

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, 2024
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
(State or other jurisdiction
of incorporation or organization)

27-1041563
(I.R.S. Employer
Identification No.)

15 Cushing
Irvine, California 92618

(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(s)	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 pursuant 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 its 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 Act): Yes ☐ No ☒

The aggregate market value of shares of voting and non-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, 2024 was approximately \$24.6 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 March 17, 2025, there were outstanding 28,599,285 shares of common stock, no par value.

DOCUMENTS INCORPORATED BY REFERENCE
None.

Oncocyte Corporation
Table of Contents
December 31, 2024

	Page Number
<u>Cautionary Note Regarding Forward-Looking Statements</u>	2
<u>Industry and Market Data</u>	3
<u>Part I</u>	
Item 1. <u>Business</u>	5
Item 1A. <u>Risk Factors</u>	18
Item 1B. <u>Unresolved Staff Comments</u>	37
Item 1C. <u>Cybersecurity</u>	37
Item 2. <u>Properties</u>	37
Item 3. <u>Legal Proceedings</u>	38
Item 4. <u>Mine Safety Disclosures</u>	38
<u>Part II</u>	
Item 5. <u>Market for Registrant’s Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities</u>	39
Item 6. <u>[Reserved]</u>	39
Item 7. <u>Management’s Discussion and Analysis of Financial Condition and Results of Operations</u>	40
Item 7A. <u>Quantitative and Qualitative Disclosures about Market Risk</u>	51
Item 8. <u>Financial Statements and Supplementary Data</u>	51
Item 9. <u>Changes in and Disagreements With Accountants on Accounting and Financial Disclosure</u>	51
Item 9A. <u>Controls and Procedures</u>	52
Item 9B. <u>Other Information</u>	53
Item 9C. <u>Disclosure Regarding Foreign Jurisdictions That Prevent Inspections</u>	53
<u>Part III</u>	
Item 10. <u>Directors, Executive Officers and Corporate Governance</u>	54
Item 11. <u>Executive Compensation</u>	59
Item 12. <u>Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters</u>	72
Item 13. <u>Certain Relationships and Related Transactions, and Director Independence</u>	74
Item 14. <u>Principal Accountant Fees and Services</u>	76
<u>Part IV</u>	
Item 15. <u>Exhibits and Financial Statement Schedules</u>	78
Item 16. <u>Form 10-K Summary</u>	82
<u>Signatures</u>	83

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

Certain statements contained in this Annual Report on Form 10-K for the year ended December 31, 2024 (this “Report”) 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. 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” or similar expressions or the negative of such terms) 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 in Part I, Item 1A. 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; 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 Report, 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™, GraftAssureCore™, GraftAssureIQ™ and GraftAssureDx™ are trademarks of Oncocyte, regardless of whether the “TM” symbol accompanies the use of or reference to the applicable trademark in this Report.

We are in the process of rebranding our VitaGraft assay (VitaGraft Kidney and VitaGraft Liver), which is our lab developed test, under the name GraftAssureCore. For purposes of this filing, references to “GraftAssureCore” shall be deemed to include the test previously marketed as VitaGraft. We are also in the process of rebranding our research use only assay, GraftAssure, as “GraftAssureIQ,” and rebranding our future kitted clinical assay as “GraftAssureDx.”

INDUSTRY AND MARKET DATA

This Report 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.

PART I

Summary of Risk Factors

We face many risks and uncertainties, as more fully described in this section under the heading “Risk Factors.” Some of these risks and uncertainties are summarized below. The summary below does not contain all of the information that may be important to you, and you should read this summary together with the more detailed discussion of these risks and uncertainties contained in “Risk Factors.”

Summary - Risks Related to Our Capital Resources

- We have incurred operating losses since inception, and we do not know if we will attain profitability.
- We have historically been dependent upon outside financing capital to fund our operations and until such time as our revenues are sufficient to finance our operating expenses, we may need to issue additional equity or debt securities to raise the capital needed to pay our operating expenses.
- We may incur significant cash payment and common stock issuance obligations under our agreements arising from our investments in Insight and Chronix.

Summary - 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.
- There is a risk of product liability claims in our business. If we are unable to obtain or maintain sufficient insurance, a product liability claim against us could adversely affect our business.
- 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 required to 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.
- Security breaches and other disruptions could compromise our information and expose us to liability, and could cause our business and reputation to suffer.
- We are subject to state laws in California that require gender and diversity quotas for boards of directors of public companies headquartered in California.

Summary - 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.
- Our products are subject to the FDA’s final rule ending enforcement discretion for LDTs and regulating such tests as medical devices. Implementing the requirements under the final rule 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 currently market certain IVDs that have not been cleared by the FDA in reliance on the regulatory exemption for IVDs intended for RUO, but if the FDA determines that our RUO tests do not meet the applicable requirements for exemption or have intended uses that are inconsistent with RUO tests, we may be required to suspend commercialization of such products until we can obtain the requisite FDA clearance and/or subject to FDA warning or untitled letters, seizure, injunction, fines, or other enforcement action.
- We will also need to obtain FDA and other regulatory approvals for any IVDs that we may develop, or for any currently marketed products the FDA determines are IVDs instead of LDTs, 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.
- 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.
- 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.

