize and measure acquired contract assets and contract liabilities from revenue contracts from customers in a business combination consistent with revenue contracts with customers not acquired in an acquisition. The amendments in this update provide that the acquirer should consider the terms of the acquired contracts, such as timing of payment, identify each performance obligation in the contracts, and allocate the total transaction price to each identified performance obligation on a relative standalone selling price basis as of contract inception (that is, the date the acquiree entered into the contracts) or contract modification to determine what should be recorded at the acquisition date. These amendments are effective for the Company beginning with fiscal year 2023. The impact of the adoption of the amendments in this update will depend on the magnitude of any customer contracts assumed in a business combination in 2023 and beyond.

COVID-19 impact and related risks

The recent global outbreak of COVID-19, and the various attempts throughout the world to contain it, have created significant volatility, uncertainty and disruption. In response to government directives and guidelines, health care advisories and employee and other concerns, Oncocyte has altered certain aspects of its operations. A number of Oncocyte's employees have had to work remotely from home and those on site have had to follow Oncocyte's social distance guidelines, which could impact their productivity. COVID-19 could also disrupt Oncocyte's operations due to absenteeism by infected or ill members of management or other employees, or absenteeism by members of management and other employees who cannot effectively work remotely but who elect not to come to work due to the illness affecting others in Oncocyte's office or laboratory facilities, or due to quarantines.

In addition to operational adjustments, the consequences of the COVID-19 pandemic have led to uncertainties related to Oncocyte's business growth and ability to forecast the demand for its laboratory tests and Pharma Services and resulting revenues. Concerns over available hospital, staffing, equipment, and other resources, and the risk of exposure to the virus, have led to delays in clinical trials of drugs under development by pharma companies, and the continued deferral of drug development clinical trials due to resurgence in COVID-19 cases could continue to result in delayed or reduced use of Oncocyte's Pharma Services.

It is possible that impacts of COVID-19 on Oncocyte's operations or revenues or its access to capital could prevent Oncocyte from complying, or could result in a material noncompliance, with one or more obligations or covenants under material agreements to which Oncocyte is a party, with the result that Oncocyte would be in material breach of the applicable obligation, covenant, or agreement. Any such material breach could cause Oncocyte to incur material financial liabilities or an acceleration of the date for paying a financial obligation to the other party to the applicable agreement, or could cause Oncocyte to lose material contractual rights, such as rights to use leased equipment or laboratory or office space, or rights to use licensed patents or other intellectual property the use of which is material to Oncocyte's business. Similarly, it is possible that impacts of COVID-19 on the business, operations, or financial condition of any third party with whom Oncocyte has a contractual relationship could cause the third party to be unable to perform its contractual obligations to Oncocyte, resulting in Oncocyte's loss of the benefits of a contract that could be material to Oncocyte's business.

The full extent to which the COVID-19 pandemic and the various responses to it might impact Oncocytes' business, operations and financial results will depend on numerous evolving factors that are not subject to accurate prediction and that are beyond Oncocyte's control.

3. Business Combinations

Acquisition of Insight Genetics, Inc.

On January 31, 2020 (the "Insight Merger Date"), Oncocyte completed its acquisition of Insight pursuant to the Insight Merger Agreement.

Contingent consideration liabilities – ASC 805 requires that contingent consideration be estimated and recorded at fair value as of the acquisition date as part of the total consideration transferred. Contingent consideration is an obligation of the acquirer to transfer additional assets or equity interests to the selling shareholders in the future if certain future events occur or conditions are met, such as the attainment of product development milestones. Contingent consideration also includes additional future payments to selling shareholders based on achievement of components of earnings, such as "earn-out" provisions or percentage of future revenues, including royalties paid to the selling shareholders based on a percentage of revenues generated from DetermaIO and Insight Pharma Services over their respective useful life. Accordingly, Oncocyte determined there are two types of contingent consideration in connection with the Insight Merger, the Milestone Contingent Consideration and the Royalty Contingent Consideration discussed below, which are collectively referred to as the "Contingent Consideration".

There are three milestones comprising the Milestone Contingent Consideration, collectively referred to as the Milestones, in connection with the Insight Merger which Oncocyte valued and recorded as part of Contingent Consideration as of the Insight Merger Date (see table below), which consist of (i) a payment for clinical trial completion and related data publication ("Milestone 1"), (ii) a payment for an affirmative final local coverage determination from CMS for a specified lung cancer test ("Milestone 2"), and (iii) a payment for achieving specified CMS reimbursement milestones ("Milestone 3"). If achieved, any respective Milestone will be paid at the contractual value shown below, with the payment made either in cash or in shares of Oncocyte common stock as determined by Oncocyte. There can be no assurance that any of the Milestones will be achieved.

There are two separate components of the Royalty Contingent Consideration, collectively referred to as the Royalty Payments, in connection with the Insight Merger which Oncocyte valued and recorded as part of Contingent Consideration as of the Insight Merger Date (see table below); Royalty Payments consist of (i) revenue share payments based on a percentage of future sales generated from DetermaIO ("Royalty 1"), and (ii) revenue share payments based on percentage of future sales generated from current Insight Pharma Service offerings, as defined in the Insight Merger Agreement ("Royalty 2"). There can be no assurance that any revenues on which the Royalty Payments are based will be generated from DetermaIO or Pharma Service offerings.

The following table shows the Insight Merger Date contractual payment amounts, as applicable, and the corresponding fair value of each respective Contingent Consideration liability (in thousands):

	Contractual Value	Fair Value on the Merger Date
Milestone 1	$ 1,500	$ 1,340
Milestone 2	3,000	1,830
Milestone 3 [(a)]	1,500	770
Royalty 1 [(b)]	See(b)	5,980
Royalty 2 [(b)]	See(b)	1,210
Total	$ 6,000	$ 11,130

(a) Indicates the maximum payable if the Milestone is achieved.

(b) As defined, Royalty Payments are based on a percentage of future revenues of DetermaIO and Pharma Services over their respective useful life, accordingly there is no fixed contractual value for the Royalty Contingent Consideration.

The fair value of the Milestone Contingent Consideration was determined using a scenario analysis valuation method which incorporates Oncocyte's assumptions with respect to the likelihood of achievement of the Milestones, credit risk, timing of the Milestone Contingent Consideration payments and a risk-adjusted discount rate to estimate the present value of the expected payments. The discount rate was estimated at approximately 15.8% after adjustment for the probability of achievement of the Milestones. No Milestone Contingent Consideration is payable with respect to a particular Milestone unless and until the Milestone is achieved. Since the Milestone Contingent Consideration payments are based on nonfinancial, binary events, management believes the use of the scenario analysis method is appropriate. The fair value of each Milestone after the Insight Merger Date is reassessed by Oncocyte as changes in circumstances and conditions occur, with the subsequent change in fair value recorded in Oncocyte's consolidated statements of operations.

The fair value of the Royalty Contingent Consideration was determined using a single scenario analysis method to value the Royalty Payments. The single scenario method incorporates Oncocyte's assumptions with respect to specified future revenues generated from DetermaIO and current Insight Pharma Services over their respective useful lives, credit risk, and a risk-adjusted discount rate to estimate the present value of the expected royalty payments. The credit and risk-adjusted discount rate was estimated at approximately 45%. Since the Royalty Contingent Consideration payments are based on future revenues and linear payouts, management believes the use of the single scenario method is appropriate.

The fair value of the Contingent Consideration after the Insight Merger Date is reassessed by Oncocyte as changes in circumstances and conditions occur, with the subsequent change in fair value recorded in Oncocyte's consolidated statements of operations. As of December 31, 2022, based on Oncocyte's reassessment of the significant assumptions noted above, there was a decrease of approximately $1.7 million to the fair value of the Contingent Consideration primarily attributable to revised estimates of the timing of the possible future payouts and, accordingly, this decrease was recorded as change in fair value of contingent consideration in the consolidated statements of operations for the year ended December 31, 2022.

The following tables reflect the activity for Oncocyte's Contingent Consideration for the years ended December 31, 2022 and December 31, 2021, measured at fair value using Level 3 inputs (in thousands):

	Fair Value
Balance at December 31, 2020	$ 7,120
Change in estimated fair value	(60)
Balance at December 31, 2021	$ 7,060
Change in estimated fair value	(1,690)
Balance at December 31, 2022	$ 5,370

Contingent consideration is not deductible for tax purposes, even if paid; therefore, no deferred tax assets related to the Contingent Consideration were recorded.

Asset acquisition of Razor Genomics, Inc.

On December 31, 2019, Oncocyte completed the purchase of 1,329,870 shares of Razor Series A Convertible Preferred Stock, par value $0.0001 per share (the "Razor Preferred Stock"), representing 25% of the outstanding equity of Razor on a fully diluted basis, for $10 million in cash (the "Initial Closing"), pursuant to a Subscription and Stock Purchase Agreement (the "Purchase Agreement") dated September 4, 2019, among Oncocyte, Encore Clinical, Inc. ("Encore"), and Razor. Pursuant to the Purchase Agreement, Oncocyte entered into Minority Holder Stock Purchase Agreements of like tenor (the "Minority Purchase Agreements") with the shareholders of Razor other than Encore (the "Minority Shareholders") for the future purchase of the shares of Razor common stock they own. Oncocyte has also entered into certain other agreements with Razor and Encore, including a Sublicense and Distribution Agreement (the "Sublicense Agreement"), a Development Agreement (the "Development Agreement"), and an amendment to a Laboratory Services Agreement (the "Laboratory Agreement") pursuant to which Oncocyte became a party to that agreement.

Purchase Option

The Purchase Agreement and Minority Shareholder Agreements granted Oncocyte the option to acquire the balance of the outstanding shares of Razor common stock from Encore under the Purchase Agreement and from the Minority Shareholders under the Minority Purchase Agreements (the "Option") for an additional $10 million in cash and Oncocyte common stock valued at $5 million in total (the "Additional Purchase Payment"). Oncocyte agreed to exercise the Option if, within a specified time frame, certain milestones are met related to the contracting of clinical trial sites for a clinical trial of DetermaRx.

On January 29, 2021, the principal shareholder of Razor informed Oncocyte that the milestone requiring Oncocyte to purchase the outstanding shares of Razor common stock had been attained under the Purchase Agreement and Minority Shareholder Purchase Agreements. On February 24, 2021, Oncocyte exercised the Option and completed the purchase of all the issued and outstanding shares of common stock of Razor and paid the selling shareholders in total $10 million in cash and issued a total of 982,318 shares of Oncocyte common stock having a market value of $5.7 million on that date. As a result of Oncocyte exercising the Option and purchasing the Razor common stock, Oncocyte is now the sole shareholder of Razor.

Development Agreement

Under the Development Agreement, Razor reserved as a "Clinical Trial Expense Reserve" $4 million of the proceeds it received at the Initial Closing from the sale of the Razor Preferred Stock to Oncocyte, to fund Razor's share of costs incurred in connection with a clinical trial of DetermaRx for purposes of promoting commercialization ("Clinical Trial").

On February 24, 2021, upon the completion of the outstanding shares of Razor common stock and consolidation of Razor's accounts, Oncocyte obtained control of approximately $3.4 million in cash from Razor, which was the remaining balance in the Clinical Trial Expense Reserve account that Razor was using to pay for the Clinical Trial expenses. Beginning on February 24, 2021, this balance was transferred to Oncocyte's control as part of the acquisition date assets and liabilities recorded from the Razor entity shown below. Oncocyte agreed to be responsible for all expenses for the Clinical Trial up to the total budget amount approved by representatives of Oncocyte and Encore on a Steering Committee, which is expected to cover multiple years and is estimated to cost up to $16 million.

Upon completion of enrollment of the full number of patients for the Clinical Trial, it was agreed that Oncocyte will issue to Encore and the Minority Shareholders shares of Oncocyte common stock with an aggregate market value at the date of issue equal to $3 million ("Clinical Trial Milestone Payment"). If the issuance of shares of common stock having a market value of $3 million would require Oncocyte to issue a number of shares that, when combined with any shares issued under the Purchase Agreement and the Minority Shareholder Purchase Agreements, would exceed the number of shares that may be issued without shareholder approval under applicable stock exchange rules, Oncocyte may deliver the number of shares permissible under stock exchange rules and an amount of cash necessary to bring the combined value of cash and shares to $3 million.

The Development Agreement was terminated on February 16, 2023 in connection with the Razor Stock Purchase Agreement. See Notes 16 and 17 for more details regarding the Razor Stock Purchase Agreement.

If, within a specified time frame, Encore is substantially responsible for obtaining funding to Oncocyte or Razor for the Clinical Trial from any third-party pharmaceutical company, a portion of such additional funding amount will be paid to Encore, subject to a $3 million cap on the payment to Encore if the funding is provided by a designated pharmaceutical company.

Sublicense Agreement

Under the Sublicense Agreement, Razor granted to Oncocyte an exclusive worldwide sublicense under certain patent rights applicable to DetermaRx in the field of use covered by the applicable license held by Razor for purposes of commercialization and development of DetermaRx.

Pursuant to the Razor Sublicense Agreement, Oncocyte will pay all royalties and all revenue sharing and earnout payments owed by Razor to certain third parties with respect to DetermaRx revenues, including the licensor of the patent rights sublicensed to Oncocyte, but those payments will be deducted from gross revenues to determine net revenues for the purpose of paying royalties to the former Razor shareholders. Total royalty and earnout payments to the former Razor shareholders, the licensor, and other third parties will be a low double-digit percentage, and in addition certain milestone payments may become due if cumulative net revenue benchmarks are reached. Royalties and earnout payments will be payable on a quarterly basis. This payment obligation will continue after Oncocyte's purchase of the Razor common stock from Encore and the Minority Shareholders.

The Sublicense Agreement was terminated on February 16, 2023 in connection with the Razor Stock Purchase Agreement. See Notes 16 and 17 for more details regarding the Razor Stock Purchase Agreement.

Laboratory Agreement

Under the Laboratory Agreement, Oncocyte has assumed Razor's Laboratory Agreement payment obligations of $450,000 per year (see Note 10). The Laboratory Agreement gives Oncocyte the right to use Razor's laboratory in Brisbane, California. Oncocyte pays Encore a quarterly fee for services related to operating and maintaining the CLIA laboratory, including certain staffing. The Laboratory Agreement expired on September 29, 2021.

Accounting for the Razor Investment

Beginning on the Initial Closing and through February 23, 2021, Oncocyte has accounted for the Razor investment under the equity method of accounting under ASC 323 because prior to the Additional Purchase Payment discussed above Oncocyte exercised significant influence over, but did not control, the Razor entity. Oncocyte did not control Razor because, among other factors, Oncocyte was entitled to designate one person to serve on a three-member board of directors of Razor, with the other two members designated by Encore. Also, any deadlocked decisions by a Steering Committee of Oncocyte and Encore representatives that makes decisions with respect to the Clinical Trial, other than with respect to the Clinical Trial budget, will be resolved by a member designated by Encore.

Prior to February 24, 2021, the aggregate Razor acquisition payments of $11.245 million incurred during September 2019 and a $4 million CMS milestone payment made by Oncocyte during June 2020 under the Development Agreement, were amortized over a 10-year useful life of DetermaRx and were reflected in Oncocyte's pro rata earnings and losses of the equity method investment in Razor in the consolidated statements of operations. Beginning on February 24, 2021, Razor's results are included with Oncocyte's consolidated results, primarily consisting of outside research and development expenses incurred by Razor for the Clinical Trial.

The Initial Closing equity method investment in Razor and the Additional Purchase Payment for the remaining interests in Razor are both considered an asset acquisition, rather than a business combination, because, among other factors, Razor had no workforce, no commercial product (Razor had granted all commercial rights to Oncocyte), no revenues, no distribution system and no facilities. Substantially all of the fair value of Razor's assets at the Initial Closing and on February 24, 2021 was concentrated in Razor's intangible asset, the DetermaRx patent and related know-how, thus satisfying the requirements of the practical screen test to be considered an asset acquisition in accordance with ASU 2017-01, *Business Combinations (Topic 805): Clarifying the Definition of a Business*. Accordingly, no goodwill may be recognized in an asset acquisition in accordance with ASC 805-50.

As Razor became a wholly owned subsidiary of Oncocyte on February 24, 2021, the DTA associated with the previous equity method investment was reversed. There is no tax effect of this reversal as the DTA had been fully offset by a valuation allowance (see Note 8). However, upon payment of the Additional Purchase Payment, Oncocyte recorded an additional step-up to fair value for the Razor intangible asset under ASC 805-50 for financial reporting purposes but this "step-up" is not recognized for income tax purposes. As a result, the fair value adjustment of the Razor intangible asset on the acquisition date generated a DTL in accordance with ASC 740. This DTL is computed using the fair value of the intangible assets on the acquisition date multiplied by Oncocyte's federal and state effective income tax rates, using the simultaneous equations method for asset acquisitions under the guidance provided in ASC 740-10-25-51, which requires that the DTL be recognized as part of the investment of the acquired asset instead of any immediate income tax expense or benefit arising from the recognition of the DTL. Furthermore, ASC 740 allows Oncocyte to treat acquired available deferred tax assets, such as Razor's NOLs (subject to the annual limitation under Section 382 of the Internal Revenue Code) as available DTAs to offset against the DTLs, as the DTLs are expected to reverse within the NOL carryforward period. Any excess DTAs over those DTLs would be assessed for a valuation allowance in accordance with ASC 740.

On February 24, 2021, Oncocyte estimated and recorded a net DTL of $7.1 million after offsetting the acquired available NOLs with the intangible asset shown in the table below. See Note 8 for a discussion related to the partial release of Oncocyte's valuation allowance pertaining to the DTL generated above in accordance with ASC 740.

On February 24, 2021, upon Oncocyte's acquisition of the outstanding common stock of Razor, the Razor intangible asset balance recorded on the acquisition date and included in Intangible Assets was as follows (in thousands):

	As of February 24, 2021
Razor intangible asset recorded on the acquisition date:	
Equity method investment carrying value	$ 13,147
Cash paid as Additional Purchase Payment for the Razor asset	10,000
Oncocyte common stock issued (982,318 shares issued at market value) as Additional Purchase Payment	5,756
Less: cash balance received from Razor for Clinical Trial expenses	(3,352)
Deferred tax liability generated from the Razor asset	7,077
Other	169
Total Razor investment asset balance as of February 24, 2021 [(a)]	$ 32,797

(a) *This balance will be amortized over the remaining useful life of the Razor asset, approximating 8.5 years, as of the February 24, 2021 acquisition date, with the amortization expense included in "Cost of revenues – amortization of acquired intangibles" on the consolidated statements of operations.*

Under ASC 805-50, for asset acquisitions, the remaining Clinical Trial Milestone Payment will be recorded only if the consideration is both probable (milestone has been achieved) and estimable in accordance with ASC 450, *Contingencies*, and as of December 31, 2022, no contingent consideration payment was recorded as the Clinical Trial Milestone Payment was not deemed probable of achievement as of that date.