Summary - 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 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.
- Obtaining and maintaining patent protection depends on compliance with various procedures and other requirements, and our patent protection could be reduced or eliminated in case of non-compliance with these requirements.

Summary - Risks Related to Our Common Stock

- We previously identified and remediated a material weakness in our internal control over financial reporting. If we are unable to 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.
- Because we do not pay dividends, our stock may not be a suitable investment for anyone who needs to earn 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.
- Our former parent company may sell our shares to raise capital to finance its operations.

Item 1. Business.

Overview

We are a pioneering diagnostics technology company. Our mission is to democratize access to novel molecular diagnostic testing to improve patient outcomes.

We do this primarily by developing molecular diagnostic test kits that empower our customers to run their own tests to participate in the patient-care value chain, which is counter-positioned with the central laboratory model. Our decentralized approach also puts testing in the hands of researchers to enable more studies, which inspires innovation, which we believe can improve standards of care while also creating demand for more testing. We develop tests that measure both established biomarkers as well as pioneer the adoption of new and more effective biomarkers.

We believe that combining innovative science with a simple, but disruptive, business model can create enormous value. This model is designed to empower doctors to reduce uncertainty to make better decisions to save lives as well as enable researchers to measure biomarkers to inspire innovation.

Our customer institutions are hospitals, transplant centers, and labs. The decision to deploy our tests on behalf of patients or research studies supports front line doctors, including surgeons, nephrologists and oncologists, as well as researchers, pathologists, lab directors, medical directors, department heads, lab managers, and chief medical officers.

Our operating premise is that democratizing access to testing to foster scientific innovation and better treatments ultimately reduces the cost of care, while expanding access and improving outcomes.

At the heart, we are a science-driven organization that champions scientific integrity and inquiry. We employ world-renowned scientists who generate intellectual property in our strategic target markets. We have built and acquired an intellectual property portfolio that we believe will enable us to gain share in well-established clinical and research markets.

Our current intellectual property comprises three general areas: 1) organ transplant, 2) oncology therapy selection and 3) oncology therapy monitoring. Within these categories, we have developed or are in the process of developing laboratory developed tests (“LDTs”) that can be run at our Nashville, Tennessee lab, kitted research use only (“RUO”) tests, and kitted clinical tests that can be run by local labs.

Our primary near-term strategic market is organ transplant. Oncocyte’s molecular diagnostic tests are designed to help the industry to better address one of the leading challenges in the transplantation market – which is the body’s potential to reject the donor organ. We do this by detecting early evidence of graft organ damage in the blood through assessing a known biomarker known as donor-derived cell-free DNA. GraftAssureCore (Kidney), for example, can find donor kidney damage up to 11 months sooner than other protocols. GraftAssureCore is analytically and clinically validated in three major solid organ transplant types (kidney, liver and heart) by peer reviewed international publications. We received a positive coverage decision from MolDx for GraftAssureCore (Kidney) in August of 2023, and it became commercially available for ordering in January 2024 through our Clinical Laboratory Improvements Amendment (“CLIA”) laboratory in Nashville, Tennessee. GraftAssureCore (Kidney) is now broadly available to transplant professionals upon request. In December 2024, we confirmed Medicare reimbursement for also monitoring certain high-risk patients, that is, those with newly developed donor-specific antibodies.

In July 2024, we began to commercialize the technology underlying GraftAssureCore (Kidney) by distributing its sister product, GraftAssureIQ, which is intended to be sold and used for research purposes and is labeled as RUO. We expect to distribute our RUO production through a mix of direct sales, partnering and distribution agreements, and licensing. We have entered into a global strategic partnership agreement with Bio-Rad Laboratories, Inc. (“Bio-Rad”) to collaborate in the development and the commercialization of RUO and in vitro diagnostic (“IVD”) kitted transplant products for clinical use (see Note 10, “Collaborative Arrangements,” to our consolidated financial statements included elsewhere in this Report for additional information).

Under strict regulatory rules, our kitted tests may not be used in a clinical treatment setting until they have attained IVD clearance from the Food and Drug Administration (“FDA”) in the U.S. and In Vitro Diagnostic Medical Devices Regulation approval in the European Union. As such, we are working with these regulatory bodies to attain such clearance and approval, as applicable, supporting future distribution and higher sales of our products for clinical use.

We also have a laboratory and pharma services lab, certified under the CLIA and accredited by the College of American Pathologists (“CAP”), in Nashville, Tennessee, and a research and development lab in Göttingen, Germany. Our innovation centers in Nashville and Germany employ world-renowned research scientists who, we believe, are leaders in their fields.