Summarized standalone financial data for Razor from January 1, 2021 through February 23, 2021

The unaudited standalone results of operations for Razor prior to being consolidated with Oncocyte is summarized below (in thousands):

Condensed Statement of Operations [1]	For the period from January 1, 2021 through February 23, 2021 (unaudited)
Research and development expense	$ 125
General and administrative expense	-
Loss from operations	(125)
Net loss	$ (125)

(1) The unaudited condensed standalone statement of operations of Razor is provided for informational purposes only. Razor's results for the period from January 1, 2021 through February 23, 2021 are not included in Oncocyte's consolidated results of operations because Razor was not consolidated with Oncocyte's financial statements but had been accounted for under the equity method of accounting since the December 31, 2019 Initial Closing date, however, Oncocyte's results included its pro rata losses from Razor. Beginning on February 24, 2021, Razor's results are included with Oncocyte's consolidated results, primarily consisting of outside research and development expenses incurred by Razor for the Clinical Trial discussed above.

On December 15, 2022, the Company, entered into the Razor Stock Purchase Agreement with Dragon and Razor. Pursuant to the Razor Stock Purchase Agreement, Oncocyte agreed to sell to Dragon, 3,188,181 shares of common stock of Razor, which constitutes approximately 70% of the issued and outstanding equity interests of Razor on a fully-diluted basis, and transfer to Razor all of the assets and liabilities related to DetermaRx. Following the Razor Closing, Oncocyte will own approximately 30% of the issued and outstanding equity interests of Razor on a fully-diluted basis. See Notes 16 and 17 for more details.

Acquisition of Chronix Biomedical, Inc.

On April 15, 2021, the Chronix Merger Date, Oncocyte completed its acquisition of Chronix pursuant the Chronix Merger Agreement.

Merger Consideration at Closing

Pursuant to the Chronix Merger Agreement, Oncocyte agreed to deliver closing consideration consisting of approximately (i) 648,000 shares of Oncocyte common stock (the "Closing Shares"), which represents approximately $1.43 million of Closing Shares issued to Chronix stockholders and approximately $1.87 million of Closing Shares issued to payoff assumed liabilities, based on the $5.09 closing price per share of Oncocyte common stock on the NYSE American on February 1, 2021; (ii) $4.0 million in cash; and (iii) $550,000 net settlement of acquirer/acquiree pre-combination activity (collectively, the "Chronix Closing Consideration").

Contingent Consideration

As additional consideration for holders of certain classes and series of Chronix capital stock, the Chronix Merger Agreement also provides for Oncocyte to pay "Chronix Contingent Consideration" consisting of (i) "Chronix Milestone Payments" of up to $14 million in any combination of cash or Oncocyte common stock if certain milestones specified in the Chronix Merger Agreement are achieved, (ii) "Royalty Payments" of up to 15% of net collections for sales of specified tests and products during the five-to-ten year earnout periods, and (iii) "Transplant Sale Payments" of up to 75% of net collections from the sale or license to a third party of Chronix's patents for use in transplantation medicine during a seven-year earnout period.

The Chronix Closing Consideration and Chronix Contingent Consideration include amounts payable to certain directors, officers and employees of Chronix, including officers and employees who are expected to continue to provide services to Chronix following the Chronix Merger.

Liabilities

Pursuant to the Chronix Merger Agreement, to the extent that Oncocyte or any of its subsidiaries, including Chronix, pays, performs or discharges an amount of liabilities of Chronix in excess of $8.25 million (the "Excess Liabilities"), Oncocyte may set off the Excess Liabilities against any Chronix Contingent Consideration payments that subsequently become due and payable pursuant to the Chronix Merger Agreement. Chronix had Excess Liabilities approximating $4.6 million as of the Chronix Merger Date. Prior to Chronix equity holders receiving any Chronix Contingent Consideration payments, all or a partial amount of any funds that would otherwise be payable as Chronix Contingent Consideration payments may be used to pay Excess Liabilities.

Deferred Revenue - In June 2018 and subsequently amended in June 2019, Chronix and a medical diagnostic service company in Germany ("the German customer") entered into a licensing and testing service agreement ("the German agreement") for intellectual property related to VitaGraft CNI Monitor and VitaGraft Transplant Monitor. Under the terms of the agreement, Chronix received from the German customer an upfront payment of €3.7 million, less applicable VAT obligations, which Chronix recognized ratably over the contract term of 3.5 years. The German agreement contains a stipulation that requires Chronix to refund to the German customer a portion of the upfront fee on a pro rata basis if the German agreement is terminated prior to December 31, 2021. The deferred revenue of $738,000 recorded at the acquisition date represents the refund Oncocyte would pay to the German customer should it terminate the agreement prior to the agreed upon term. Oncocyte amortized the deferred revenue and recorded revenue ratably over the remaining period as the German customer's refund rights expire. As of December 31, 2021, Oncocyte has fully amortized the deferred revenue and recorded revenue of $738,000. As of December 31, 2022, no revenues were recorded as a result of amortized deferred revenue.

Registration Rights

Pursuant to the Chronix Merger Agreement, Oncocyte filed a registration statement with the SEC to register the resale of the shares of common stock under the Securities Act issued in connection with the Chronix Merger, which the SEC declared effective in July 2021.

Workforce

At the Chronix Merger Date, all of Chronix's employees ceased employment with Chronix, and Oncocyte offered employment to certain of those former Chronix employees, principally in laboratory roles and certain administrative roles in Germany, and granted new equity awards to them under the Oncocyte 2018 Equity Incentive Plan. All these Oncocyte stock option awards granted have vesting terms and conditions consistent with stock options granted to most other Oncocyte employees.

Aggregate Chronix Merger Consideration and Purchase Price Allocation

Measurement period adjustments reflect new information obtained about facts and circumstances that existed as of the acquisition date. Final determination of the fair values may result in further adjustments to the values presented. To the extent that significant changes occur in the future, Oncocyte will disclose such changes in the reporting period in which they occur.

The calculation of the aggregate merger consideration, consisting of the Closing Consideration and Chronix Contingent Consideration (the "Aggregate Chronix Merger Consideration"), at fair value, is shown in the following table (in thousands, except for share and per share amounts). In accordance with ASC 805, the Chronix Contingent Consideration, at fair value, is part of the total considered transferred on the Chronix Merger Date, as further discussed below.

Cash consideration	$	3,960
Settlement of acquirer/acquiree activity pre-combination, net	$	550
Stock consideration		
Shares of Oncocyte common stock issued on the Merger Date		647,911
Closing price per share of Oncocyte common stock on the Merger Date	$	5.09
Market value of Oncocyte common stock issued	$	3,298
Contingent Consideration	$	42,295
Total fair value of consideration transferred on the Merger Date	$	50,103

Pursuant to ASC 805, *Business Combinations* ("ASC 805"), Oncocyte accounted for the Chronix acquisition as a business combination using the acquisition method of accounting. Identifiable assets and liabilities of Chronix, including identifiable intangible assets, were recorded based on their fair values as of the date of the closing of the acquisition. The excess of the purchase price over the fair value of the net assets acquired was recorded as goodwill.

Upon further review of the assets acquired and liabilities assumed, it was determined that the amount previously reported as assumed liabilities were not properly reflected. The following has been updated to reflect the assets acquired and liabilities as of the date of acquisition. The following table sets forth the allocation of the Aggregate Chronix Merger Consideration transferred to Chronix's tangible and identifiable intangible assets acquired and liabilities assumed (in thousands):

	April 15, 2021
Assets acquired:	
Cash and cash equivalents	$ 50
Accounts receivable and other current assets	25
Long-term assets	12
Acquired in-process research and development	46,800
Total identifiable assets acquired (a)	46,887
Liabilities assumed:	
Deferred revenue	738
Assumed liability	3,352
Long-term deferred income tax liability	2,184
Total identifiable liabilities assumed (b)	6,274
Net assets acquired, excluding goodwill (a) - (b) = (c)	40,613
Total cash, contingent consideration, and stock consideration transferred (d)	50,103
Goodwill (d) - (c)	$ 9,490

All tangible assets and liabilities were valued at their respective carrying amounts as management believes that these amounts approximated their acquisition date fair values.

The following is a discussion of the valuation methods and significant assumptions used to determine the fair value of Chronix's material assets and liabilities in connection with the Chronix Merger:

Acquired In-Process Research and Development and Deferred Income Tax Liability – The fair value of identifiable IPR&D intangible assets consists of $46.8 million allocated to VitaGraft CNI Monitor and VitaGraft Transplant Monitor. Oncocyte determined the estimated aggregate fair value of the VitaGraft test assets using the MPEEM under the income approach. MPEEM calculates the economic benefits by determining the income attributable to an intangible asset after the returns are subtracted for contributory assets such as working capital, assembled workforce, and fixed assets. The resulting after-tax net earnings are discounted at a rate commensurate with the risk inherent in the economic benefit projections of the assets.

To calculate fair value of the Test Assets under MPEEM, Oncocyte used probability-weighted, projected cash flows discounted at a rate considered appropriate given the significant inherent risks associated with similar assets. Cash flows were calculated based on projections of revenues and expenses related to the asset and were assumed to extend through a multi-year projection period. The discount rate used to value Test Assets was approximately 12%. The projected cash flows were based on significant assumptions, including the time and resources needed to complete development of the asset, timing and reimbursement rates from CMS, regulatory approvals, if any, to commercialize the asset, estimates of the number of tests that might be performed, revenue and operating profit expected to be generated by the asset, the expected economic life of the asset, market penetration and competition, and risks associated with achieving commercialization, including delay or failure to obtain CMS and any required regulatory approval, failure of clinical trials, and intellectual property litigation.

Because the IPR&D is considered an indefinite-lived asset for accounting purposes but is not recognized for tax purposes, the fair value of the IPR&D on the acquisition date generated a DTL in accordance with ASC 740, *Income Taxes*. This DTL is computed using the fair value of the IPR&D assets on the acquisition date multiplied by Oncocyte's federal and state effective income tax rates. ASC 740 allows Oncocyte to treat acquired available DTAs, such as Chronix's NOLs (subject to the annual limitation under Section 382 of the Internal Revenue Code) as available DTAs to offset against the DTLs, as the DTLs are expected to reverse within the NOL carryforward period. Any excess DTAs over those DTLs would be assessed for a valuation allowance in accordance with ASC 740. This accounting treatment is acceptable if, at the time of the acquisition, Oncocyte can both reasonably estimate a timeline to commercialization and the economic useful life of the IPR&D assets upon commercialization, which will be amortized during the carryforward period of the offsetting DTAs. Oncocyte estimated and recorded a net DTL of $2.2 million after offsetting the acquired available NOLs with the IPR&D generated DTLs (see Note 8).

Contingent consideration liabilities – ASC 805 requires that contingent consideration be estimated and recorded at fair value as of the acquisition date as part of the total consideration transferred. Contingent consideration is an obligation of the acquirer to transfer additional assets or equity interests to the selling shareholders in the future if certain future events occur or conditions are met, such as the attainment of product development milestones. Contingent consideration also includes additional future payments to selling shareholders based on achievement of components of earnings, such as "earn-out" provisions or percentage of future revenues, including royalties paid to the former Chronix shareholders based on a percentage of revenues generated from VitaGraft tests over the useful life of the assets. Accordingly, Oncocyte determined there are three types of contingent consideration in connection with the Chronix Merger: the Milestone Payments, the Royalty Payments, and Transplant Sale Payments, discussed below, which comprise the "Chronix Contingent Consideration".

The fair value of the Milestone Payments was determined using a scenario analysis valuation method which incorporates Oncocyte's assumptions with respect to the likelihood of achievement of the milestones defined in the Chronix Merger Agreement, credit risk, timing of the Milestone Payments and a risk-adjusted discount rate to estimate the present value of the expected payments. The discount rate was estimated at approximately 16.2% after adjustment for the probability of achievement of the milestones.

The fair value of the Royalty Payments was determined using a single scenario analysis method. The single scenario method incorporates Oncocyte's assumptions with respect to specified future revenues generated from DetermaCNI, over its estimated useful life, taking into account credit risk and a risk-adjusted discount rate to estimate the present value of the expected Royalty Payments. The credit and risk-adjusted discount rate was estimated at approximately 18.6%.

The fair value of the Transplant Sale Payments was determined using a single scenario analysis method. The single scenario method incorporates Oncocyte's assumptions with respect to specified future licensing revenues generated from VitaGraft, over its estimated useful life, taking into account credit risk and a risk-adjusted discount rate to estimate the present value of the expected Transplant Sale Payments. The credit and risk-adjusted discount rate was estimated at approximately 18.6%.

The fair value of the Chronix Contingent Consideration after the Chronix Merger Date is reassessed by Oncocyte as changes in circumstances and conditions occur, with the subsequent change in fair value recorded in Oncocyte's consolidated statements of operations. As of December 31, 2022, based on Oncocyte's reassessment of the significant assumptions noted above, there was a decrease of approximately $29.3 million to the fair value of the Contingent Consideration primarily attributable to revised estimates of the timing of the possible future payouts and, accordingly, this decrease was recorded as a change in fair value of the consolidated statements of operations for the year ended December 31, 2022.

The following tables reflect the activity for Oncocyte's Contingent Consideration for the years ended December 31, 2022 and December 31, 2021, measured at fair value using Level 3 inputs (in thousands):

	Fair Value
Balance at April 15, 2021	$ 42,295
Change in estimated fair value	27,326
Balance at December 31, 2021	$ 69,621
Change in estimated fair value	(29,329)
Balance at December 31, 2022	$ 40,292

Goodwill – Goodwill is calculated as the difference between the acquisition date fair value of the Aggregate Chronix Merger Consideration transferred and the values assigned to the assets acquired and liabilities assumed. Goodwill also includes the $2.2 million of net deferred tax liabilities recorded principally related to the VitaGraft discussed above. Oncocyte recognized approximately $9.5 million of goodwill related to the Chronix acquisition.

None of the goodwill recognized is expected to be deductible for income tax purposes. Goodwill is not amortized but is tested for impairment at least annually, or more frequently if circumstances indicate potential impairment. During 2022, the Company identify circumstances that could indicate a potential impairment and after a valuation of the Company's assets and liabilities was performed, management concluded that Goodwill was impaired as of December 31, 2022. (see Notes 2 and 4).

4. Goodwill and Intangible Assets, net

We account for our historical acquisitions in accordance with ASC 805, *Business Combinations*. We recorded the amount exceeding the fair value of net assets acquired and the date of acquisition as goodwill.

In accordance with ASC 350, *Intangible-Goodwill and Other*, we review and evaluate our long-lived assets, including intangible assets with finite lives, for impairment whenever events or changes in circumstances indicate that we may not recover their net book value. We test goodwill for impairment on an annual basis in the fourth quarter of each year, and between annual tests, if indicators of potential impairment exist, using a fair-value approach.

We typically use an income method to estimate the fair value of these assets, which is based on forecasts of the expected future cash flows attributable to the respective assets. Significant estimates and assumptions inherent in the valuations reflect a consideration of other marketplace participants and include the amount and timing of future cash flows (including expected growth rates). Estimates utilized in the projected cash flows include consideration of macroeconomic conditions, overall category growth rates, competitive activities, cost containment and margin expansion, Company business plans, the underlying product or technology life cycles, economic barriers to entry, and the discount rate applied to the cash flows. Unanticipated market or macroeconomic events and circumstances may occur, which could affect the accuracy or validity of the estimates and assumptions.

During 2022, and upon the eminent sale of Razor Genomics, the Company assessed its current environment and concluded that it was more likely than not that the fair value of the goodwill was less than the carrying value. As such, the Company performed a quantitative test to estimate the fair value of the enterprise. Using the discounted cash flow method and taking into consideration the loss of Razor's future cash flows, the calculated enterprise fair value was lower than carrying value. As a result, the Company recorded a goodwill impairment of $18.7 million as part of its operating expenses; as of December 31, 2022. No impairment was noted for IPR&D assets.

We amortize intangible assets not considered to have an indefinite useful life using the straight-line method over their estimated period of benefit, which generally ranges from one to nine years. Each reporting period, we evaluate the estimated remaining useful life of intangible assets and assess whether events or changes in circumstances warrant a revision to the remaining period of amortization or indicate that impairment exists.

At December 31, 2022 and December 31, 2021, goodwill and intangible assets, net, consisted of the following (in thousands):

	December 31, 2022	December 31, 2021
Goodwill - Insight Merger[(1)]	$ -	$ 9,194
Goodwill - Chronix Merger[(1)]	-	9,490
Total Goodwill	-	18,684
Intangible assets:		

Acquired IPR&D - DetermaIO [2]	$ 14,650	$ 14,650
Acquired IPR&D - DetermaCNI and VitaGraft [3]	46,800	46,800
Intangible assets subject to amortization:		
Acquired intangible assets - customer relationship	440	440
Total intangible assets	61,890	61,890
Accumulated amortization - customer relationship[4]	(257)	(169)
Intangible assets, net	$ 61,633	$ 61,721

(1) Goodwill represents the excess of the purchase price over the fair value of the net tangible and identifiable intangible assets acquired in the Insight Merger and the Chronix Merger (see Note 3). The Company recorded an impairment loss as of December 31, 2022 for the entire goodwill balance.

(2) See Note 3 for information on the Insight Merger.

(3) See Note 3 for information on the Chronix Merger.

(4) Amortization of intangible assets is included in “Cost of revenues – amortization of acquired intangibles” on the consolidated statements of operations in the current year because the intangible assets pertain directly to the revenues generated from the acquired intangibles.

Future amortization expense is expected to be the following (in thousands):

	Amortization
Year ending December 31,	
2023	88
2024	88
2025	7
	183

5. Shareholders' Equity

Series A Redeemable Convertible Preferred Stock

On April 13, 2022, the Company entered into the Securities Purchase Agreement with the Investors in a registered direct offering of 11,765 shares of the Company's Series A Preferred Stock, which shares of Series A Preferred Stock are convertible into a total of 7,689,542 shares of common stock, at a conversion price of $1.53. The purchase price of each share of Series A Preferred Stock was $850, which included an original issue discount to the stated value of $1,000 per share. The rights, preferences and privileges of the Series A Preferred Stock are set forth in the Company's Certificate of Determination, which the Company filed with the Secretary of State of the State of California. The Securities Purchase Agreement provides that the closing of the Series A Preferred Stock Offering will occur, subject to the satisfactory of certain closing conditions, in two equal tranches of $5,000,000 each for aggregate gross proceeds from both closings of $10,000,000. The first closing occurred on June 1, 2022, and Oncocyte received net proceeds of approximately $4.9 million from the Series A Preferred Stock issued from the first tranche. The second closing would occur, subject to the satisfactory of certain closing conditions (including but not limited to a requirement that the Company has not received, in the 12 months preceding the second closing, a notice from The Nasdaq Stock Market LLC ("Nasdaq") that the Company is not in compliance with the listing and maintenance and listing requirements of Nasdaq), on the earlier of (a) the second trading day following the date that Oncocyte receives notice from an Investor to accelerate the second closing and (b) a date selected by Oncocyte on or after October 8, 2022 and on or prior to March 8, 2023. On August 9, 2022, Oncocyte received a letter from Nasdaq indicating that the Company no longer meets the minimum bid price requirement of Nasdaq Listing Rule 5450(a)(1) of the Nasdaq continued listing requirements. Accordingly as of December 31, 2022, no additional proceeds are expected from the second closing of the Security Purchase Agreement. See Note 15 for additional information about the Series A Preferred Stock Offering.

The Series A Preferred Stock is convertible into shares of the Company's common stock at any time at the holder's option. The conversion price will be subject to customary anti-dilution adjustments for matters such as stock splits, stock dividends and other distributions on our common stock, and recapitalizations. A holder is prohibited from converting shares of Series A Preferred Stock into shares of common stock if, as a result of such conversion, the holder, together with its affiliates, would own more than 4.99% of the shares of our common stock then issued and outstanding (provided a holder may elect, at the first closing, to increase such beneficial ownership limitation solely as to itself up to 19.99% of the number of shares of our common stock outstanding immediately after giving effect to the conversion, provided further that following the receipt of shareholder approval required by applicable Nasdaq rules with respect to the issuance of common stock that would exceed the beneficial ownership limitation, such beneficial ownership limitation will no longer apply to the holder if the holder notified the Company that the holder wishes the Company to seek such shareholder approval). On July 15, 2022, the Company received such shareholder approval to remove the beneficial ownership limitation with respect to the Series A Preferred Stock held by Broadwood Partners, L.P. The Company may force the conversion of up to one-third of the shares of Series A Preferred Stock originally issued, subject to customary equity conditions, if the daily volume weighted average price of our common stock for 20 out of 30 trading days exceeds 140% of the conversion price and on 20 out of the same 30 trading days the daily trading volume equals or exceeds 400,000 shares of our common stock. The Company may only effect one forced conversion during any 30-trading day period.

In the event of the Company's liquidation, dissolution, or winding up, holders of Series A Preferred Stock will receive a payment equal to the stated value of the Series A Preferred Stock plus accrued but unpaid dividends and any other amounts that may have become payable on the Series A Preferred Stock due to any failure or delay that may have occurred in issuing shares of common stock upon conversion of a portion of the Series A Preferred Stock, before any distribution or payment to the holders of common stock or any of our other junior equity.

Shares of Series A Preferred Stock will generally have no voting rights, except as required by law and except that the consent of holders of a majority of the outstanding Series A Preferred Stock will be required to amend any provision of our certificate of incorporation that would have a materially adverse effect on the rights of the holders of the Series A Preferred Stock. Additionally, as long as any shares of Series A Preferred Stock remain outstanding, unless the holders of at least 51% of the then outstanding shares of Series A Preferred Stock shall have otherwise given prior written consent, we, on a consolidated basis with our subsidiaries, are not permitted to (1) have less than $8 million of unrestricted, unencumbered cash on hand ("Cash Minimum Requirement"); (2) other than certain permitted indebtedness, incur indebtedness to the extent that our aggregate indebtedness exceeds $15 million; (3) enter into any agreement (including any indenture, credit agreement or other debt instrument) that by its terms prohibits, prevents, or otherwise limits our ability to pay dividends on, or redeem, the Series A Preferred Stock in accordance with the terms of the Certificate of Determination; or (4) authorize or issue any class or series of preferred stock or other capital stock of the Company that ranks senior or pari passu with the Series A Preferred Stock.

Shares of Series A Preferred Stock will be entitled to receive cumulative dividends at a rate per share (as a percentage of stated value) of 6% per annum, payable quarterly in cash or, at our option, by accreting such dividends to the stated value.

The Company is required to redeem, for cash, the shares of Series A Preferred Stock on the earlier to occur of (1) April 8, 2024, (2) the commencement of certain a voluntary or involuntary bankruptcy, receivership, or similar proceedings against the Company or its assets, (3) a Change of Control Transaction (as defined herein) and (4) at the election and upon notice of 51% in interest of the holders, if the Company fails to meet the Cash Minimum Requirement. A "Change of Control Transaction" means the occurrence of any of (a) an acquisition by an individual or legal entity or "group" (as described in Rule 13d-5(b)(1) promulgated under the Exchange Act) of effective control (whether through legal or beneficial ownership of capital stock of the Company, by contract or otherwise) of in excess of 50% of the voting securities of the Company (other than by means of conversion of Series A Preferred Stock), (b) the Company merges into or consolidates with any other person, or any person merges into or consolidates with the Company and, after giving effect to such transaction, the stockholders of the Company immediately prior to such transaction own less than 50% of the aggregate voting power of the Company or the successor entity of such transaction, or (c) the Company sells or transfers all or substantially all of its assets to another person. Additionally, the Company has the right to redeem the Series A Preferred Stock for cash upon 30 days prior notice to the holders; provided if the Company undertakes a capital raise in connection with such redemption, the Investors will have the right to participate in such financing.

As of December 31, 2022, Oncocyte had 11,765 preferred shares, no-par value, authorized, and 5,882.4 shares issued and outstanding. The future right or obligation associated with the Series A Preferred Stock to be issued in the second closing of $0.4 million was written off since the second closing is not expected as of December 31, 2022.

Common Stock

As of December 31, 2022 and December 31, 2021, Oncocyte has 230,000,000 shares of common stock, no-par value, authorized. As of December 31, 2022 and December 31, 2021, Oncocyte had 118,643,821 and 92,231,917 shares of common stock issued and outstanding, respectively.

Common Stock Purchase Warrants

As of December 31, 2022, Oncocyte had an aggregate of 16,395,343 common stock purchase warrants issued and outstanding with exercise prices ranging from $1.53 to $5.46 per warrant. The warrants will expire on various dates ranging from February 2024 to October 2029. Certain warrants have "cashless exercise" provisions meaning that the value of a portion of warrant shares may be used to pay the exercise price rather than payment in cash, which may be exercised under any circumstances in the case of the 2017 Bank Warrants and 2019 Bank Warrants or, in the case of certain other warrants, only if a registration statement for the warrants and underlying shares of common stock is not effective under the Securities Act or a prospectus in the registration statement is not available for the issuance of shares upon the exercise of the warrants.

Oncocyte has considered the guidance in ASC 815-40, *Accounting for Derivative Financial Instruments Indexed to, and Potentially Settled in, a Company's Own Stock*, which states that contracts that require or may require the issuer to settle the contract for cash are liabilities recorded at fair value, irrespective of the likelihood of the transaction occurring that triggers the net cash settlement feature. This liability classification guidance also applies to financial instruments that may require cash or other form of settlement for transactions outside of the company's control and, in which the form of consideration to the warrant holder may not be the same as to all other shareholders in connection with the transaction. However, if a transaction is not within the company's control but the holder of the financial instrument can solely receive the same type or form of consideration as is being offered to all the shareholders in the transaction, then equity classification of the financial instrument is not precluded, if all other applicable equity classification criteria are met. Based on the above guidance and, among other factors, the fact that the warrants cannot be cash settled under any circumstance but require share settlement, all of the outstanding warrants meet the equity classification criteria and have been classified as equity.

6. Stock-Based Compensation

Oncocyte had a 2010 Stock Option Plan (the "2010 Plan") under which 5,200,000 shares of common stock were authorized for the grant of stock options or the sale of restricted stock. On August 27, 2018, Oncocyte shareholders approved a new Equity Incentive Plan (the "2018 Incentive Plan") to replace the 2010 Plan. In adopting the 2018 Incentive Plan, Oncocyte terminated the 2010 Plan and will not grant any additional stock options or sell any stock under restricted stock purchase agreements under the 2010 Plan; however, stock options issued under the 2010 Plan will continue in effect in accordance with their terms and the terms of the 2010 Plan until the exercise or expiration of the individual options.

During the year ended December 31, 2022, the Company awarded executive share-based payment awards under the 2018 Plan to certain executive officers and employees with time-based, market-based and performance-based vesting conditions ("2022 Equity Awards").

The fair value of the 2022 Equity Awards with performance-based vesting condition was estimated using the Black-Scholes option-pricing model assuming that performance goals will be achieved. If such performance conditions are not met, no compensation cost is recognized and any recognized compensation cost is reversed. The probability of 2022 equity awards performance-based vesting conditions will be evaluated each reporting period and the Company will true-up the amount of cumulative cost recognized for the 2022 performance-based awards at each reporting period based on the most up-to-date probability estimates. The Company will recognize the compensation expense for 2022 performance-based awards expected to vest on a straight-line basis over the respective service period for each separately vesting tranche.

The fair value of the 2022 Equity Awards with market-based vesting condition was estimated using the Monte Carlo simulation model. Assumptions and estimates utilized in the model include the risk-free interest rate, dividend yield, expected stock volatility and the estimated period to achievement of the performance and market conditions, which are subject to the achievement of the market-based goals established by the Company and the continued employment of the participant. These awards vest only to the extent that the market-based conditions are satisfied as specified in the vesting conditions. Unlike the performance-based awards, the grant date fair value and associated compensation cost of the market-based awards reflect the probability of the market condition being achieved, and the Company will recognize this compensation cost regardless of the actual achievement of the market condition. Assumptions utilized in connection with the Monte Carlo valuation technique included: estimated risk-free interest rate of 2.0 percent; term of 2.8 years; expected volatility of 100 percent; and expected dividend yield of 0 percent. The risk-free interest rate was determined based on the yields available on U.S. Treasury zero-coupon issues. The expected stock price volatility was determined using historical volatility. The expected dividend yield was based on expectations regarding dividend payments. The total grant date fair value of the market-based awards was $117,625.

In May 2022, the Company approved amendments to vesting conditions of 1,237,500 performance-based and 250,000 market-based awards of certain executive officers and employees. The performance-based awards were modified such that the stock awards will be eligible to vest as follows: (i) 50% will vest on December 31, 2023 if the Company achieves LCD reimbursement for VitaGraft (formerly VitaGraft Transplant Monitor) for one organ no later than December 31, 2022 and (ii) 50% will vest on December 31, 2023 if DetermaIO or DetermaCNI (formerly VitaGraft - CNI Monitor) submission for LCD is completed no later than December 31, 2022. Additional performance-based RSU awards were modified to be eligible to vest upon the achievement by the Company of average market capitalization minimum, target, and maximum goals of (i) $300 million; (ii) $400 million; and (iii) $500 million, respectively, during the period beginning on January 1, 2022 and ending on December 31, 2024.The market-based RSU awards were modified such that the awards will be eligible to vest upon the achievement of product commercial launch minimum, target, and maximum goals as follows: (i) 1 laboratory test product in the US; (ii) 2 laboratory test products in US, and (iii) 3 laboratory test products in the US, respectively.

In accordance with ASC 718, the Company calculated the fair value of the market-based awards on the date of modification, noting an increase in the fair value of approximately $58,500 on the date of modification, with the incremental increase in fair value representing additional unrecognized stock-based compensation expense. The following assumptions were used in calculating the fair value of the market-based options on the date of modification:

Risk-free interest rates		2.72 %
Expected term (in years)		2.6
Volatility		95.0 %
Grant date fair value of awards granted during the period	$	1.13

In July 2022, the Company approved amendments to vesting conditions of 475,000 performance-based awards of certain executive officers and employees. Certain performance-based awards were modified such that the stock awards will be eligible to vest as follows: (i) fifty percent (50%) of the options will vest on December 31, 2023 (the “Vesting Date”), subject to Continuous Service through the Vesting Date, if local coverage determination is issued and priced for VitaGraft (Transplant) with respect to one organ no later than December 31, 2022; and (ii) fifty percent (50%) of the options will vest on the Vesting Date, subject to Continuous Service through the Vesting Date, if the Company submits a local coverage determination request for DetermaIO or DetermaCNI no later than December 31, 2022. Additional performance-based stock awards were modified to be eligible to vest upon the achievement of performance minimum, target, and maximum goals of (i) 90% of revenue goal; (ii) 100% of revenue goal; and (iii) exceed revenue goal by up to 150%, respectively, during fiscal year 2022. These same awards contained budget performance goals which were modified to be eligible to vest upon the achievement of performance minimum, target, and maximum goals of (i) complete fiscal year 2022 with sufficient cash to continue operations for 12 months; (ii) complete fiscal year 2022 with sufficient cash to continue operations for 15 months; and (iii) complete fiscal year 2022 with sufficient cash to continue operations for 16 months, respectively.

As of December 31, 2022, 50% of the performance-based were forfeited since the Company did not achieve LCD reimbursement for VitaGraft. The remaining 50% is eligible to vest on December 31, 2023, since the Company completed the LCD submission for Determa CNI on December 16, 2022.

During the year ended December 31, 2022, the Company accelerated the vesting of certain equity awards in accordance with the 2018 Incentive Plan after the departure of officers of the Company and the adoption of the workforce reduction plan. Due to the acceleration of such awards all associated unrecognized compensation was accelerated and recognized in full.

A summary of Oncocyte's 2010 Plan activity and related information follows (in thousands except weighted average exercise price):

Options	Shares Available for Grant	Number of Options Outstanding	Weighted Average Exercise Price
Balance at December 31, 2021	-	923	$ 3.65
Options exercised	-	-	$ -
Options forfeited, canceled and expired	-	(316)	$ 2.76
Balance at December 31, 2022	-	607	$ 4.04
Exercisable at December 31, 2022		607	$ 4.04

As of December 31, 2022, 21,000,000 shares of common stock were reserved under the 2018 Incentive Plan for the grant of stock options or the sale of restricted stock or for the settlement of hypothetical units issued with reference to common stock ("RSUs"). Oncocyte may also grant stock appreciation rights under the 2018 Incentive Plan.

A summary of Oncocyte's 2018 Incentive Plan activity and related information follows (in thousands except weighted average exercise price):

	Shares Available for Grant	Number of Options Outstanding	Number of RSUs Outstanding	Weighted Average Exercise Price
Balance at December 31, 2021	9,006	10,679	121	$ 3.63
RSUs vested	341	-	(341)	$ -
RSUs granted	(511)	-	511	$ -
Performance RSUs granted	(1,150)	-	1,150	$ -
Performance RSUs vested	425	-	(425)	$ -
Options granted	(4,365)	4,365	-	$ 1.10
Options exercised	-	-	-	$ -
Options forfeited/cancelled	6,484	(6,484)	-	$ 2.80
RSUs forfeited/cancelled	575	-	(575)	$ -
Balance at December 31, 2022	10,805	8,560	441	$ 2.96
Options exercisable at December 31, 2022		5,256		$ 4.76

Oncocyte recorded stock-based compensation expense in the following categories on the accompanying consolidated statements of operations for the years ended December 31, 2022 and 2021 (in thousands):

	Year Ended December 31,	
	2022	2021
Cost of revenues	$ 10	$ 96
Research and development	773	378
Sales and marketing	261	114
General and administrative	5,435	3,773
Discontinued operations	3,563	2,480
Total stock-based compensation expense	$ 10,042	$ 6,841

The assumptions that were used to calculate the grant date fair value of Oncocyte's employee and non-employee stock option grants for the years ended December 31, 2022 and 2021 were as follows:

	Year Ended December 31,	
	2022	2021
Expected life (in years)	6.01	6.00
Risk-free interest rates	2.43%	1.02%
Volatility	106.74%	98.88%
Dividend yield	-%	-%

The determination of stock-based compensation is inherently uncertain and subjective and involves the application of valuation models and assumptions requiring the use of judgment. If Oncocyte had made different assumptions, its stock-based compensation expense and net loss for the years ended December 31, 2022 and 2021 may have been significantly different.

Oncocyte does not recognize deferred income taxes for incentive stock option compensation expense and records a tax deduction only when a disqualified disposition has occurred.

7. Disaggregation of Revenues and Concentration Risk

The following table presents the percentage of consolidated revenues attributable to products or services classes that represent greater than ten percent of consolidated revenues:

	Year Ended December 31,	
	2022	2021
Pharma Services	17%	19%
Licensing	-%	10%
Discontinued operations	83%	71%
Total	100%	100%

The following table presents the percentage of consolidated revenues received from unaffiliated customers that individually represent greater than ten percent of consolidated revenues:

	Year Ended December 31,	
	2022	2021
Pharma services - Company A	43%	*
Pharma services - Company B	14%	*
Pharma services - Company C	11%	*
Pharma services Other	31%	66%
Licensing - Company A	*	34%

**Less than 10%*

The following table presents the percentage of consolidated revenues attributable to geographical locations:

	Year Ended December 31,	
	2022	2021
United States – Pharma Services	13%	13%
Outside of the United States – Pharma Services	4%	6%
Outside of the United States – Licensing	-%	10%
Discontinued operations – Outside of the United States - Licensing	18%	40%
Discontinued operations – United States - DetermaRx	65%	31%
Total	100%	100%

The total consolidated accounts receivables, from third-party payers and other customers outstanding as of December 31, 2022 from continuing operations are mainly related to Pharma Services.