Our secondary strategic market is in the field of oncology – namely through diagnostic tests that can measure and predict which patients will best respond to certain types of therapies, as well as provide efficacy monitoring for therapies. For example, we are continuing to develop 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, and triple negative breast cancer. A kitted research product format of the underlying technology began proof-of-concept development in 2023. The application of immunotherapy is a global problem, so we expect partnering opportunities for each of our products as they reach clinical maturity. We also expect to begin commercializing our oncology product line, which includes DetermaIO, over the next 15 months.

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, nor 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 expect that our operating expenses will continue to increase if we successfully complete the development of DetermaIO and commercialize this test.

We also perform other assay development and clinical testing services for pharmaceutical and biotechnology companies through our pharma services operations (“Pharma Services”).

We believe that the experience of our team with diverse technologies through our Pharma Services activities, strong scientific integrity regarding evidence generation and innovation mentality, alongside our flexibility in operations and regulatory strategy, will drive our success, differentiate us from our competition, and are foundational to our future. We are focusing on executing the technology priorities discussed herein, which have evolved to reflect our operations and strategic vision.

Billing, Coverage, and Reimbursement for our Laboratory Tests

We are currently in the process of developing and commercializing GraftAssureCore, GraftAssureIQ, GraftAssureDx, DetermaIO and DetermaCNI.

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. Due to 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 the Centers for Medicare & Medicaid Services (“CMS”) reimbursement approval is critical. CMS relies on a network of Medicare Administrative Contractors (“MACs”) to make a local coverage determination (“LCD”) approving a test for reimbursement. The 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 LCDs 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 LCDs, 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 LCD. 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. While these definitions can vary among payers, an in-network provider usually has a contract with the payer or benefits provider. Such 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 reconsideration 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 limited resources and 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.

Our organ transplant rejection monitoring tests compete with other methods of assessing graft organ health, such as performing a manual biopsy, as well as liquid biopsy tests from competitors that measure donor-derived cell-free DNA, including CareDx, Inc., Natera, Inc., Transplant Genomics, Omixon Inc. and Devyser. Three of our competitors (CareDx, Inc., Natera, Inc. and Transplant Genomics) have an established customer base. We aim to compete by enabling labs to run patient samples locally. We believe that through the use of digital PCR, our tests have attractive sample economics even at low volumes, offer fast turnaround times and offer native absolute quantification, which are expected to be differentiators in the marketplace. Based on our research of customer needs, we believe that turnaround time matters to practitioners while sample economics are important to local labs.

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 Programmed Death-Ligand 1 ("PD-L1") expression testing and Tumor Mutational Burden ("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 the Society for Immunotherapy of Cancer, suggested that DetermaIO outperformed both PD-L1 and TMB in predicting response to checkpoint inhibitors in patients with non-small lung cancer. 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 the European Society for Medical Oncology and the San Antonio Breast Cancer Symposium demonstrated the predictive value of the test. In October 2024, we announced the results of a Phase II clinical trial that demonstrated that DetermaIO was predictive of response to atezolizumab in triple negative breast cancer patients. These results were published in the peer-reviewed journal, Clinical Cancer Research, and validated DetermaIO's utility in potentially identifying breast cancer patients most likely to benefit from atezolizumab.

Facilities

We lease a building located at 15 Cushing in Irvine, California that serves as our principal executive and administrative offices. We also operate a CLIA certified laboratory in Nashville, Tennessee, and through the 2021 acquisition of Chronix Biomedical, Inc. ("Chronix"), we also have a research and development facility in Göttingen, Germany, which serves as the center of excellence for our 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 tests. Additionally, the chemical reagents used with the testing equipment we choose are available only from the equipment manufacturer. This situation poses a risk to us. If we were to encounter inconsistent results using testing equipment and reagents from one manufacturer, we would need to switch 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 in providing the tests to patients and we would lose revenue and potentially market share as a result. See “Part I, Item 1A. Risk Factors – Risks Related to Our Business Operations – *There is a limited number of manufacturers of molecular diagnostic testing equipment and related chemical reagents necessary for the provision of our diagnostic tests.*”

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, to protect our intellectual property rights, and to operate without infringing upon the proprietary rights of others.

Through our acquisition of Insight Genetics, Inc. (“Insight”) 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 our acquisition of Insight, 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-free DNA, with numerous already issued patents in the United States and European Union (“EU”), 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 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 weigh the biomarkers to produce a score. We 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. For additional information regarding the risks related to obtaining and enforcing patent protection, see “Part I, Item 1A. Risk Factors – Risks Related to Intellectual Property.”

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 the simple 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 GraftAssureCore, GraftAssureIQ, GraftAssureDx, DetermaIO and DetermaCNI will continue to be regulated under the CLIA as 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. Since our laboratory in Nashville, Tennessee meets 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. CMS enforces CLIA compliance. CMS granted the CAP Laboratory Accreditation Program deeming authority, which allows CAP inspection in lieu of a CMS inspection. Our laboratory in Nashville, Tennessee is CLIA-certified and CAP-accredited.