8. Income Taxes

In 2022, the Company incurred $72.9 million of net operating losses in the United States and $10 thousand of net operating income internationally. In 2021, the Company incurred $73.1 million of net operating losses in the United States and $212 thousand of net operating loss internationally.

A deferred income tax benefit of $0 and $9.3 million ($8.1 million federal and $1.2 million state) was recorded for the years ended December 31, 2022 and December 31, 2021, respectively. Oncocyte has filed standalone U.S. federal income tax returns since its inception and will file a consolidated return with its subsidiaries for the years ended December 31, 2022 and 2021.

Deferred income taxes reflect the net tax effects of temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes.

The primary components of the deferred tax assets and liabilities at December 31, 2022 and 2021 were as follows (in thousands):

	December 31,	
	2022	2021
Deferred tax assets/(liabilities):		
Net operating loss carryforwards and capital loss carryforwards	$ 52,302	$ 51,051
Research and development credit carryforwards	3,680	3,148
Marketable equity securities	364	193
Stock-based and other compensation	5,067	2,398
Right-of-use liability	952	949
Razor Investment(1)	5,373	-
Capitalized R&D(2)	4,011	-
Other	49	-
Total deferred tax assets	71,798	57,739
Valuation allowance	(54,408)	(37,167)
Deferred tax assets, net of valuation allowance	17,390	20,572
Right-of-use asset	(580)	(591)
Intangibles and fixed assets	(16,810)	(19,981)
Total deferred tax liabilities	(17,390)	(20,572)
Net deferred tax assets	$ -	$ -

(1) Relates to outside basis difference for Razor which meets the criteria for held for sale as of December 31, 2022.

(2) Relates to Research and Development expenditures required to be capitalized as of December 31, 2022.

In connection with the Merger discussed in Note 3 and in accordance with ASC 805, a change in the acquirer's valuation allowance that stems from a business combination should be recognized as an element of the acquirer's income tax expense or benefit in the period of the acquisition. Accordingly, for the year ended December 31, 2021, Oncocyte recorded a $9.3 million partial release of its valuation allowance and a corresponding income tax benefit stemming from the DTLs generated by the IPR&D and customer relationships intangible assets acquired in the Merger.

Income taxes differed from the amounts computed by applying the applicable U.S. federal income tax rates indicated to pretax losses from operations as a result of the following:

	December 31,	
	2022	2021
Computed tax benefit at federal statutory rate	21%	21%
Permanent differences	(14)%	(1)%
State tax benefit	1%	2%
Research and development credits	(3)%	-%
Change in fair value consideration	35%	(8)%
Change in valuation allowance	(19)%	(1)%
Goodwill impairment	(21)%	-%
	-%	13%

As of December 31, 2022, Oncocyte had net operating loss carryforwards of approximately $209.9 million for U.S. federal income tax purposes and $103.8 million for state income tax purposes. Federal net operating losses generated on or prior to December 31, 2017 expire in varying amounts between 2023 and 2037, while federal net operating losses generated after December 31, 2017 carryforward indefinitely. The state net operating losses expire in varying amounts between 2023 and 2042.

As of December 31, 2022, Oncocyte has research and development credit carryforwards for federal and state purposes of $3.1 million and $2.4 million, respectively. The federal credits will expire between 2030 and 2042, while the state credits have no expiration.

A valuation allowance is provided when it is more likely than not that some portion of the deferred tax assets will not be realized. Other than the partial release discussed above, Oncocyte established a full valuation allowance for all periods presented due to the uncertainty of realizing future tax benefits from its net operating loss carryforwards and other deferred tax assets. The change in the valuation allowance was $17.2 million and $5.4 million for the years ended December 31, 2022 and 2021, respectively.

Oncocyte has uncertain tax benefits (“UTBs”) totaling $1.9 million and $1.4 million as of December 31, 2022 and 2021, respectively, which were netted against deferred tax assets subject to valuation allowance as shown below. The UTBs had no effect on the effective tax rate and there would be no cash tax impact for any period presented. Oncocyte recognizes interest and penalties related to UTBs, when they occur, as a component of income tax expense. There were no interest or penalties recognized for the years ended December 31, 2022 and 2021. In 2021, Oncocyte received approval for its petition for alternative apportionment in California by the Franchise Tax Board. As a result, Oncocyte has derecognized its uncertain tax position of $2.2 million in 2021. There is no financial statement impact as the uncertain tax positions were previously offset against Oncocyte’s California net operating losses, which would otherwise have a full valuation allowance. Oncocyte does not expect its UTBs to change significantly over the next twelve months.

A reconciliation of the beginning and ending unrecognized tax benefit amount is as follows (in thousands):

	December 31,	
	2022	2021
	(in thousands)	
Balance at the beginning of the year	$ 1,390	$ 3,052
Additions based on tax positions related to current year	531	511
Adjustments based on tax positions related to prior years	-	-
Settlements	-	(2,173)
Balance at end of year	$ 1,921	$ 1,390

Other Income Tax Matters

Internal Revenue Code Section 382 places a limitation (“Section 382 Limitation”) on the amount of taxable income that can be offset by NOL carryforwards after a change in control (generally greater than 50% change in ownership within a three-year period) of a loss corporation. California has similar rules. Generally, after a change in control, a loss corporation cannot deduct NOL carryforwards in excess of the Section 382 Limitation. Due to these “change in ownership” provisions, utilization of the NOL and tax credit carryforwards may be subject to an annual limitation regarding their utilization against taxable income in future periods.

In general, Oncocyte is no longer subject to tax examination by the Internal Revenue Service or state taxing authorities for years before 2017. Although the federal and state statutes are closed for purposes of assessing additional income tax in those prior years, the taxing authorities may still make adjustments to the NOL and credit carryforwards used in open years. Therefore, the tax statutes should be considered open as it relates to the NOL and credit carryforwards used in open years. For tax years that remain open to examination, potential examinations may include questioning of the timing and amount of deductions, the nexus of income among various tax jurisdictions and compliance with the Internal Revenue Code or state tax laws. Oncocyte’s management does not expect that the total amount of unrecognized tax benefits will materially change over the next twelve months.

9. Right-of-use Assets, Machinery and Equipment, Net and Construction in Progress

As of December 31, 2022 and 2021, rights-of-use assets, machinery and equipment, net, and construction in progress were comprised of the following (in thousands):

	December 31, 2022	December 31, 2021
Right-of-use assets [(1)]	3,499	3,499
Machinery and equipment	9,408	6,290
Accumulated depreciation and amortization	(4,196)	(2,662)
Right-of-use assets, machinery and equipment, net	8,711	7,127
Construction in progress	2,140	1,242
Right-of-use assets, machinery and equipment, net, and construction in progress from continuing operations	10,851	8,369
Right-of-use assets, machinery and equipment, net, and construction in progress from discontinuing operations	211	158
Right-of-use assets, machinery and equipment, net, and construction in progress	11,062	8,527

(1) Oncocyte recorded certain right-of-use assets and liabilities for operating leases in accordance with ASC 842 (see Note 10).

Depreciation expense included in continuing operations amounted to approximately $1.5 million and $0.8 million for the years ended December 31, 2022 and 2021, respectively.

10. Commitments and Contingencies

Oncocyte has certain commitments other than those discussed in Note 3.

Office Lease Agreement

On December 23, 2019, Oncocyte entered into an Office Lease Agreement (the "Irvine Lease") of a building containing approximately 26,800 square feet of rentable space located at 15 Cushing in Irvine California (the "Premises") that will serve as Oncocyte's new principal executive and administrative offices and laboratory facility. Oncocyte completed the relocation of its offices to the Premises in January 2020. Oncocyte has constructed a laboratory at the Irvine facility to perform cancer diagnostic tests.

The Irvine Lease has an initial term of 89 calendar months (the "Term"), which commenced on June 1, 2020 (the "Commencement Date"). Oncocyte has an option to extend the Term for a period of five years (the "Extended Term").

Oncocyte will pay base monthly rent in the amount of $61,640 during the first 12 months of the Term. Base monthly rent will increase annually, over the base monthly rent then in effect, by 3.5%. Oncocyte will be entitled to an abatement of 50% of the base monthly rent during the first ten calendar months of the Term. If the Lease is terminated based on the occurrence of an "event of default," Oncocyte will be obligated to pay the abated rent to the lessor.

If Oncocyte exercises its option to extend the Term, the initial base monthly rent during the Extended Term will be the greater of the base monthly rent in effect during the last year of the Term or the prevailing market rate. The prevailing market rate will be determined based on annual rental rates per square foot for comparable space in the area where the Premises are located. If Oncocyte does not agree with the prevailing market rate proposed by the lessor, the rate may be determined through an appraisal process. The base monthly rent during the Extended Term shall be subject to the same annual rent adjustment as applicable for base monthly rent during the Term.

In addition to base monthly rent, Oncocyte will pay in monthly installments (a) all costs and expenses, other than certain excluded expenses, incurred by the lessor in each calendar year in connection with operating, maintaining, repairing (including replacements if repairs are not feasible or would not be effective) and managing the Premises and the building in which the Premises are located ("Expenses"), and (b) all real estate taxes and assessments on the Premises and the building in which the Premises are located, all personal property taxes for property that is owned by Landlord and used in connection with the operation, maintenance and repair of the Premises, and costs and fees incurred in connection with seeking reductions in such tax liabilities ("Taxes"). Subject to certain exceptions, Expenses shall not be increased by more than 4% annually on a cumulative, compounded basis.

Oncocyte was entitled to an abatement of its obligations to pay Expenses and Taxes while constructing improvements to the Premises constituting "Tenant's Work" under the Lease prior to the Commencement Date, except that Oncocyte was obligated to pay 43.7% of Expenses and Taxes during the period prior to the Commencement Date for its use of the second floor of the Premises, which was already built out as office space.

The lessor has agreed to provide Oncocyte with a "Tenant Improvement Allowance" in the amount of $1.3 million to pay for the plan, design, permitting, and construction of the improvements constituting Tenant's Work. The lessor shall be entitled to retain 1.5% of the Tenant Improvement Allowance as an administrative fee. As of December 31, 2021, the lessor had provided $1.3 million of the total Tenant Improvement Allowance.

Oncocyte has provided the lessor with a security deposit in the amount of $150,000 and a letter of credit in the amount of $1.7 million. The lessor may apply the security deposit, in whole or in part, for the payment of rent and any other amount that Oncocyte is or becomes obligated to pay under the Irvine Lease but fails to pay when due and beyond any cure period. The lessor may draw on the letter of credit from time to time to pay any amount that is unpaid and due, or if the original issuing bank notifies the lessor that the letter of credit will not be renewed or extended for the period required under the Irvine Lease and Oncocyte fails to timely provide a replacement letter of credit, or an event of default under the Irvine Lease occurs and continues beyond the applicable cure period, or if certain insolvency or bankruptcy or insolvency with respect to Oncocyte occur. Oncocyte is required to restore any portion of the security deposit that is applied by the lessor to payments due under the Lease, and Oncocyte is required to restore the amount available under the letter of credit to the required amount if any portion of the letter of credit is drawn by the lessor. Commencing on the 34th month of the Term, (a) the amount of the letter of credit that Oncocyte is required to maintain shall be reduced on a monthly basis, in equal installments, to amortize the required amount to zero at the end of the Term, and (b) Oncocyte will have the right to cancel the letter of credit at any time if it meets certain market capitalization and balance sheet thresholds; provided, in each case, that Oncocyte is not in then default under the Lease beyond any applicable notice and cure period and the lessor has not determined that an event exists that would lead to an event of default.

To obtain the letter of credit, Oncocyte has provided the issuing bank with a restricted cash deposit that the bank will hold to cover its obligation to pay any draws on the letter of credit by the lessor. The restricted cash may not be used for any other purpose.

On August 27, 2021, Oncocyte entered into a lease agreement to add an additional suite to its Nashville office space, containing approximately 1,928 square feet of rentable space located at 2 International Plaza, Suite 103, Nashville TN. The term of the lease commences on October 1, 2021 and extends through April 9, 2024 and will serve as additional office space for Insight Genetics' operations.

The Irvine Lease is an operating lease under ASC 842 included in the tables below. The tables below provide the amounts recorded in connection with the application of ASC 842 as of, and during, the year ended December 31, 2022, for Oncocyte's operating and financing leases (see Note 2).

Under the Laboratory Agreement discussed in Note 3, Oncocyte assumed all of Razor's Laboratory Agreement payment obligations. Although Oncocyte is not a party to any lease agreement with Razor or Encore, under the terms of the Laboratory Agreement, Oncocyte received the landlord's consent for the use of the laboratory at Razor's Brisbane, California location (the "Brisbane Facility") under the terms of a sublease to which Encore is the sublessee. The sublease expires on March 31, 2023 (the "Brisbane Lease"). The laboratory fee payments to Encore include both laboratory services and the use of the Brisbane Facility. Under the provisions of the Laboratory Agreement, if Oncocyte terminates the Laboratory Agreement prior to the expiration of the Brisbane Lease, Oncocyte shall assume the costs related to the subletting or early termination of the Brisbane Lease. If the Laboratory Agreement were to be terminated on December 31, 2022, the aggregate payments due to the landlord for early cancellation of the Brisbane Lease would be approximately $39,000 (aggregate payments from January 1, 2023 through March 31, 2023). Oncocyte determined that the Laboratory Agreement contains an embedded operating lease for the Brisbane Facility and Oncocyte allocated the aggregate payments to this lease component for purposes of calculating the net present value of the right-of-use asset and liability as of the inception of the Laboratory Agreement in accordance with ASC 842, as shown in the table below.

Financing lease

As of December 31, 2022, Oncocyte has one financing lease remaining through December 2023 for certain laboratory equipment with aggregate remaining payments of $124,000 shown in the table below.

Operating and Financing leases

The following table presents supplemental cash flow information related to operating and financing leases for the years ended December 31, 2022 and 2021 (in thousands):

	Year Ended December 31,	
	2022	**2021**
Cash paid for amounts included in the measurement of financing lease liabilities:		
Operating cash flows from operating leases	1,143	1,042
Operating cash flows from financing leases	20	147
Financing cash flows from financing leases	104	34

The following table presents supplemental balance sheet information related to operating and financing leases as of December 31, 2022 and December 31, 2021 (in thousands, except lease term and discount rate):

	December 31, 2022
Operating lease	
Right-of-use assets, net	$ 2,088
Right-of-use lease liabilities, current	$ 698
Right-of-use lease liabilities, noncurrent	2,730
Total operating lease liabilities	$ 3,428
Financing lease	
Machinery and equipment	$ 537
Accumulated depreciation	(446)
Machinery and equipment, net	$ 91
Current liabilities	$ 117

Noncurrent liabilities		-
Total financing lease liabilities	$	117
Weighted average remaining lease term		
Operating lease		4.5 years
Financing lease		1.0 years
Weighted average discount rate		
Operating lease		11.24 %
Financing lease		11.55 %

The following table presents future minimum lease commitments as of December 31, 2022 (in thousands):

	Operating Leases	Financing Leases
Year Ending December 31,		
2023	$ 1,048	$ 124
2024	903	-
2025	869	-
2026	899	-
2027	694	-
Total minimum lease payments	$ 4,413	$ 124
Less amounts representing interest	(985)	(7)
Present value of net minimum lease payments	$ 3,428	$ 117

Litigation – General

Oncocyte will be subject to various claims and contingencies in the ordinary course of its business, including those related to litigation, business transactions, employee-related matters, and other matters. When Oncocyte is aware of a claim or potential claim, it assesses the likelihood of any loss or exposure. If it is probable that a loss will result and the amount of the loss can be reasonably estimated, Oncocyte will record a liability for the loss. If the loss is not probable or the amount of the loss cannot be reasonably estimated, Oncocyte discloses the claim if the likelihood of a potential loss is reasonably possible and the amount involved could be material.

Tax Filings

Oncocyte tax filings are subject to audit by taxing authorities in jurisdictions where it conducts business. These audits may result in assessments of additional taxes that are subsequently resolved with the authorities or potentially through the courts. Management believes Oncocyte has adequately provided for any ultimate amounts that are likely to result from these audits; however, final assessments, if any, could be significantly different than the amounts recorded in the consolidated financial statements.

Employment Contracts

Oncocyte has entered into employment and severance benefit contracts with certain executive officers. Under the provisions of the contracts, Oncocyte may be required to incur severance obligations for matters relating to changes in control, as defined, and certain terminations of executives. As of December 31, 2022, Oncocyte accrued approximately $4.4 million in severance obligations for certain executive officers, in accordance with the severance benefit provisions of their respective employment, and severance benefit agreements, related to Oncocyte's acquisition of Chronix Biomedical Inc. in 2021.

Indemnification

In the normal course of business, Oncocyte may provide indemnification of varying scope under Oncocyte's agreements with other companies or consultants, typically Oncocyte's clinical research organizations, investigators, clinical sites, suppliers and others. Pursuant to these agreements, Oncocyte will generally agree to indemnify, hold harmless, and reimburse the indemnified parties for losses and expenses suffered or incurred by the indemnified parties arising from claims of third parties in connection with the use or testing of Oncocyte's diagnostic tests. Indemnification provisions could also cover third party infringement claims with respect to patent rights, copyrights, or other intellectual property pertaining to Oncocyte's diagnostic tests. Oncocyte's office and laboratory facility leases also will generally contain indemnification obligations, including obligations for indemnification of the lessor for environmental law matters and injuries to persons or property of others, arising from Oncocyte's use or occupancy of the leased property. The term of these indemnification agreements will generally continue in effect after the termination or expiration of the particular research, development, services, lease, or license agreement to which they relate. The Purchase Agreement also contains provisions under which Oncocyte has agreed to indemnify Razor and Encore from losses and expenses resulting from breaches or inaccuracy of Oncocyte's representations and warranties and breaches or nonfulfillment of Oncocyte's covenants, agreements, and obligations under the Purchase Agreement. The potential future payments Oncocyte could be required to make under these indemnification agreements will generally not be subject to any specified maximum amounts. Historically, Oncocyte has not been subject to any claims or demands for indemnification. Oncocyte also maintains various liability insurance policies that limit Oncocyte's financial exposure. As a result, Oncocyte management believes that the fair value of these indemnification agreements is minimal. Accordingly, Oncocyte has not recorded any liabilities for these agreements as of December 31, 2022 and 2021.