FDA Regulation of Diagnostic Tests

We currently believe we have designed, developed, and are validating our tests as LDTs. 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.

However, in May 2024, the FDA finalized a rule, ending its enforcement discretion policy for LDTs. The new rule amends the definition of “in vitro diagnostic products” in FDA regulations to state that IVDs are devices under the FD&C Act “including when the manufacturer of these products is a laboratory.” The FDA determined that the general enforcement discretion approach should be phased out in a manner that accounts for the level of public health concern and the importance of avoiding undue disruption to the testing market, including undue disruption to the provision of care. Therefore, the FDA’s final rule gradually phases out enforcement discretion over a period of four years. The FDA anticipates that this phaseout policy should ultimately enable IVDs offered as LDTs that are supported by sound science to remain on the market. The FDA also recognizes that some IVDs may need to come off the market, because, for example, the IVD cannot meet applicable requirements under the FD&C Act and its implementing regulations, or the laboratory chooses not to invest resources to meet those requirements. Notably, the phaseout policy does not change the FDA’s longstanding expectation that IVDs designed, manufactured, or used outside of a single CLIA-certified laboratory are medical devices and, thus, subject to medical device regulations.

The FDA has structured the phaseout policy to contain five key stages:

- Stage 1: End the general enforcement discretion approach with respect to MDR requirements and correction and removal reporting requirements. Compliance is required by May 6, 2025.
- Stage 2: End the general enforcement discretion approach with respect to requirements other than MDR, correction and removal reporting, quality system (“QS”), and premarket review requirements. Compliance is required by May 6, 2026.
- Stage 3: End the general enforcement discretion approach with respect to QS requirements three years after FDA publishes a final phaseout policy. Compliance is required by May 6, 2027.
- Stage 4: End the general enforcement discretion approach with respect to premarket review requirements for high-risk IVDs. Compliance is required by November 6, 2027.
- Stage 5: End the general enforcement discretion approach with respect to premarket review requirements for moderate risk and low risk IVDs (that require premarket submissions). Compliance is required by May 6, 2028.

As a result of this rule, our tests are currently subject to additional regulatory requirements under the final rule. Complying with the FDA’s requirements can be expensive, time-consuming, and subject us to significant or unanticipated delays. 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.

Further, if any of our current or future LDTs are 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.

While the final rule is currently in effect, the American Clinical Laboratory Association and the Association for Molecular Pathology filed suit against HHS and the FDA seeking to strike down the FDA’s new rule regulating LDTs. The case is currently pending before the Eastern District of Texas.

In addition, Congress has previously considered, and may consider in the future, legislative proposals that would amend the regulatory framework for LDTs, including, among other requirements, FDA premarket review of certain LDTs. We cannot predict the outcome of the lawsuit or any future legislation relating to the FDA’s regulation of LDTs, and we will comply with all regulatory requirements for our current and future LDTs, as long as the final rule remains effective.

International Regulations

The EU has adopted the EU in vitro Diagnostics Regulation (the “EU IVDR”), which imposes stricter requirements for the marketing and sale of in vitro diagnostics products (as compared to the predecessor in vitro Diagnostics Directive), including in the areas of clinical evaluation requirements, quality systems, economic operators and post-market surveillance. Manufacturers of currently marketed in vitro diagnostics products had until May 2022 to meet the requirements of the EU IVDR, though the EU Council and Parliament signed an amendment that delays certain previously mandated deadlines to allow more time for Notified Body of EU countries to manage the entire portfolio of IVD products on the European market.

In addition, Russia has enacted more stringent medical product registration and labeling regulations, China has enacted stricter labeling requirements, and we expect other countries, such as Brazil and India, to impose more regulations that impact our product registrations. The United Kingdom's ("UK") withdrawal from the EU is resulting in additional regulatory requirements associated with goods manufactured and sold in the UK and additional complexities and delays with respect to goods, raw materials and personnel moving between the UK and the EU. In addition, new government administrations may interpret existing regulations or practices differently. Due to these evolving and diverse requirements, we face uncertain product approval timelines, additional time and effort to comply, as well as the potential for reduced sales and/or fines for noncompliance.

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 (i.e. Pennsylvania, Rhode Island, Maryland and California). 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 laboratory in Nashville, Tennessee is licensed by the appropriate state agencies in the states in which we do business, if such licensure is required. If our 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 applicable to us.

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 or accept samples from. These requirements may vary by jurisdiction and differ from those in the United States, and may require us to implement additional compliance measures. We believe that we are in material compliance with all applicable licensing laws and regulations applicable to us.

Regulation of Research Use Only Products

Some of our product development projects are intended to be sold for research purposes in the U.S., and labeled "For Research Use Only" or "for molecular biology applications." RUO refers to devices that are in the laboratory phase of development, while investigational use only, or IUO, refers to devices that are in the product testing phase of development. These types of devices are exempt from most regulatory controls pursuant to long-standing FDA guidance on RUO/IUO products. These products are exempt from FDA's premarket review and other requirements as long as they are not promoted for clinical diagnostic use, and Oncocyte does not provide technical assistance to clinical laboratories with respect to these tests. If FDA were to disagree with our designation of any of these products, we could be forced to obtain the appropriate regulatory clearances or approval prior to commercialization.

Regulation of 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 FD&C 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 Premarket Approval (“PMA”) is required to market Class III devices.

If we elect to develop additional IVDs or LDTs, our future screenings diagnostics may require a 510(k) submission or a 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 (“HITECH”), the U.S. Department of Health and Human Services (“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 HHS 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. The public comment period for these most recently proposed updates to the HIPAA Privacy Rule closed on May 6, 2021, and the final, updated HIPAA Privacy Rule is expected to be published in the Federal Register at some point in 2025. Additionally, on April 22, 2024, HHS issued a final rulemaking containing modifications to the HIPAA Privacy Rule to address the use or disclosure of PHI in relation to the provision of reproductive health care to update the conditions under which PHI relating to reproductive healthcare can be used or disclosed. In January 2025, HHS proposed to modify the HIPAA Security Rule to address prescriptive requirements for administrative, physical, and technical safeguards in response to increased cybersecurity incidents in the health care industry. While a final rule has not yet been issued, if adopted, these proposed changes would potentially require significant operational adjustments and costs to comply.

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, effective in January 2020, California enacted the California Consumer Privacy Act of 2018 ("CCPA"). The CCPA established 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, in November 2020, California passed the California Privacy Rights Act ("CPRA") through a ballot initiative. The CPRA created 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 created a new category of "sensitive personal information" and offers 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 took effect on January 1, 2023, and generally apply to personal information collected by businesses on or after January 1, 2022. Similarly, Colorado, Connecticut, Utah and Virginia enacted comprehensive state privacy laws that took effect in 2023. Additional states - including Delaware, Indiana, Iowa, Montana, New Jersey, Oregon, Tennessee, and Texas - have enacted similar comprehensive state privacy laws that have either taken effect or will take effect at various points between 2025 and 2026. 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 General Data Protection Regulation (“GDPR”), which went into effect in May 2018. The GDPR applies to any company established in the European Economic Area (“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 €20.0 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 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 EU.

Further, from January 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 €20.0 million (£17.5 million) or 4% of global turnover. In June 2021, the European Commission implemented an adequacy decision enabling data transfers from EU member states to the UK without additional security measures. However, this adequacy decision includes a so-called “sunset-clause” stipulating that it will expire after four years, and providing that the European 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 European 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: (i) fair market value compensation for the provision of items or services; (ii) payments by physicians to a laboratory for clinical laboratory services; (iii) certain space and equipment rental arrangements that satisfy certain requirements, and (iv) 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.

In November 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 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 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 is 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 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.

In May 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, and the final rule issued by HHS on July 1, 2024, health care providers that violate the information blocking prohibition will be subject to appropriate disincentives effective July 31, 2024, while disincentives associated with the Medicare Shared Savings Program became effective January 1, 2025. Developers of certified information technology and health information networks and health information exchanges may be subject to civil monetary penalties of up to \$1.0 million per violation. The HHS Office of Inspector General has the authority to impose such penalties and, in July 2023, published a final rule to codify its new authority in regulation, which became effective in August and September 2023.

Human Capital

As of December 31, 2024, we employed 49 persons, of which 46 were on a full-time basis and three were 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, our financial condition, and the value of an investment in our business. If any of the following risks, either alone or taken together, or other risks not presently known to us or that we currently believe to not be significant, develop into actual events, then our business, financial condition, results of operations or prospects could be materially adversely affected. If that happens, the market price of our common stock could decline, and stockholders may lose all or part of their investment.

Risks Related to Our Capital Resources

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, 2024 and 2023 were \$60.7 million and \$27.8 million, respectively, and we had an accumulated deficit of \$350.5 million as of December 31, 2024. 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.

We have historically been dependent upon outside financing capital to fund our operations and until such time as our revenues are sufficient to finance our operating expenses, we may need to issue additional equity or debt securities to raise the capital needed to pay 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 stockholders.

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, based on current estimates, we have agreed to pay contingent consideration of up to \$4.5 million in any combination of cash or shares of our common stock if certain milestones related to DetermaIO are achieved, which consist of (i) \$3.0 million for an affirmative final LCD from CMS for a specified lung cancer test, and (ii) 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's stock earnout consideration of (i) 10% of net collections for sales of specified tests and products, until the expiration of intellectual property related to such tests and products, and (ii) 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.

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.