11. Workforce Reduction

In August 2022, the Company initiated a workforce reduction plan to strategically realign its operations and implement cost reduction programs to prioritize near term revenue generators and to manage and preserve cash. In connection with the reduction, the Company eliminated 14 positions, implemented tighter expense controls, and ceased non-core activities.

Further, on December 16, 2022, Oncocyte initiated an additional reduction in work force involving over 40% of its full-time employees. The transition began on December 16, 2022 and was completed in February 2023. As of December 31, 2022, the Company incurred an aggregate of $1.9 million related to employee severance and benefits costs in connection with its reductions in force during fiscal year 2022.

12. Related Party Transactions

Financing Transactions

On January 20, 2021, Oncocyte entered into Subscription Agreements with certain institutional investors for a registered direct offering of 7,301,410 shares of common stock, no par value, at an offering price of $3.424 per share, for an aggregate purchase price of $25.0 million. The price per share was the average of the closing price of our common stock on the NYSE American for the five trading days prior to the date on which we and the investors executed the Subscription Agreements. Oncocyte did not pay any fees or commissions to broker-dealers or any finder's fees, nor did it issue any stock purchase warrants, in connection with the offer and sale of the shares. The investors included Broadwood Partners, L.P., the Company's largest shareholder, and certain investment funds and accounts managed by Pura Vida Investments, LLC ("Pura Vida").

On February 9, 2021, Oncocyte completed an underwritten public offering of 8,947,000 shares of common stock at a public offering price of $4.50 per share, before underwriting discounts and commissions (the "2021 Offering"). Oncocyte received aggregate net proceeds of approximately $37.5 million, after deducting commissions, discounts and estimated expenses related to the 2021 Offering. Broadwood purchased 600,000 shares in the 2021 Offering.

On September 23, 2021, Oncocyte entered into a Warrant Exercise Agreement with Broadwood, pursuant to which (i) Oncocyte agreed to reduce the exercise price of a common stock warrant held by Broadwood to purchase up to 573,461 shares of common stock from $3.25 per share to $3.1525 per share; and (ii) Broadwood agreed to exercise the common stock warrant in full on or prior to December 31, 2021. Shortly after executing the Warrant Exercise Agreement, Broadwood exercised the common stock warrant in full and received 573,461 shares in exchange for payment to Oncocyte of $1,807,835.81.

On April 13, 2022, Oncocyte entered into the Securities Purchase Agreement with Investors, including Broadwood and John Peter Gutfreund, a director of Oncocyte, for the Series A Preferred Stock Offering. Each of Broadwood and Mr. Gutfreund has a direct material interest in the Series A Preferred Stock Offering and agreed to purchase 5,882.35 and 1,176.48 shares, respectively, in the Series A Preferred Stock Offering and on the same terms as other investors. Additionally, Halle Capital Management, L.P. received $85,000 from the Company as reimbursement for its legal fees and expenses. Mr. Gutfreund is the Managing Partner of Halle Capital Management, L.P. See Note 15 for additional information about the Series A Preferred Stock Offering.

Further, on April 13, 2022, Oncocyte entered into the Underwriting Agreement with the Underwriters for the Underwritten Offering. Pursuant to the Underwritten Offering, Broadwood acquired from us (i) 5,220,654 shares of common stock, and (ii) 6,003,752 April 2022 Warrants to purchase up to 3,001,876 shares of common stock at an exercise price of $1.53 per share. However, the total number of shares of common stock that Broadwood purchased in the Underwritten Offering was 6,003,752, of which 783,098 existing shares were acquired by the underwriters in the open market and re-sold to Broadwood. Pura Vida acquired from us (i) 4,984,093 shares of common stock, and (ii) 5,731,707 April 2022 Warrants to purchase up to 2,865,853 shares of common stock. However, the total number of shares of common stock that Pura Vida purchased in the Underwritten Offering was 5,731,707, of which 747,614 existing shares were acquired by the underwriters in the open market and re-sold to Pura Vida. Halle Special Situations Fund LLC purchased from us (i) 6,199,527 shares of common stock, and (ii) 7,129,456 2022 Warrants to purchase up to 3,564,728 shares of common stock. Mr. Gutfreund is the investment manager and a control person of Halle Capital Partners GP LLC, the managing member of Halle Special Situations Fund LLC. However, the total number of shares of common stock that Halle Special Situations Fund LLC purchased in the Underwritten was 7,129,456, of which 929,929 existing shares were acquired by the underwriters in the open market and re-sold to Halle Special Situations Fund LLC. See Note 15 for additional information about the Underwritten Offering.

13. Loan Payable to Silicon Valley Bank

Amended Loan Agreement

On October 17, 2019, Oncocyte entered into a First Amendment to Loan and Security Agreement (the "Amended Loan Agreement") with Silicon Valley Bank ("the Bank") pursuant to which Oncocyte obtained a new $3 million secured credit facility ("Tranche 1"), a portion of which was used to repay the remaining balance of approximately $400,000 on outstanding loans from the Bank, plus a final payment of $116,000, under the February 21, 2017 Loan Agreement. The credit line under the Amended Loan Agreement may be increased by an additional $2 million ("Tranche 2") if Oncocyte obtains at least $20 million of additional equity capital, as was the case with the original Loan Agreement, and a positive final coverage determination is received from CMS for DetermaRx at a specified minimum price point per test (the "Tranche 2 Milestone"), and Oncocyte is not in default under the Amended Loan Agreement. As of December 31, 2022, Oncocyte had satisfied the Tranche 2 Milestone, however, did not borrow any funds under Tranche 2.

Payments of interest only on the principal balance were due monthly from the draw date through March 31, 2020, followed by 24 monthly payments of principal and interest, but the Bank agreed to a deferral of principal payments, as discussed below. The outstanding principal balance of the loan bore interest at a stated floating annual interest equal to the greater of (a) the prime rate or (b) 5% per annum. During August 2022, period in which the loan was paid of, the published prime rate was 5.5% per annum.

On April 2, 2020, as part of the Bank's COVID-19 pandemic relief program, Oncocyte and the Bank entered into a Loan Deferral Agreement ("Loan Deferral") with respect to the Amended Loan Agreement. Under the Loan Deferral Agreement, the Bank agreed to (i) extend the scheduled maturity date of the Amended Loan Agreement from March 31, 2022 to September 30, 2022, and (ii) deferred the principal payments by an additional 6 months whereby payments of interest only on the Bank loan principal balance will be due monthly from May 1, 2020 through October 1, 2020, followed by 23 monthly payments of principal and interest beginning on November 1, 2020, all provided at no additional fees to Oncocyte.No other terms of the Amended Loan Agreement were changed or modified.

At maturity of the loan, Oncocyte agreed to pay the Bank an additional final payment fee of $200,000, which was recorded as a deferred financing charge in October 2019 and is being amortized to interest expense over the term of the loan using the effective interest method. As of December 31, 2022, there is no remaining unamortized deferred financing cost and the full principal balance of the loan in addition to the final payment fee have been paid off.

Bank Warrants

In 2017, in connection with the Loan Agreement, Oncocyte issued common stock purchase warrants to the Bank (the "2017 Bank Warrants") entitling the Bank to purchase shares of Oncocyte common stock in tranches related to the loan tranches under the Loan Agreement. In conjunction with the availability of the loan, the Bank was issued warrants to purchase 8,247 shares of Oncocyte common stock at an exercise price of $4.85 per share, through February 21, 2027. On March 23, 2017, the Bank was issued warrants to purchase an additional 7,321 shares at an exercise price of $5.46 per share, through March 23, 2027. The Bank may elect to exercise the 2017 Bank Warrants on a "cashless exercise" basis and receive a number of shares determined by multiplying the number of shares for which the applicable tranche is being exercised by (A) the excess of the fair market value of the common stock over the applicable exercise price, divided by (B) the fair market value of the common stock. The fair market value of the common stock will be the last closing or sale price on a national securities exchange, interdealer quotation system, or over-the-counter market.

On October 17, 2019, in conjunction with Tranche 1 becoming available under the Amended Loan Agreement, Oncocyte issued a common stock purchase warrant to the Bank (the "2019 Bank Warrant") entitling the Bank to purchase 98,574 shares of Oncocyte common stock at the initial "Warrant Price" of $1.69 per share through October 17, 2029. The number of shares of common stock issuable upon the exercise of the 2019 Bank Warrant will increase on the date of each draw, if any, on Tranche 2. The number of additional shares of common stock issuable upon the exercise of the 2019 Bank Warrant will be equal to 0.02% of Oncocyte's fully diluted equity outstanding for each $1 million draw under Tranche 2. The Warrant Price for Tranche 2 warrant shares will be determined upon each draw of Tranche 2 funds and will be closing price of Oncocyte common stock on the NYSE American or other applicable market on the date immediately before the applicable date on which Oncocyte borrows funds under Tranche 2. The Bank may elect to exercise the 2019 Bank Warrant on a "cashless exercise" basis and receive a number of shares determined by multiplying the number of shares for which the 2019 Bank Warrant is being exercised by (A) the excess of the fair market value of the common stock over the applicable Warrant Price, divided by (B) the fair market value of the common stock. The fair market value of the common stock will be last closing or sale price on a national securities exchange, interdealer quotation system, or over-the-counter market. As of December 31, 2022, Oncocyte has not borrowed any funds under Tranche 2.

14. Co-Development Agreement with Life Technologies Corporation

On January 13, 2022, Oncocyte entered into a Collaboration Agreement (the "LTC Agreement") with Life Technologies Corporation, a Delaware corporation and subsidiary of Thermo Fisher Scientific ("LTC" and together with Oncocyte, the "Parties" or individually, a "Party"), in order to partner in the development and collaborate in the commercialization of Thermo Fisher Scientific's existing Oncomine Comprehensive Assay Plus ("OCA Plus") and Oncocyte's DetermaIO assay for use with LTC's Ion Torrent™ Genexus™ Integrated Sequencer and LTC's Ion Torrent™ Genexus™ Purification System ("Genexus system") in order to obtain *in vitro* diagnostic ("IVD") regulatory approval.

Development

Under the terms of the LTC Agreement, Oncocyte will clinically validate LTC's OCA Plus assay, which is LTC's proprietary NGS-based assay designed to be run on the Genexus system as an IVD assay (the "Collaboration LTC Product") and Oncocyte's Determa IO assay, which is a multivariate gene expression test performed on FFPE biopsy specimens, as an IVD assay run on the Genexus system (the "Collaboration Determa Product"), paving the way toward regulatory approval for use in tumor profiling and guidance of therapy selection for solid tumor cancers in humans. LTC retains the exclusive right to partner with therapeutics companies to develop the Collaboration LTC Product as a companion diagnostic. Oncocyte retains the exclusive right to partner with therapeutics companies to develop the Collaboration Determa Product as a companion diagnostic. All development work will be conducted pursuant to development plans agreed by the Parties through a series of governance committees that will oversee the collaboration.

Costs Associated with Product Development

Oncocyte will be responsible for all costs associated with Oncocyte activities under the LTC product development budget. Oncocyte and LTC will share development costs associated with LTC activities under the LTC product development budget. LTC will be responsible for costs associated with the performance of research and development activities for the RUO-labeled OCA Plus and related components as is necessary to enable the development of the Collaboration LTC Product as contemplated by the LTC product development plan. Oncocyte will be responsible for all costs associated with activities of both Parties under the Determa product development budget. LTC will be responsible, at LTC's own cost, for the performance of research and development activities for the RUO-labeled OCA Plus and related components as is necessary to enable the development of the Collaboration LTC Product as contemplated by the development plan for the Collaboration LTC Product.

Commercialization

LTC will be responsible for the commercialization of the Collaboration LTC Product throughout the world, but the Parties will co-market it in the United States, Canada, the United Kingdom, European Union, Switzerland, Australia, and New Zealand (the "LTC Product Territory"). Oncocyte will be responsible for the commercialization of the Collaboration Determa Product in the United States (the "Determa Product Territory"), and LTC will be responsible for commercializing it in the rest of the world. All commercialization activities for the Collaboration LTC Product and the Collaboration Determa Product will be conducted pursuant to commercialization plans agreed by the Parties through the collaboration's governance committees.

Economic Terms

Under the LTC Agreement, LTC will pay Oncocyte a percentage of revenue received by LTC on sales of the Collaboration LTC Product throughout the world and on sales of the Collaboration Determa Product outside the United States. The revenue share percentage for the Collaboration LTC Product will vary based on the timing of the sale, the territory of the sale, and the degree to which consumables, reagents, and other products are included in the kit being sold, but the Company estimates that the average revenue share percentage that it will receive under the LTC Agreement will likely range from the low teens to the low twenties. The revenue share percentage LTC will pay to Oncocyte on sales of the Collaboration Determa Product will vary based on the timing of the sale, and the degree to which consumables, reagents, and other products are included in the kit being sold, but the Company estimates that the average revenue share that it will receive under the LTC Agreement will likely range in the low twenties. Oncocyte will pay LTC a mid single-digit percentage of its revenue on sales of the Collaboration Determa Product in the United States. Oncocyte will also receive up to two milestone payments in the low seven figures if LTC successfully commercializes the OCA Plus IVD assay as a companion diagnostic with certain claims.

Exclusivity

During the term of the LTC Agreement, (a) LTC will not enter into any agreement or arrangement with any third party with respect to the development or commercialization of OCA Plus on the Genexus system in the field of distributed IVD assay kits for the tumor profiling of and guidance of therapy selection for solid tumor cancers in humans (the "LTC Field") in the LTC Product Territory, (b) Oncocyte will not partner with any third-party NGS equipment manufacturer with respect to the development and commercialization of a comprehensive genomic profiling assay on an instrument platform similar to or competitive with LTC's NGS systems in the LTC Field in the LTC Product Territory, and (c) LTC will not develop, market or sell a new panel or other substantially similar comprehensive genomic profiling assay that would compete with the Collaboration LTC Product in the LTC Field in the LTC Product Territory on the Genexus system.

Manufacturing

LTC is responsible for the manufacture and supply of all OCA Plus assays and Collaboration LTC products, among other consumables and reagents required for the development of the Collaboration LTC Product. LTC will supply Oncocyte all consumables and reagents necessary for use in developing the Collaboration LTC Product pursuant to the LTC product development plan.

In addition, following the effective date of the LTC Agreement, the Parties will negotiate in good faith a supply agreement pursuant to which LTC will supply Oncocyte with the Collaboration Determa Products for commercialization in the United States. LTC will also supply Oncocyte with all Genexus instruments, consumables and reagents, necessary for use in developing Collaboration Determa Products pursuant to the Determa product development plan.

Term; Termination

Unless earlier terminated as described in the LTC Agreement, the LTC Agreement will remain in effect until December 31, 2035. The LTC Agreement may be (i) terminated for cause by either Party based on any uncured material breach or insolvency by the other Party, and (ii) terminated by either Party with respect to specific termination events occurring for either the Collaboration LTC products or the Collaboration Determa Products, including but not limited to, the failure to achieve certain milestones and failure to agree to initial development or commercialization plans for the Collaboration Determa Product. If LTC fails to meet its certain product development milestones, the term of the LTC Agreement shall be extended on a proportionate basis.

As of December 31, 2022, the Company owned 10 Genexus Integrated Sequencers and 10 Genexus Purification Instruments in connection with submission of an initial PO of $3.1 million by February 11, 2022. The Company may submit a second PO of $4.6 million for 15 Genexus Integrated Sequencers and 15 Genexus Purification Instruments by March 1, 2023. As of December 31, 2022, the Company had received all Genexus systems valued at $1.9 million for the initial purchase order.

As of December 31, 2022, LTC has incurred $749,000 in development costs associated with LTC activities under the total LTC $5 million product development budget that the Company is responsible for reimbursement.

On February 7, 2023, Oncocyte entered into a Termination Agreement (the "Termination Agreement") with LTC, pursuant to which the parties terminated the LTC Agreement.

15. April 2022 Offerings

Series A Preferred Stock Offering

On April 13, 2022, Oncocyte entered into the Securities Purchase Agreement with Investors, including Broadwood, in a registered direct offering of 11,765 shares of our Series A Preferred Stock, which shares of Series A Preferred Stock are convertible into a total of 7,689,542 shares of our common stock, at a conversion price of $1.53. The purchase price of each share of Series A Preferred Stock was $850, which included an original issue discount to the stated value of $1,000 per share. The rights, preferences and privileges of the Series A Convertible Preferred Stock are set forth in the Company's Certificate of Determination, which the Company filed with the Secretary of State of the State of California. The Securities Purchase Agreement provides that the closing of the Series A Preferred Stock Offering will occur, subject to the satisfactory of certain closing conditions, in two equal tranches of $5,000,000 each for aggregate gross proceeds from both closings of $10,000,000. The first closing occurred on June 1, 2022, and Oncocyte received net proceeds of approximately $4.9 million from the Series A Preferred Stock issued from the first tranche. The second closing would occur, subject to the satisfactory of certain closing conditions (including but not limited to a requirement that the Company has not received, in the 12 months preceding the second closing, a notice from The Nasdaq Stock Market LLC ("Nasdaq") that the Company is not in compliance with the listing and maintenance and listing requirements of Nasdaq), on the earlier of (a) the second trading day following the date that Oncocyte receives notice from an Investor to accelerate the second closing and (b) a date selected by Oncocyte on or after October 8, 2022 and on or prior to March 8, 2023. On August 9, 2022, Oncocyte received a letter from Nasdaq indicating that the Company no longer meets the minimum bid price requirement of Nasdaq Listing Rule 5450(a)(1) of the Nasdaq continued listing requirements. Accordingly as of December 31, 2022, no additional proceeds are expected from the second closing of the Security Purchase Agreement.

The Series A Preferred Stock is convertible into shares of common stock at any time at the holder's option. The conversion price will be subject to customary anti-dilution adjustments for matters such as stock splits, stock dividends and other distributions on common stock, and recapitalizations. The holder will be prohibited from converting shares of Series A Preferred Stock into shares of common stock if, as a result of such conversion, the holder, together with its affiliates, would own more than 4.99% of the shares of common stock then issued and outstanding (provided a holder may elect, at the first closing, to increase such beneficial ownership limitation solely as to itself up to 19.99% of the number of shares of common stock outstanding immediately after giving effect to the conversion, provided further that following the receipt of shareholder approval required by applicable Nasdaq rules with respect to the issuance of common stock that would exceed the beneficial ownership limitation, such beneficial ownership limitation will no longer apply to the holder if the holder notified the Company that the holder wishes the Company to seek such shareholder approval). On July 15, 2022, the Company received such shareholder approval to remove the beneficial ownership limitation with respect to the Series A Preferred Stock held by Broadwood Partners, L.P. Oncocyte may force the conversion of up to one-third of the shares of Series A Preferred Stock originally issued, subject to customary equity conditions, if the daily volume weighted average price of our common stock for 20 out of 30 trading days exceeds 140% of the conversion price and on 20 out of the same 30 trading days the daily trading volume equals or exceeds 400,000 shares of our common stock. Oncocyte may only effect one forced conversion during any 30-trading day period.

In the event of the Company's liquidation, dissolution, or winding up, holders of Series A Preferred Stock will receive a payment equal to the stated value of the Series A Preferred Stock plus accrued but unpaid dividends and any other amounts that may have become payable on the Series A Preferred Stock due to any failure or delay that may have occurred in issuing shares of common stock upon conversion of a portion of the Series A Preferred Stock, before any distribution or payment to the holders of common stock or any of Oncocyte's other junior equity.

Shares of Series A Preferred Stock generally has no voting rights, except as required by law and except that the consent of holders of a majority of the outstanding Series A Preferred Stock will be required to amend any provision of our certificate of incorporation that would have a materially adverse effect on the rights of the holders of the Series A Preferred Stock. Additionally, as long as any shares of Series A Preferred Stock remain outstanding, unless the holders of at least 51% of the then outstanding shares of Series A Preferred Stock shall have otherwise given prior written consent, the Company, on a consolidated basis with its subsidiaries, is not permitted to (1) have less than $8 million of unrestricted, unencumbered cash on hand ("Cash Minimum Requirement"); (2) other than certain permitted indebtedness, incur indebtedness to the extent that our aggregate indebtedness exceeds $15 million; (3) enter into any agreement (including any indenture, credit agreement or other debt instrument) that by its terms prohibits, prevents, or otherwise limits our ability to pay dividends on, or redeem, the Series A Preferred Stock in accordance with the terms of the Certificate of Determination; or (4) authorize or issue any class or series of preferred stock or other capital stock of the Company that ranks senior or pari passu with the Series A Preferred Stock.

Shares of Series A Preferred Stock will be entitled to receive cumulative dividends at a rate per share (as a percentage of stated value) of 6% per annum, payable quarterly in cash or, at our option, by accreting such dividends to the stated value.

The Company is required to redeem, for cash, the shares of Series A Preferred Stock on the earlier to occur of (1) April 8, 2024, (2) the commencement of certain a voluntary or involuntary bankruptcy, receivership, or similar proceedings against us or our assets, (3) a Change of Control Transaction (as defined herein) and (4) at the election and upon notice of 51% in interest of the holders, if the Company fails to meet the Cash Minimum Requirement. A "Change of Control Transaction" means the occurrence of any of (a) an acquisition by an individual or legal entity or "group" (as described in Rule 13d-5(b)(1) promulgated under the Exchange Act) of effective control (whether through legal or beneficial ownership of capital stock of the Company, by contract or otherwise) of in excess of 50% of the voting securities of the Company (other than by means of conversion of Series A Preferred Stock), (b) the Company merges into or consolidates with any other person, or any person merges into or consolidates with the Company and, after giving effect to such transaction, the stockholders of the Company immediately prior to such transaction own less than 50% of the aggregate voting power of the Company or the successor entity of such transaction, or (c) the Company sells or transfers all or substantially all of its assets to another person. Additionally, the Company has the right to redeem the Series A Preferred Stock for cash upon 30 days prior notice to the holders; provided if the Company undertakes a capital raise in connection with such redemption, the Investors will have the right to participate in such financing.

The issuance and sale of the Series A Preferred Stock was completed pursuant to the Company's effective shelf registration statement on Form S-3 (Registration No. 333-256650), filed with the Securities and Exchange Commission on May 28, 2021 and declared effective by the SEC on June 8, 2021, and an accompanying prospectus dated June 8, 2021 as supplemented by a prospectus supplement dated April 13, 2022.

The Series A Preferred Stock dividend for all issued and outstanding shares is set at 6% per annum per share. As of December 31, 2022, the Company elected to accrete dividends of $209,000, with respect to shares of Series A Preferred Stock.

As of December 31, 2022, Oncocyte had 5,882.4 shares issued and outstanding. The future right or obligation associated with the Series A Preferred Stock to be issued in the second closing was written off since the second closing is not expected as of December 31, 2022.

Underwritten Offering

On April 13, 2022, Oncocyte entered into the Underwriting Agreement with the Underwriters, pursuant to which the Company agreed to issue and sell to the Underwriters an aggregate of 26,266,417 shares of common stock and 26,266,417 April 2022 Warrants to purchase up to 13,133,208.5 shares of common stock. Each share of common stock and the accompanying April 2022 Warrant was sold at a combined offering price of $1.3325, representing an offering price of $1.3225 per share of common stock and $0.01 per accompanying April 2022 Warrant, before underwriting discounts and commissions.

Under the terms of the Underwriting Agreement, the Company also granted to the Underwriters an over-allotment option, exercisable in whole or in part at any time for a period of 30 days from the date of the Underwriting Agreement, to purchase up to an additional 3,939,962 shares of common stock and 3,939,962 April 2022 Warrants to purchase 1,969,981 shares of common stock to cover over-allotments, if any. The over-allotment option may be exercised separately for shares of common stock at a price to the underwriters of $1.24255 per share, and April 2022 Warrants at a price of $0.01 per April 2022 Warrant. On April 14, 2022, the Underwriters exercised their option to purchase the 3,939,962 April 2022 Warrants pursuant to the over-allotment option but did not exercise their option to purchase the additional 3,939,962 shares of common stock.

The Company received net proceeds of approximately $32.8 million from the Underwritten Offering, which includes the April 2022 Warrants sold upon the exercise of the Underwriters' overallotment option. The Underwritten Offering closed on April 19, 2022.

The Underwritten Offering was made pursuant to the Company's effective "shelf" registration statement on Form S-3 (Registration No. 333-256650) filed with the Securities and Exchange Commission on May 28, 2021 and declared effective by the SEC on June 8, 2021, and an accompanying prospectus dated June 8, 2021 as supplemented by a prospectus supplement dated April 13, 2022.

16. Assets Held for Sale and Discontinued Operations

On December 15, 2022, the Company entered into the Razor Stock Purchase Agreement with Dragon and Razor. Pursuant to the Razor Stock Purchase Agreement, Oncocyte agreed to sell, and Dragon agreed to purchase, 3,188,181 shares of common stock of Razor, which constitutes approximately 70% of the issued and outstanding equity interests of Razor on a fully-diluted basis. The Razor Stock Purchase Agreement provides that following the closing of the transaction, Oncocyte will own 1,366,364 shares of common stock of Razor, which will constitute approximately 30% of the issued and outstanding equity interests of Razor on a fully-diluted basis. The transfer involves the transfer of all the assets and liabilities related to DetermaRx. Other than the exchange of shares, the Agreement includes purchase of furniture, fixtures, and equipment by the buyer for a cash consideration of $115,660. Upon closing of the sale, the Company will deconsolidate the assets and liabilities of Razor as control of the Razor entity will transfer to Dragon.

As of December 31, 2022, Razor met the held for sale criteria and is reflected as a discontinued operation in the consolidated financial statements for all periods presented. Additionally, the related assets and liabilities have been reported as assets and liabilities held for sale in the Company's consolidated balance sheets as of December 31, 2022 and December 31, 2021.

Because the carrying value of the net assets of Razor exceeded the net proceeds included in the Agreement, we determined that Razor's held for sale net assets had been impaired. After performing quantitative testing, in which we used the consideration of $0.1 million as the fair value of the underlying net assets, we recorded a $25.9 million impairment of the net assets. The impairment loss has been included in the results of discontinued operations in the accompanying consolidated financial statements.

The Company's balance sheets and consolidated statements of operations report discontinued operations separate from continuing operations. Our consolidated statements of comprehensive income, statement of equity and statements of cash flows combined continuing and discontinued operations. A summary of financial information related to the Company's discontinued operations is as follows.

The following table represents the results of the discontinued operation of Razor (in thousands):

	Year Ended December 31,	
	2022	2021
Net revenue	$ 4,673	$ 5,529
Cost of revenues	7,930	6,761
Research and development	12,136	8,596
Sales and marketing	12,462	10,615
General and administrative	569	44
Loss from impairment of held for sale assets	25,866	-
Net loss from discontinued operations	$ (54,290)	$ (20,487)

The following table represents the carrying amounts of the assets and liabilities held for sale related to Razor as of December 31, 2022 and 2021 (in thousands):

	December 31,	
	2022	2021
Carrying amounts of assets of disposal group held for sale		
Current assets:		
Cash and cash equivalents	$ 1,510	$ 2,657
Prepaid expenses and other current assets	346	296
Machinery and equipment, net, and construction in progress	211	-
Intangible assets, net	25,920	-
Impairment of held for sale assets	(25,866)	-
Total current assets of disposal group held for sale	2,121	2,953
Machinery and equipment, net, and construction in progress	-	158
Intangible assets, net	-	29,524
Total assets of disposal group held for sale	2,121	32,635
Current liabilities:		
Accounts payable	492	637
Accrued compensation	248	549
Accrued expenses and other current liabilities	1,265	340
Total current liabilities of disposal group held for sale	2,005	1,526

The following table summarizes cash used related to Razor as of and for the years ended December 31, 2022 and 2021 (in thousands):

	Year Ended December 31,	
	2022	2021
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net cash used in operating activities	(20,790)	(13,643)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Net cash used in investing activities	(91)	(188)

17. Subsequent Events

Razor Genomics, Inc. Stock Purchase Agreement Closing

On February 16, 2023, Oncocyte completed the Razor Sale Transaction, which involved, among other things, the. sale of 3,188,181 shares of common stock of the Company's wholly owned subsidiary Razor, which constitutes approximately 70% of the issued and outstanding equity interests of Razor on a fully diluted basis, pursuant to the Razor Stock Purchase Agreement (the "SPA") with Dragon and Razor.

In connection with the Razor Closing, Oncocyte transferred to Razor all of the assets and liabilities related to DetermaRx. While no monetary consideration was received for the sale of 70% of the equity interests of Razor, the transaction allows the Company to eliminate all development and commercialization costs with respect to DetermaRx. Following the Razor Closing, Oncocyte continues to own 1,366,364 shares of common stock of Razor, which constitutes approximately 30% of the issued and outstanding equity interests of Razor on a fully-diluted basis. See Note 16 for more details.

As part of the SPA, the Company entered in a Bill of Sale to transfer certain assets as consideration for these assets, the Company will receive a one time cash payment of $115,660.

Chronix Biomedical, Inc. Amendment No. 1 to Amended and Restated Agreement and Plan of Merger

On February 8, 2023, Oncocyte and the party named as equity holder representative in the Chronix Merger Agreement entered into Amendment No. 1 to the Chronix Merger Agreement (the "Chronix Amendment"), pursuant to which the parties agreed to amend the terms of the Chronix Contingent Consideration such that (i) Chronix's equity holders will be paid earnout consideration of 10% of net collections for sales of specified tests and products, until the expiration of intellectual property related to such tests and products, (ii) Chronix's equity holders will be paid 5% of the gross proceeds received from any sale of all or substantially all of the rights, titles, and interests in and to Chronix's patents for use in transplantation medicine to such third party, and (iii) obligations related to the Chronix Milestone Payments, Royalty Payments and Transplant Sale Payments were eliminated.

Termination of Co-Development Agreement with Life Technologies Corporation

On February 7, 2023, Oncocyte entered into the Termination Agreement with LTC, pursuant to which the Parties terminated the LTC Agreement, by and between Oncocyte and LTC.

Public Offering of Common Stock

On April 3, 2023, Oncocyte entered into an agreement with certain members of the Company's board of directors, and several institutional and accredited investors, including Broadwood Capital, L.P., the Company's largest shareholder, and certain members of the Company's board of directors (and certain of their affiliated parties), relating to their purchase of an aggregate of up to 45,562,425 shares of its common stock at an offering price of $0.3544 per share to board members and $0.30168 per share to the other investors participating in the offering. The offering is intended to be priced at-the-market for purposes of complying with applicable NASDAQ Listing Rules. The aggregate gross proceeds from the offering were approximately $13.9 million. The Company used approximately $1.1 million of the net proceeds to immediately redeem an aggregate of 1,064 shares of its Series A Convertible Preferred Stock and may thereafter elect to redeem additional shares.

Workforce Reduction

On April 12, 2023, Oncocyte announced a reduction in force involving approximately 20% of its workforce ("Reduction"), which management believes will extend Oncocyte's cash runway in 2024. In connection with the Reduction, we estimate that we will incur charges of approximately $0.3 million related to employee severance and benefits costs in the second quarter of 2023.

Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure.

Not applicable.

Item 9A. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

It is management's responsibility to establish and maintain adequate internal control over all financial reporting pursuant to Rule 13a-15 under the Exchange Act. Our management, including our principal executive officer and our principal financial officer, have reviewed and evaluated the effectiveness of our disclosure controls and procedures as of December 31, 2022. Following this review and evaluation, management collectively determined that our disclosure controls and procedures are effective to ensure that information required to be disclosed by us in reports that we file or submit under the Exchange Act (i) is recorded, processed, summarized and reported within the time periods specified in SEC rules and forms; and (ii) is accumulated and communicated to management, including our chief executive officer and our chief financial officer, as appropriate to allow timely decisions regarding required disclosure.

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting that occurred during the fourth quarter of our fiscal year ended December 31, 2022 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Management's Report on Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting. Internal control over financial reporting, as defined in Exchange Act Rule 13a-15(f), is a process designed by, or under the supervision of, our principal executive officer, our principal operations officer, and our principal financial officer, and effected by our Board of Directors, management, and other personnel, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles and includes those policies and procedures that:

- Pertain to the maintenance of records that in reasonable detail accurately and fairly reflect the transactions and dispositions of our assets;
- Provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that our receipts and expenditures are being made only in accordance with authorizations of our management and directors; and
- Provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of our assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate. All internal control systems, no matter how well designed, have inherent limitations. Therefore, even those systems determined to be effective can provide only reasonable assurance with respect to financial statement preparation and presentation.

A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of our annual or interim financial statements will not be prevented or detected on a timely basis. Our management assessed the effectiveness of our internal control over financial reporting as of December 31, 2022. In making this assessment, our management used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) in Internal Control-Integrated Framework. Based on this assessment, Management identified the material weaknesses that have caused management to conclude that, as of December 31, 2022, our disclosure controls and procedures, and our internal control over financial reporting, were not effective at the reasonable assurance level:

- We did not maintain an effective control environment. Specifically, we did not maintain sufficient accounting resources commensurate with our structure and financial reporting requirements. This contributed to the material weakness described below:
- We did not design and maintain effective controls to address the initial application of complex accounting standards and accounting treatment of non-routine, unusual or complex events and transactions.

To address these material weaknesses, management performed additional analyses and other procedures to ensure that the financial statements included herein fairly present, in all material respects, our financial position, results of operations and cash flows for the periods presented. Accordingly, we believe that the financial statements included in this report fairly present, in all material respects, our financial condition, results of operations and cash flows for the periods presented.

Remediation of Material Weakness

To remediate the material weakness in our documentation, evaluation and testing of internal controls we plan to

- We continue to design and implement controls to address the identification, accounting for, and review of non-routine, unusual or complex and initial applications of complex accounting standards, including the continued engagement of external consultants to provide support and to assist us in our evaluation of such transactions.

Item 9B. Other Information

None.

Item 9C. Disclosure Regarding Foreign Jurisdictions That Prevent Inspections

Not applicable.

PART III

Item 10. Directors, Executive Officers, and Corporate Governance

The information required by this item will be contained in our Proxy Statement for our 2023 Annual Meeting of Shareholders, to be filed with the SEC within 120 days after December 31, 2022, and is incorporated herein by reference.

We have a written Code of Business Conduct and Ethics ("Code of Ethics") that applies to our principal executive officer, our principal financial officer and principal accounting officer, our other executive officers, our other employees, and our directors. The purpose of the Code of Ethics is to deter wrongdoing and to promote (i) honest and ethical conduct, including the ethical handling of actual or apparent conflicts of interest between personal and professional relationships; (ii) full, fair, accurate, timely, and understandable disclosure in reports and documents that we file with or submit to the SEC and in our other public communications; (iii) compliance with applicable governmental rules and regulations; (iv) prompt internal reporting of violations of the Code of Ethics to an appropriate person or persons identified in the Code; and (v) accountability for adherence to the Code. A copy of our Code of Ethics has been posted on our internet website and can be found at *www.oncocyte.com*. If we amend or waive a provision of our Code of Ethics that applies to our chief executive officer or chief financial officer, we will post the amended Code of Ethics or information about the waiver on our internet website.

Information about our compliance with Section 16(a) of the Securities Exchange Act of 1934 reported under the caption "Delinquent Section 16(a) Reports" in our Proxy Statement for our 2023 Annual Meeting of Shareholders, which will be filed no later than 120 days after December 31, 2022, and is incorporated herein by reference.

Item 11. Executive Compensation

Information about compensation of our executive officers reported under the caption "Executive Compensation," and information about compensation of directors reported under the caption "Director Compensation," in our Proxy Statement for our 2023 Annual Meeting of Shareholders is incorporated herein by reference.

Item 12. Security Ownership of Certain Beneficial Owners and Management, and Related Stockholder Matters

The information required by this item will be contained in our Proxy Statement for our 2023 Annual Meeting of Shareholders, to be filed with the SEC within 120 days after December 31, 2022, and is incorporated herein by reference.

Item 13. Certain Relationships and Related Transactions, and Director Independence

The information required by this item will be contained in our Proxy Statement for our 2023 Annual Meeting of Shareholders, to be filed with the SEC within 120 days after December 31, 2022, and is incorporated herein by reference.

Item 14. Principal Accountant Fees and Services

The information required by this item will be contained in our Proxy Statement for our 2023 Annual Meeting of Shareholders, to be filed with the SEC within 120 days after December 31, 2022, and is incorporated herein by reference.

PART IV

Item 15. Exhibit and Financial Statement Schedules

(a-1) Financial Statements.