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 GraftAssureCore, GraftAssureIQ, GraftAssureDx, 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 GraftAssureCore are currently available only in early access for non-clinical use. We plan to continue development of all five of such products for clinical and research use. However, there is no assurance that our development plans for GraftAssureCore, GraftAssureIQ, GraftAssureDx, DetermaIO or DetermaCNI will be successful or that we will 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 \$9.8 million and \$9.3 million during the years ended December 31, 2024 and 2023, respectively. The current focus of our research and development efforts is the development of GraftAssureCore, GraftAssureIQ, GraftAssureDx, DetermaIO 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.

There is a risk of product liability claims in our business. If we are unable to obtain or maintain sufficient insurance, a product liability claim against us could adversely affect our business.

Our business exposes us to potential product liability risks that are inherent in the development, testing, manufacturing and marketing of diagnostic test kits and assays. Product liability claims could delay or prevent completion of our clinical development programs. In addition, if any of our collaboration partners face product liability claims, our programs could also be affected and our business could be harmed. If we succeed in marketing products, such claims could result in an FDA investigation of the safety and effectiveness of our products, our manufacturing processes and facilities or our marketing programs, and potentially a recall of our products or more serious enforcement action, limitations on the approved indications for which they may be used, or suspension or withdrawal of approvals. Regardless of the merits or eventual outcome, liability claims may also result in decreased demand for our products, injury to our reputation, costs to defend the related litigation, a diversion of management's time and our resources, substantial monetary awards to trial participants or patients and a decline in our share price. Any insurance we obtain may not provide sufficient coverage against potential liabilities. Furthermore, clinical trial and product liability insurance is becoming increasingly expensive. As a result, we may be unable to obtain or maintain sufficient insurance at a reasonable cost to protect us against losses caused by product liability claims that could adversely affect our business.

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 United States and/or onto molecular testing instrument platforms for distribution in non-U.S. 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 U.S. laboratory 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 our merger with Chronix. Our facilities and equipment could be harmed or rendered inoperable by natural or man-made disasters, including earthquakes, power outages, wildfires, flooding, hurricanes, droughts and other extreme weather events and changing weather patterns, which are increasing in frequency due to the impacts of climate change, and may render it difficult or impossible for us to perform our tests 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 IVD 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.

There is a limited number of manufacturers of molecular testing equipment and related chemical reagents necessary for the provision of our tests. If issues were to arise with our equipment or if reagents we are using cause us to acquire different diagnostic testing equipment, 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 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 diagnostic, pharmaceutical or medical device company or to a joint venture company formed with the diagnostic, 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 are, and in the future, may become, dependent on 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 have entered into and may in the future enter into various kinds of collaborative research and development, manufacturing, and diagnostic test marketing agreements to develop and commercialize our diagnostic tests. For example, in 2024, we entered into an agreement with Bio-Rad to collaborate in the development and the commercialization of RUO and IVD kitted transplant products using Bio-Rad's ddPCR instruments and reagents, pursuant to which we are dependent on Bio-Rad with respect to many of our ongoing operations and future target performance.

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, in addition to the Bio-Rad arrangement, 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 currently, or might in the future, depend might be terminated by our collaboration partner or they might determine not to actively pursue the development or commercialization of our diagnostic tests, or they may determine to stop supporting technologies, such as instruments or consumables, upon which our diagnostic tests are reliant. A collaboration partner also may not be precluded from independently pursuing competing diagnostic tests or technologies.

There is a risk that a collaboration partner, including Bio-Rad, 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 or instrument-related 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.

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 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 could 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 our operations, or 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 United States. 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. Due to 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. Since 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 may 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 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 United States 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 Securities and Exchange Commission (“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 United States 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 further 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. In May 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, in September 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. AB 979 required that each of these companies 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, by December 31, 2022. In April 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.

Our business could be adversely impacted by inflation.

Inflation rates, particularly in the United States, have increased recently to levels not seen in years. We may experience inflationary pressures, primarily in personnel costs, with certain laboratory supplies and from inventory costs related to certain raw materials. We anticipate inflationary impacts on other cost areas in the future. The extent of any future impacts from inflation on our business and our results of operations will be dependent upon how long the elevated inflation levels persist and the extent to which the rate of inflation were to further increase, if at all, neither of which we are able to predict. If elevated levels of inflation were to persist or if the rate of inflation were to accelerate, the purchasing power of our cash and cash equivalents may be further diminished, our expenses could increase faster than anticipated and we may utilize our capital resources sooner than expected. Further, given the complexities of the reimbursement landscape in which we operate, our payers may be unwilling or unable to increase reimbursement rates to compensate for inflationary impacts. As such, the effects of inflation may adversely impact our results of operations, financial condition and cash flows.

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 our 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 EU 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 our business and we could be subject to fines and other sanctions.

Our products are subject to the FDA's final rule ending enforcement discretion for LDTs and regulating such tests as medical devices. Implementing the requirements under the final rule 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.