The following consolidated financial statements of Oncocyte Corporation are filed in the Form 10-K:

Consolidated Balance Sheets

Consolidated Statements of Operations

Consolidated Statements of Comprehensive Income

Consolidated Statements of Shareholders' Equity

Consolidated Statements of Cash Flows

Exhibit Numbers	Exhibit Description
1.1	At-The-Market Sales Agreement, dated June 11, 2021, between OncoCyte Corporation and BTIG, LLC (Incorporated by reference to Oncocyte Corporation's Current Report on Form 8-K filed with the Securities and Exchange Commission on June 11, 2021)
1.2	Underwriting Agreement, dated April 13, 2022, between Oncocyte Corporation and BTIG, LLC, as representative of the underwriters named therein (Incorporated by reference to Oncocyte Corporation's Form 8-K filed with the Securities and Exchange Commission on April 19, 2022).
2.1	Subscription and Stock Purchase Agreement, dated September 4, 2019, among Oncocyte Corporation, Encore Clinical, Inc., and Razor Genomics Inc.† (Incorporated by reference to Oncocyte Corporation's Current Report on Form 8-K filed with the Securities and Exchange Commission on October 3, 2019)
2.2	Agreement and Plan of Merger, dated as of January 10, 2020, among Oncocyte Corporation, Cancer DX Sub, Inc., Insight Genetics, Inc., the Shareholders who became a Party to the Merger Agreement and the Equityholder Representative. (Incorporated by reference to Oncocyte Corporation's Current Report on Form 8-K filed with the Securities and Exchange Commission on February 5, 2020)
2.3	Agreement and Plan of Merger, dated as of February 2, 2021, among Oncocyte Corporation, CNI Monitor Sub, Inc., Chronix Biomedical, Inc., the Shareholders who became a Party to the Merger Agreement and the Equityholder Representative (Incorporated by Reference to Current Report on Form 8-K filed with the Securities and Exchange Commission on February 3, 2021)
2.4	Agreement and Plan of Merger dated February 2, 2021, amended February 23, 2021, and amended and restated as of April 15, 2021, by and among OncoCyte Corporation, CNI Monitor Sub, Inc., Chronix Biomedical, Inc., the Stockholders who became a party to the Merger Agreement and the Equityholder Representative (Incorporated by reference to Oncocyte Corporation's Current Report on Form 8-K filed with the Securities and Exchange Commission on April 19, 2021)
2.5	Stock Purchase Agreement, dated December 15, 2022, by and among Dragon Scientific, LLC, Oncocyte Corporation and Razor Genomics Inc. (Incorporated by reference to Oncocyte Corporation's Current Report on Form 8-K filed with the Securities and Exchange Commission on December 21, 2022)
2.6	First Amendment to Stock Purchase Agreement, dated December 15, 2022, by and among Dragon Scientific, LLC, Oncocyte Corporation and Razor Genomics Inc. (Incorporated by reference to Oncocyte Corporation's Current Report on Form 8-K filed with the Securities and Exchange Commission on February 13, 2023)
2.8	Second Amendment to Stock Purchase Agreement, dated February 16, 2023, by and among Dragon Scientific, LLC, Oncocyte Corporation and Razor Genomics Inc. (Incorporated by reference to Oncocyte Corporation's Current Report on Form 8-K filed with the Securities and Exchange Commission on February 23, 2023)
2.7	Amendment No. 1 to Amended and Restated Agreement and Plan of Merger dated February 8, 2023, by and between Oncocyte Corporation and David MacKenzie, solely in his capacity as Equityholder Representative (Incorporated by reference to Oncocyte Corporation's Current Report on Form 8-K filed with the Securities and Exchange Commission on February 3, 2023)

3.1	Articles of Incorporation with all amendments (Incorporated by reference to Oncocyte Corporation's Registration Statement on Form S-3 filed with the Securities and Exchange Commission on July 14, 2021)
3.2	Certificate of Determination of Preferences, Rights and Limitations of Series A Convertible Preferred Stock (Incorporated by reference to Oncocyte Corporation's Current Report on Form 8-K filed with the Securities and Exchange Commission on April 13, 2022)
3.3	Amended and Second Amended and Restated By-Laws (Incorporated by reference to Oncocyte Corporation's Quarterly Report on Form 8-K filed with the Securities and Exchange Commission on November 9, 2022)
4.1	Specimen of Common Stock Certificate (Incorporated by reference to Oncocyte Corporation's Form 10 12(b) filed with the Securities and Exchange Commission on November 23, 2015)
4.2	Form of August 2016 Warrant (Incorporated by reference to Oncocyte Corporation's Current Report on Form 8-K filed with the Securities and Exchange Commission on August 29, 2016)
4.3	Form of 2017 Warrant, Exercise Price $3.25 (Incorporated by reference to Oncocyte Corporation's Annual Report on Form 10-K filed with the Securities and Exchange Commission on February 27, 2017)
4.4	Form of 2017 Warrant, Exercise Price $5.50 (Incorporated by reference to Oncocyte Corporation's Annual Report on Form 10-K filed with the Securities and Exchange Commission on February 27, 2017)
4.5	Silicon Valley Bank Warrant (Incorporated by reference to Oncocyte Corporation's Annual Report on Form 10-K filed with the Securities and Exchange Commission on February 27, 2017)
4.6	Form of July 2017 Warrant, Exercise Price $5.50; five-year term (Incorporated by reference to Oncocyte Corporation's Current Report on Form 8-K filed with the Securities and Exchange Commission on July 26, 2017)
4.7	Form of July 2017 Warrant, Exercise Price $3.25, five-year term (Incorporated by reference to Oncocyte Corporation's Current Report on Form 8-K filed with the Securities and Exchange Commission on July 26, 2017)
4.8	Form of July 2018 Warrant (Incorporated by reference to Oncocyte Corporation's Current Report on Form 8-K filed with the Securities and Exchange Commission on August 1, 2018)
4.9	Warrant to Purchase Shares of Common Stock, dated August 1, 2019 (Incorporated by reference to Oncocyte Corporation's Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission on August 14, 2019)
4.10	Warrant to Purchase Common Stock, dated October 17, 2019, between Oncocyte Corporation and Silicon Valley Bank (Incorporated by Reference to Oncocyte Corporation's Current Report on Form 8-K filed with the Securities and Exchange Commission on October 21, 2019)
4.11	Form of Common Stock Warrant (Incorporated by reference to Oncocyte Corporation's Current Report on Form 8-K filed with the Securities and Exchange Commission on April 19, 2022)
4.12	Description of Securities*
10.1	Form of Director/Consultant Option Agreement (Incorporated by reference to Oncocyte Corporation's Form 10 12(b) filed with the Securities and Exchange Commission on November 23, 2015)
10.2	Form of Employee Incentive Stock Option Agreement (Incorporated by reference to Oncocyte Corporation's Form 10 12(b) filed with the Securities and Exchange Commission on November 23, 2015)

10.3	Registration Rights Agreement dated October 15, 2009 (Incorporated by reference to Oncocyte Corporation's Form 10 12(b) filed with the Securities and Exchange Commission on November 23, 2015)
10.4	Amendment of Registration Rights Agreement, dated August 23, 2011 (Incorporated by reference to Oncocyte Corporation's Form 10 12(b) filed with the Securities and Exchange Commission on November 23, 2015)
10.5	Second Amendment of Registration Rights Agreement, dated May 8, 2015 (Incorporated by reference to Oncocyte Corporation's Form 10 12(b) filed with the Securities and Exchange Commission on November 23, 2015)
10.6	Third Amendment to Registration Rights Agreement, dated November 16, 2015 (Incorporated by reference to Oncocyte Corporation's Form 10 12(b) A-1 filed with the Securities and Exchange Commission on December 29, 2015)
10.7	Form of Alternate Warrant Exercise Agreement, dated February 17, 2017 (Incorporated by reference to Oncocyte Corporation's Current Report on Form 8-K filed with the Securities and Exchange Commission on February 24, 2017)
10.8	Loan and Security Agreement, dated February 21, 2017, between Oncocyte Corporation and Silicon Valley Bank (Incorporated by reference to Oncocyte Corporation's Annual Report on Form 10-K filed with the Securities and Exchange Commission on February 27, 2017)
10.9	2017 Amendment to 2010 Stock Option Plan (Incorporated by reference to Registration Statement on Form S-8, File Number 333-219109 filed with the Securities and Exchange Commission on June 30, 2017)
10.10	Form of July 2017 Warrant Exercise Agreement, dated July 21, 2017 (July 2017 Warrant for 100% of shares received on exercise of Original Warrant, at $5.50 exercise price with five-year term) (Incorporated by reference to Oncocyte Corporation's Current Report on Form 8-K filed with the Securities and Exchange Commission on July 26, 2017)
10.11	Form of July 2017 Warrant Exercise Agreement, dated July 21, 2017 (July 2017 Warrant for 50% of shares received on exercise of Original Warrant, at $3.25 exercise price with five-year term) (Incorporated by reference to Oncocyte Corporation's Current Report on Form 8-K filed with the Securities and Exchange Commission on July 26, 2017)
10.12	Employment Agreement, dated November 15, 2017, between Oncocyte Corporation and Mitchell Levine (Incorporated by reference to Oncocyte Corporation's Annual Report on Form 10-K filed with the Securities and Exchange Commission on April 2, 2018)
10.13	2018 Equity Incentive Plan (Incorporated by reference to Oncocyte Corporation's Current Report on Form 8-K filed with the Securities and Exchange Commission on August 29, 2018)
10.14	Amendment to 2018 Equity Incentive Plan (Incorporated by reference to Oncocyte Corporation's Current Report on Form 8-K filed with the Securities and Exchange Commission on June 28, 2021)
10.15	Form of 2018 Equity Incentive Plan Employee Stock Option Agreement (Incorporated by reference to Oncocyte Corporation's Current Report on Form 8-K filed with the Securities and Exchange Commission on August 29, 2018)
10.16	Form of 2018 Equity Incentive Plan Non-Employee Director Stock Option Agreement (Incorporated by reference to Oncocyte Corporation's Current Report on Form 8-K filed with the Securities and Exchange Commission on August 29, 2018)

10.17	Form of 2018 Equity Incentive Plan Restricted Stock Unit Agreement (Incorporated by reference to Oncocyte Corporation's Current Report on Form 8-K filed with the Securities and Exchange Commission on August 29, 2018)
10.18	Employment Agreement, dated May 22, 2019, between Oncocyte Corporation and Padma Sundar (Incorporated by Reference to Annual Report on Form 10-K Filed with the Securities and Exchange Commission on March 26, 2020)
10.19	Employment Agreement, dated June 4, 2019, between Oncocyte Corporation and Ronald Andrews (Incorporated by reference to Oncocyte Corporation's Current Report on Form 8-K filed with the Securities and Exchange Commission on June 6, 2019)
10.20	Amendment to 2018 Equity Incentive Plan (Incorporated by reference to Oncocyte Corporation's Current Report on Form 8-K filed with the Securities and Exchange Commission on July 23, 2019)
10.21	Development Agreement, dated December 31, 2019, among Oncocyte Corporation, Encore Clinical, Inc., and Razor Genomics Inc.† (Incorporated by reference to Oncocyte Corporation's Current Report on Form 8-K filed with the Securities and Exchange Commission on October 3, 2019)
10.22	Sublicense and Distribution Agreement, dated December 31, 2019, among Oncocyte Corporation, Encore Clinical, Inc., and Razor Genomics Inc.† (Incorporated by reference to Oncocyte Corporation's Current Report on Form 8-K filed with the Securities and Exchange Commission on October 3, 2019)
10.23	Laboratory Services Agreement, dated August 15, 2015, as amended, among Oncocyte Corporation, Encore Clinical, Inc., and Razor Genomics Inc.† (Incorporated by reference to Oncocyte Corporation's Current Report on Form 8-K filed with the Securities and Exchange Commission on October 3, 2019)
10.24	First Amendment to Loan and Security Agreement, dated October 17, 2019, between Oncocyte Corporation and Silicon Valley Bank† (Incorporated by reference to Oncocyte Corporation's Current Report on Form 8-K filed with the Securities and Exchange Commission on October 21, 2019)
10.25	Office Lease Agreement, dated December 23, 2019, as amended between Oncocyte Corporation and Cushing Ventures, LLC (Incorporated by reference to Oncocyte Corporation's Current Report on Form 8-K filed with the Securities and Exchange Commission on December 27, 2019)
10.26	Lease Agreement, dated November 10, 2011, between Insight Genetics, Inc. and MPC Holdings, LLC, as renewed by notice dated January 3, 2019 (Incorporated by Reference to Annual Report on Form 10-K Filed with the Securities and Exchange Commission on March 26, 2020)
10.27	Oncocyte Corporation Change in Control and Severance Plan (Incorporated by Reference to Annual Report on Form 10-K Filed with the Securities and Exchange Commission on March 26, 2020)
10.28	Form of Change in Control and Severance Agreement (Incorporated by Reference to Annual Report on Form 10-K Filed with the Securities and Exchange Commission on March 26, 2020)
10.29	Form of Subscription Agreement between Oncocyte Corporation and Certain Investors (Incorporated by Reference to Current Report on Form 8-K filed with the Securities and Exchange Commission on April 28, 2020)
10.30	U.S. Small Business Administration Paycheck Protection Program Note (Incorporated by Reference to Current Report on Form 8-K filed with the Securities and Exchange Commission on April 29, 2020)
10.31	Loan Deferral Agreement, dated April 2, 2020, between OncocCyte Corporation and Silicon Valley Bank (Incorporated by Reference to Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission on May 12, 2020)

10.32	Acknowledgement and Agreement, dated May 7, 2020, between Oncocyte Corporation and Ronald Andrews (Incorporated by Reference to Current Report on Form 8-K filed with the Securities and Exchange Commission on May 12, 2020)
10.33	Acknowledgement and Agreement, dated May 7, 2020, between Oncocyte Corporation and Mitchell Levine (Incorporated by Reference to Current Report on Form 8-K filed with the Securities and Exchange Commission on May 12, 2020)
10.34	Acknowledgement and Agreement, dated May 7, 2020, between Oncocyte Corporation and Lyndal Hesterberg (Incorporated by Reference to Current Report on Form 8-K filed with the Securities and Exchange Commission on May 12, 2020)
10.35	Employment Agreement, dated March 23, 2020, between Oncocyte Corporation and Doug Ross (Incorporated by Reference to Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission on July 29, 2020)
10.36	Reduction in Salary Agreement between Oncocyte Corporation and Albert Parker (Incorporated by Reference to Current Report on Form 8-K filed with the Securities and Exchange Commission on September 28, 2020)
10.37	Reduction in Salary Agreement between Oncocyte Corporation and Lyndal Hesterberg (Incorporated by Reference to Current Report on Form 8-K filed with the Securities and Exchange Commission on September 28, 2020)
10.38	Reduction in Salary Agreement between Oncocyte Corporation and Tony Kalajian (Incorporated by Reference to Current Report on Form 8-K filed with the Securities and Exchange Commission on September 28, 2020)
10.39	Change in Control and Executive Severance Plan Agreement, dated October 4, 2021, between Oncocyte Corporation and Gisela Paulsen (Incorporated by Reference to Current Report on Form 8-K filed with the Securities and Exchange Commission on October 7, 2021)
10.40	Subscription Agreements, dated January 20, 2021, between Oncocyte Corporation and the Investors Named Therein (Incorporated by Reference to Current Report on Form 8-K filed with the Securities and Exchange Commission on January 21, 2021)
10.41	Amended and Restated Exclusive License Agreement, effective February 15, 2018, between Razor Genomics, Inc. and the licensor named therein † (Incorporated by Reference to Annual Report on Form 10-K Filed with the Securities and Exchange Commission on March 19, 2021)
10.42	Addendum No. 2 to Exclusive Sublicense Agreement in the PRC Territory, dated December 5, 2021, by and among Razor Genomics, Inc., Oncocyte Corporation, Encore Clinical, Inc., and Burning Rock Biotech Limited (Incorporated by Reference to Current Report on Form 8-K filed with the Securities and Exchange Commission on December 8, 2021)
10.43	Collaboration Agreement, dated January 13, 2022, by and between Oncocyte Corporation and Life Technologies Corporation† (Incorporated by reference to Oncocyte Corporation's Annual Report on Form 10-K filed with the Securities and Exchange Commission on March 11, 2022)
10.44	Form of Securities Purchase Agreement, among us and certain investors, dated April 13, 2022 (Incorporated by reference to Oncocyte Corporation's Current Report on Form 8-K filed with the Securities and Exchange Commission on April 13, 2022)
10.45	Separation Agreement and General Release of All Claims, by and between the Company and Ronald Andrews, dated December 1, 2022 (Incorporated by reference to Oncocyte Corporation's Current Report on Form 8-K filed with the Securities and Exchange Commission on December 5, 2022)
10.46	Consulting Agreement, by and between the Company and Ronald Andrews, dated as of December 1, 2022 (Incorporated by reference to Oncocyte Corporation's Current Report on Form 8-K filed with the Securities and Exchange Commission on December 5, 2022)

10.47	Employment Agreement, by and between the Company and Joshua Riggs, effective as of December 2, 2022 (Incorporated by reference to Oncocyte Corporation's Current Report on Form 8-K filed with the Securities and Exchange Commission on December 5, 2022)
10.48	Amended & Restated Change in Control and Executive Severance Plan Agreement, by and between the Company and Joshua Riggs, effective as of December 2, 2022 (Incorporated by reference to Oncocyte Corporation's Current Report on Form 8-K filed with the Securities and Exchange Commission on December 5, 2022)
10.49	Separation Agreement and General Release of All Claims, by and between the Company and Gisela Paulsen, dated December 16, 2022 (Incorporated by reference to Oncocyte Corporation's Current Report on Form 8-K filed with the Securities and Exchange Commission on December 21, 2022)
10.50	Separation Agreement and General Release of All Claims, by and between the Company and Douglas Ross, dated December 16, 2022 (Incorporated by reference to Oncocyte Corporation's Current Report on Form 8-K filed with the Securities and Exchange Commission on December 21, 2022)
10.51	Consulting Agreement, by and between the Company and Douglas Ross, dated as of December 16, 2022 (Incorporated by reference to Oncocyte Corporation's Current Report on Form 8-K filed with the Securities and Exchange Commission on December 21, 2022)
10.52	Termination Agreement, dated February 7, 2023, by and between Oncocyte Corporation and Life Technologies Corporation (Incorporated by reference to Oncocyte Corporation's Current Report on Form 8-K filed with the Securities and Exchange Commission on February 13, 2023)
16.1	Letter from OUM to the Securities and Exchange Commission dated July 20, 2021 (Incorporated by Reference to Current Report on Form 8-K filed with the Securities and Exchange Commission on July 20, 2021)
21	Subsidiaries*
23.1	Consent of Withum Smith+Brown, PC*
31.1	Certification of the Chief Executive Officer of Oncocyte Corporation pursuant to Rule 13a-14 of the Securities Exchange Act of 1934, as amended, as adopted pursuant to Rule 302 of the Sarbanes-Oxley Act of 2002*
31.2	Certification of the Chief Financial Officer of Oncocyte Corporation pursuant to Rule 13a-14 of the Securities Exchange Act of 1934, as amended, as adopted pursuant to Rule 302 of the Sarbanes-Oxley Act of 2002*
32.1	Certifications pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002**
101	Interactive Data Files *
101.INS	Inline XBRL Instance Document*
101.SCH	Inline XBRL Taxonomy Extension Schema8
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase*
101.DEF	Inline XBRL Taxonomy Extension Definition Document*
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase*
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase*
104	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101)*

*Filed herewith

**Furnished herewith

† Portions of this exhibit have been omitted because the omitted information is (i) not material and (ii) is the type that the registrant treats as private or confidential.