In May 2024, the FDA published a final rule that phases out its enforcement discretion for LDTs, unless exempt, and amends the FDA's regulations to make explicit that IVDs are medical devices under the Federal Food, Drug, and Cosmetic Act ("FDCA"), including when the manufacturer of the diagnostic product is a laboratory. The American Clinical Laboratory Association and the Association of Molecular Pathology have filed lawsuits against the FDA to challenge its authority to regulate LDTs under this final rule. The full impact of this final rule and the existing (and any future) challenges against currently remains to be seen.

If the FDA were to ultimately regulate our tests as traditional IVDs, some or all of our tests may become subject to certain FDA medical device regulations, including, in some cases, 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 for any of our tests, 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 applicable 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 any applicable FDA medical device regulations to which we could become subject in connection with any of our tests that FDA may regulate as traditional IVDs would increase the cost of conducting our business, and subject us to inspection by, and potential enforcement of certain regulatory requirements, of the FDA, for example registration and listing, adherence to good manufacturing practices under the Quality System Regulation ("QSR"), and medical device reporting. Enforcement action for noncompliance with these requirements could range from warning or untitled letters to civil and criminal penalties, injunctions, product seizure or recall, import bans, restrictions on the conduct of our operations and total or partial suspension of production. Our laboratories are operating under CLIA and are not currently operating as registered device manufacturing facilities or in compliance with FDA's QSR. 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, which is likely, given the current state of industry challenges to FDA's final rule, 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.

If the FDA is successful in overcoming challenges to the final rule and ultimately regulates certain LDTs as intended under the final rule, our tests may be subject to certain additional regulatory requirements, the scope of which may vary from one test to another based on various considerations. Complying with the FDA's requirements can be expensive, time-consuming, and subject us to significant or unanticipated delays. To the extent we are required to obtain premarket clearance or approval to perform or continue performing any of our tests, we cannot guarantee 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. Based on these and other considerations, the implementation of the FDA's final rule on LDTs could materially and adversely affect our business, financial condition, and results of operations.

In addition, the final rule does not change the FDA's policy of regulating IVDs as medical devices. As a result, most IVDs are currently subject to FDA requirements, including pre-market authorization. While we currently believe our products qualify as LDTs, the FDA may disagree. If the FDA determines that our products do not qualify as LDTs, we may be subject to FDA enforcement action, such as warning letters, seizure, injunction, criminal prosecution, monetary penalties, and others. In addition, if our products are classified as IVDs instead of LDTs, we may be required to obtain 510(k) clearance or a PMA before re-marketing the products, which would result in a significant increase in costs, as well as a potential loss in revenue.

We currently market certain IVDs that have not been cleared by the FDA in reliance on the regulatory exemption for IVDs intended for RUO, but if the FDA determines that our RUO tests do not meet the applicable requirements for exemption or have intended uses that are inconsistent with RUO tests, we may be required to suspend commercialization of such products until we can obtain the requisite FDA clearance and/or subject to FDA warning or untitled letters, seizure, injunction, fines, or other enforcement action.

Some of our tests are marketed for RUO, which allows us to sell such products without the premarket clearance that FDA requires for the marketing of traditional devices. An RUO product may not be marketed for clinical diagnostic use and must be labeled "For Research Use Only. Not for use in diagnostic procedures." Products that are intended for research use only and are properly labeled as RUO are exempt from compliance with the FDA's pre- and post-market requirements to which traditional devices are subject, including the requirement that the product be cleared or approved before commercialization and QSR requirements. However, merely including the required RUO labeling will not necessarily exempt the device from the FDA's 510(k) clearance, premarket approval, or other requirements if the circumstances surrounding the distribution of the product indicate an objective intent to market the product for clinical diagnostic use.

According to the FDA guidance, circumstances indicating manufacturer intent to market an in vitro device for diagnostic use may include written or verbal marketing claims regarding a product's clinical efficacy or performance in clinical applications, instructions for clinical interpretation, clinical information, product names, or descriptors that claim or suggest that the IVD product may be used for any clinical diagnostic use, including a clinical investigation that is not exempt from the FDA's investigational device exemption regulations. Other indications include a manufacturer's provision of technical support for clinical validation or clinical applications or solicitation of business from clinical laboratories that do not conduct research activities, all of which could be considered evidence of intended uses that conflict with RUO labeling.

In general, if (i) evidence shows that one or more of our IVDs are inappropriately labeled RUO (but marketed for clinical diagnostic use), such test(s) will not qualify for an IDE exemption and will be deemed misbranded under the FDCA. Device manufacturers found in violation of the FDCA may be subject to a wide range of enforcement action, including warning letters, seizure, injunction, criminal prosecution, monetary penalties, and others.

We believe that our promotional activities for our RUO products fall within the scope of the applicable premarket exemptions for RUO tests and the FDA's enforcement discretion, as described in its relevant guidance. However, the FDA could disagree and require us to (i) stop promoting our RUO devices unless/until we obtain FDA clearance or approval (among other possible outcomes). Any adverse determination in relation to our marketing of current or future products for RUO will likely have a material adverse impact on our business.