Item 16. Form 10-K Summary

None.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the Registrant has duly caused this report on Form 10-K to be signed on its behalf by the undersigned, thereunto duly authorized on the 12th day of April 2023.

ONCOCYTE CORPORATION

By: */s/ Josh Riggs*

Josh Riggs

Chief Executive Officer

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the Registrant and in the capacities and on the dates indicated.

Signature	Title	Date
/s/ Josh Riggs	President and Chief Executive Officer and Director	April 12, 2023
JOSH RIGGS	(Principal Executive Officer)	
/s/ Anish John	Chief Financial Officer	April 12, 2023
ANISH JOHN	(Principal Financial Officer)	
/s/ James Liu	Controller & Principal Accounting Officer	April 12, 2023
JAMES LIU	(Principal Accounting Officer)	
/s/ Andrew Arno	Director	April 12, 2023
ANDREW ARNO		
/s/ Alfred D. Kingsley	Director	April 12, 2023
ALFRED D. KINGSLEY		
/s/ Andrew Last	Director	April 12, 2023
ANDREW LAST		
/s/ Jennifer L Carter	Director	April 12, 2023
JENNIFER L. CARTER		
/s/ Louis E. Silverman	Director	April 12, 2023
LOUIS E. SILVERMAN		
/s/ John Peter Gutfreund	Director	April 12, 2023
JOHN PETER GUTFREUND		

Exhibit 4.12 4.13

DESCRIPTION OF SECURITIES

The following description of certain terms of Oncocyte Corporation ("Oncocyte" or the "Company") common stock is a summary and is qualified in its entirety by reference to (i) Oncocyte's Articles of Incorporation, as amended, (ii) Oncocyte's Certificate of Determination of Preferences, Rights and Limitations of Series A Convertible Preferred Stock, (iii) Oncocyte's Second Amended and Restated Bylaws, and (iv) the California General Corporation Law.

Common Stock

The Oncocyte Articles of Incorporation currently authorize the issuance of up to 230,000,000 shares of common stock, no par value. Each holder of record of common stock is entitled to one vote for each outstanding share owned, on every matter properly submitted to the shareholders for their vote; provided, that if any shareholder entitled to vote at a meeting at which directors are to be elected gives timely notice of their intention to cumulate votes in the election of directors, shareholders may cumulate votes for the election of directors.

Subject to the dividend rights of holders of any preferred stock that may be issued from time to time, holders of common stock are entitled to any dividend declared by the Oncocyte Board of Directors out of funds legally available for that purpose.

Subject to the prior payment of the applicable liquidation preference to holders of any preferred stock that may be issued from time to time, holders of common stock are entitled to receive on a pro rata basis all remaining assets available for distribution to the holders of common stock in the event of the liquidation, dissolution, or winding up of Oncocyte's operations.

Holders of common stock do not have any preemptive, subscription, redemption, or conversion rights. There are no redemption or sinking fund provisions applicable to the common stock. The rights, powers, preferences and privileges of holders of Oncocyte common stock will be subject to those of the holders of any shares of Oncocyte preferred stock that may be issued in the future.

Preferred Stock

The Oncocyte Articles of Incorporation currently authorize the issuance of up to 5,000,000 shares of common stock, no par value. The Preferred Stock may be issued in one or more series as the Oncocyte board Board of directors Directors may by resolution designate. The Oncocyte board Board of directors Directors is authorized to fix the number of shares of any series of Preferred Stock and to determine or alter the rights, preferences, privileges, and restrictions granted to or imposed upon the Preferred Stock as a class, or upon any wholly unissued series of Preferred Stock. The Oncocyte board Board of directors Directors may, by resolution, increase or decrease (but not below the number of shares of such series then outstanding) the number of shares of any series of Preferred Stock subsequent to the issue of shares of that series. On May 27, 2022, Oncocyte filed a Certificate of Determination of Preferences, Rights and Limitations of Series A Convertible Preferred Stock with the California Secretary of State, establishing the rights, preferences and privileges relating to 11,765 shares of Oncocyte's Series A Convertible Preferred Stock, no par value. The Series A Convertible Preferred Stock rank senior to Oncocyte common stock, with respect to rights as to as to dividends, distributions, redemptions and payments upon the liquidation, dissolution and winding up of Oncocyte.

The Series A Convertible Preferred Stock generally have no voting rights, except as required by law and except that the consent of holders of a majority of the outstanding Series A Convertible Preferred Stock is required to amend any provision of the Oncocyte Articles of Incorporation that would have a materially adverse effect on the rights of the holders of the Series A Convertible Preferred Stock. Additionally, as long as any shares of Series A Convertible Preferred Stock remain outstanding, unless the holders of at least 51% of the then outstanding shares of Series A Convertible Preferred Stock shall have otherwise given prior written consent, Oncocyte, on a consolidated basis with its subsidiaries, is not permitted to (1) have less than $8 million of unrestricted, unencumbered cash on hand ("Cash Minimum Requirement"); (2) other than certain permitted indebtedness, incur indebtedness to the extent that Oncocyte's aggregate indebtedness exceeds $15 million; (3) enter into any agreement (including any indenture, credit agreement or other debt instrument) that by its terms prohibits, prevents, or otherwise limits our ability to pay dividends on, or redeem, the Series A Convertible Preferred Stock in accordance with the terms of the Certificate of Determination of Preferences, Rights and Limitations of Series A Convertible Preferred Stock; or (4) authorize or issue any class or series of preferred stock or other capital stock that ranks senior or pari passu with the Series A Convertible Preferred Stock.

Oncocyte is required to redeem, for cash, the shares of Series A Convertible Preferred Stock on the earlier to occur of (1) April 8, 2024, (2) the commencement of certain a voluntary or involuntary bankruptcy, receivership, or similar proceedings against us or our assets, (3) a Change of Control Transaction (as defined herein) and (4) at the election and upon notice of 51% in interest of the holders, if Oncocyte fails to meet the Cash Minimum Requirement. A “Change of Control Transaction” means the occurrence of any of (a) an acquisition by an individual or legal entity or “group” (as described in Rule 13d-5(b)(1) promulgated under the Exchange Act) of effective control (whether through legal or beneficial ownership of capital stock of the Company, by contract or otherwise) of in excess of 50% of the voting securities of the Company (other than by means of conversion of Series A Convertible Preferred Stock), (b) the Company merges into or consolidates with any other person, or any person merges into or consolidates with the Company and, after giving effect to such transaction, the stockholders of the Company immediately prior to such transaction own less than 50% of the aggregate voting power of the Company or the successor entity of such transaction, or (c) the Company sells or transfers all or substantially all of its assets to another person. Additionally, Oncocyte has the right to redeem the Series A Convertible Preferred Stock for cash upon 30 days prior notice to the holders; provided if the Company undertakes a capital raise in connection with such redemption, the holders of the Series A Convertible Preferred Stock will have the right to participate in such financing.

Warrants

Generally

The Company may issue warrants to purchase the Company’s common stock or preferred stock. Warrants may be issued independently or together with any other securities and may be attached to, or separate from, such securities. Each series of warrants will be issued under a separate warrant agreement to be entered into between the Company and a warrant agent. The terms of any warrants to be issued and a description of the material provisions of the applicable warrant agreement will be set forth in applicable filings with the Securities and Exchange Commission. The number of shares of the Company’s common stock to be received upon the exercise of each warrant may be adjusted from time to time upon the occurrence of certain events, including but not limited to the payment of a dividend or other distribution in respect of common stock, subdivisions, reclassifications, combinations of the Company’s common stock or subsequent rights offerings. The securities receivable upon exercise of each warrant may be adjusted in the event of any reorganization, consolidation, merger, liquidation or similar event.

Outstanding Warrants

As of March 13, 2023 April 3, 2024, the Company has outstanding warrants to purchase 16,395,343 819,767 shares of the Company’s common stock. The warrants are fully vested, exercisable at prices ranging from $1.53 $30.60 to $5.46 $109.20 per share and expire on dates ranging from February 2024 to October 2029. The Company has authorized and reserved for issuance all shares of common stock issuable upon exercise of each warrant. Certain warrants have “cashless exercise” provisions meaning that the value of a portion of warrant shares may be used to pay the exercise price rather than payment in cash, which may be exercised under any circumstances in the case of the 2017 Bank Warrants and 2019 Bank Warrants or, in the case of certain other warrants, only if a registration statement for the warrants and underlying shares of common stock is not effective under the Securities Act or a prospectus in the registration statement is not available for the issuance of shares upon the exercise of the warrants.

Exhibit 21 23.1

ONCOCYTE CORPORATIONINDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM’S CONSENT

The following is a list of subsidiaries We consent to the incorporation by reference in the Registration Statements of Oncocyte Corporation omitting some subsidiaries on Form S-1 (File No. 333-213810), Form S-3 (File Nos. 333-220769, 333-231980, 333-240207, 333-252765, 333-256650 and 333-257905) and Form S-8 (File Nos. 333-219109, 333-208935, 333-227118, 333-232773 and 333-257740) of our report dated April 15, 2024, which considered includes an explanatory paragraph as to the Company’s ability to continue as a going concern, with respect to our audits of the consolidated financial statements of Oncocyte Corporation as of December 31, 2023 and for the year ended December 31, 2023, which report is included in this Annual Report on Form 10-K of Oncocyte Corporation for the year ended December 31, 2023.

Our report on the consolidated financial statements refers to a change in the aggregate, would not constitute a significant subsidiary. method of accounting for allowance for credit losses effective January 1, 2023.

Subsidiary	State or Jurisdiction of Incorporation
Insight Genetics, Inc.	Tennessee
Chronix Biomedical, Inc.	Delaware
Chronix Biomedical GmbH	Germany

/s/ Marcum LLP

Marcum LLP
Costa Mesa, CA
April 15, 2024

Exhibit 23.1 23.2

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We hereby consent to the incorporation by reference in Amendment No. 2 to Registration Statement on Form S-1 (No. 333-213810), Registration Statements on Form S-3 (Nos. 333-220769, 333 231980, 333-231980, 333-240207, 333-252765, 333-256650 and 333-257905) and Registration Statements on Form S-8 (Nos. 333-219109, 333-208935, 333-227118, 333-232773 and 333-257740) of Oncocyte Corporation of our report dated April 12, 2023, relating to the consolidated financial statements which appears as of and for the year ended December 31, 2022, appearing in this Annual Report on Form 10-K.

/s/ WithumSmith+Brown, PC

East Brunswick, New Jersey
April 12, 2023 15, 2024

Exhibit 10.28

Exhibit 10.29

Exhibit 10.30

Exhibit 31.1

CERTIFICATIONS CERTIFICATION

I, Josh Riggs, certify that:

1. I have reviewed this annual report on Form 10-K of Oncocyte Corporation;

2 Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rule 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this periodic report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: April 12, 2023 April 15, 2024

/s/ Josh Riggs

Josh Riggs
President and Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

CERTIFICATIONS CERTIFICATION

I, Anish John, James Liu, certify that:

1. I have reviewed this annual report on Form 10-K of Oncocyte Corporation;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rule 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this periodic report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

(c) (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: April 12, 2023April 15, 2024

/s/ Anish John James Liu

Anish John James Liu
Chief
Controller, Principal Accounting Officer and interim Principal Financial Officer
(Principal Financial Officer)

Exhibit 32.1

CERTIFICATION CERTIFICATIONS PURSUANT TO 18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report on Form 10-K of Oncocyte Corporation (the "Company") for the year ended December 31, 2022 December 31, 2023 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), we, Josh Riggs, President and Chief Executive Officer of the Company, and Anish John, Chief James Liu, Controller, Principal Accounting Officer and interim Principal Financial Officer of the Company, certify pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

1 The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and

2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: April 12, 2023Date: April 15, 2024

/s/ Josh Riggs

Josh Riggs
President and Chief Executive Officer
(Principal Executive Officer)

/s/ Anish John James Liu

Anish John James Liu
Chief
Controller, Principal Accounting Officer and interim Principal Financial Officer
(Principal Financial Officer)

Exhibit 97.1

ONCOYTE CORPORATION
(The "Company")
CLAWBACK POLICY
Adopted November 2, 2023

Introduction

The Board of Directors of the Company (the "**Board**") believes that it is in the best interests of the Company and its shareholders to create and maintain a culture that emphasizes integrity and accountability in furtherance of the Board's intention to follow sound corporate governance practices. The Board has therefore adopted this policy which provides for the recoupment of certain executive compensation in the event of an accounting restatement resulting from material noncompliance with financial reporting requirements under the federal securities laws (the "**Policy**"). This Policy is designed to comply with Section 10D of the Securities Exchange Act of 1934 (the "**Exchange Act**").

Administration

This Policy shall be administered by the Board or, if so designated by the Board, the Compensation Committee, in which case references herein to the Board shall be deemed references to the Compensation Committee. Any determinations made by the Board shall be final and binding on all affected individuals.

Covered Executives

This Policy applies to the Company's Section 16 officers, Chief Science Officer, Chief Technology Officer and General Counsel ("**Covered Executives**").

Recoupment; Accounting Restatement

In the event the Company is required to prepare an accounting restatement of its financial statements due to the Company's material noncompliance with any financial reporting requirement under the securities laws, the Board will require reimbursement or forfeiture of any excess Incentive Compensation received by any Covered Executive during the three completed fiscal years immediately preceding the date on which the Company is required to prepare an accounting restatement.

Incentive Compensation

For purposes of this Policy, Incentive Compensation means any of the following; provided that, such compensation is granted, earned, or vested based wholly or in part on the attainment of a financial reporting measure:

- Annual bonuses and other short- and long-term cash incentives.
- Stock options.
- Stock appreciation rights.
- Restricted stock.
- Restricted stock units.
- Performance shares.
- Performance units.

Financial reporting measures include:

- Company stock price.
- Total shareholder return.
- Revenues.
- Net income.
- Earnings before interest, taxes, depreciation, and amortization (EBITDA).
- Funds from operations.
- Liquidity measures such as working capital or operating cash flow.
- Return measures such as return on invested capital or return on assets.
- Earnings measures such as earnings per share.

Excess Incentive Compensation: Amount Subject to Recovery

The amount to be recovered will be the excess of the Incentive Compensation paid to the Covered Executive based on the erroneous data over the Incentive Compensation that would have been paid to the Covered Executive had it been based on the restated results, as determined by the Board.

If the Board cannot determine the amount of excess Incentive Compensation received by the Covered Executive directly from the information in the accounting restatement, then it will make its determination based on a reasonable estimate of the effect of the accounting restatement.

Method of Recoupment

The Board will determine, in its sole discretion, the method for recouping Incentive Compensation hereunder which may include, without limitation:

(a) requiring reimbursement of cash Incentive Compensation previously paid;

(b) seeking recovery of any gain realized on the vesting, exercise, settlement, sale, transfer, or other disposition of any equity-based awards;

(c) offsetting the recouped amount from any compensation otherwise owed by the Company to the Covered Executive;

(d) cancelling outstanding vested or unvested equity awards; and/or

(e) taking any other remedial and recovery action permitted by law, as determined by the Board.

No Indemnification

The Company shall not indemnify any Covered Executives against the loss of any incorrectly awarded Incentive Compensation.

Interpretation

The Board is authorized to interpret and construe this Policy and to make all determinations necessary, appropriate, or advisable for the administration of this Policy. It is intended that this Policy be interpreted in a manner that is consistent with the requirements of Section 10D of the Exchange Act and any applicable rules or standards adopted by the Securities and Exchange Commission or any national securities exchange on which the Company's securities are listed.

Effective Date

This Policy shall be effective as of the date it is adopted by the Board (the "**Effective Date**") and shall apply to Incentive Compensation that is approved, awarded or granted to Covered Executives on or after that date.

Amendment; Termination

The Board may amend this Policy from time to time in its discretion and shall amend this Policy as it deems necessary to reflect final regulations adopted by the Securities and Exchange Commission under Section 10D of the Exchange Act and to comply with any rules or standards adopted by a national securities exchange on which the Company's securities are listed. The Board may terminate this Policy at any time.

Other Recoupment Rights

The Board intends that this Policy will be applied to the fullest extent of the law. The Board may require that any employment agreement, equity award agreement, or similar agreement entered into on or after the Effective Date shall, as a condition to the grant of any benefit thereunder, require a Covered Executive to agree to abide by the terms of this Policy. Any right of recoupment under this Policy is in addition to, and not in lieu of, any other remedies or rights of recoupment that may be available to the Company pursuant to the terms of any similar policy in any employment agreement, equity award agreement, or similar agreement and any other legal remedies available to the Company.

Impracticability

The Board shall recover any excess Incentive Compensation in accordance with this Policy unless such recovery would be impracticable, as determined by the Board in accordance with Rule 10D-1 of the Exchange Act and the listing standards of the national securities exchange on which the Company's securities are listed.

Successors

This Policy shall be binding and enforceable against all Covered Executives and their beneficiaries, heirs, executors, administrators or other legal representatives.

DISCLAIMER

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