We will also need to obtain FDA and other regulatory approvals for any IVDs that we may develop, or for any currently marketed products the FDA determines are IVDs instead of LDTs, 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 IVD test. Additionally, while we believe our tests qualify as LDTs, if the FDA determines otherwise, our products will likely need to be withdrawn from the market until receiving pre-market authorization, such as 510(k) clearance or a PMA, before re-entering the market. This means that:

- The IVDs cannot be sold until the CMS or the FDA, and corresponding foreign regulatory authorities approve or authorize 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; and
- 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 tests 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.

Any of the foregoing factors as well as other unforeseen events could delay or prevent commercialization of our current or future diagnostic tests and adversely affect our business, financial condition and results of operations.

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 healthcare reform legislation known as the “Patient Protection and Affordable Care Act,” also known as the ACA, the expansion of the federal and state governments’ role in the U.S. healthcare industry, and the changes to the reimbursement amounts paid by payers for our tests and future tests and products may reduce our profits and have a material 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,” a provision that required individuals to buy health insurance or pay a fine, which has impacted the number of covered lives participating in exchange plans. In June 2021, the U.S. Supreme Court dismissed a judicial challenge to the ACA brought by several states without specifically ruling on the constitutionality of the ACA. We cannot be certain that there will not be further legislative efforts or judicial challenges in the future.

The new presidential administration may also significantly alter the current regulatory framework and the healthcare industry, including any further challenges of certain ACA provisions. These changes could have an adverse and material impact on our operations. For example, the staff of the Department of Government Efficiency (the “DOGE”), an executive administrative agency created by the second Trump Administration, have been provided access to key payment and contracting systems at CMS to look for opportunities for improving efficiency and to identify fraud and ineffective use of resources. While we cannot predict other actions of the DOGE, there is a possibility that additional changes will be made to CMS spending, which could ultimately affect our financial condition and results of operations.

In addition, the new administration recently issued a memorandum instructing U.S. executive agencies to prepare for reductions in workforce at governmental agencies, which likely includes the FDA. If the new administration takes action that substantially reduces FDA’s workforce, in particular, at the Center for Devices and Radiological Health, we may face significant delay in obtaining approval, if required, and subsequently marketing future product candidates.

Additionally, the Protecting Access to Medicare Act (“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 the CMS, the administrator of CLIA, 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.

If future reimbursement price levels are less than the current price, our revenues and our ability to achieve profitability could be impaired, and the market price of our common stock could decline. Additionally, any decision by CMS or its local contractors to reduce or deny coverage for our tests would have a significant adverse effect on our revenue and results of operations and ability to operate and raise capital. Any such decision could also cause affected clinicians treating Medicare-covered patients to reduce or discontinue the use of our tests.

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 and we may not receive complete reimbursement for tests provided to Medicare patients due to such 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. However, private third-party payers often follow Medicare coverage policy and payment limitations in setting their own coverage and payment rates. 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 PHI in electronic form. We also may be required to comply with state laws that are more stringent than HIPAA or that provide individuals with greater rights with respect to the privacy or security of, and access to, their health care records. HITECH established certain health information security breach notification obligations that require covered entities to notify each individual whose PHI 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, 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.

Tariff policies and potential countermeasures could increase our costs and disrupt our global supply chain, which could negatively impact the results of our operations.

President Trump has increased, and has indicated his willingness to continue to increase, the use of tariffs by the U.S. to accomplish certain U.S. policy goals. Such tariffs and any countermeasures could increase the cost of raw materials and components necessary for our operations, disrupt our global supply chain and create additional operational challenges. Further, it is possible that government policy changes and related uncertainty about policy changes could increase market volatility. Because of these dynamics, we cannot predict the impact of any future changes to the U.S.'s or other countries' trading relationships or the impact of new laws or regulations adopted by the U.S. or other countries on our business. Such changes in tariffs and trade regulations could have a material adverse effect on our financial condition, results of operations and cash flows.

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.

The patent positions of biotechnology companies, including our patent position, involve complex legal and factual questions, and, therefore, the issuance, scope, validity and enforceability of any patent claims that we may obtain cannot be predicted with certainty. Patents, if issued, may be challenged, deemed unenforceable, invalidated, or circumvented. A third-party may submit prior art, or we may become involved in opposition, derivation, reexamination, inter partes review, post-grant review, supplemental examination, or interference proceedings challenging our patent rights or the patent rights of our licensors or development partners. The costs of defending or enforcing our proprietary rights in these proceedings can be substantial, and the outcome can be uncertain. An adverse determination in any such submission or proceeding could reduce the scope of, or invalidate, our patent rights, allow third parties to commercialize our technology or products and compete directly with us, or reduce our ability to manufacture or commercialize products. Furthermore, if the scope or strength of protection provided by our patents and patent applications is threatened, it could discourage companies from collaborating with us to license, develop or commercialize current or future products. The ownership of our proprietary rights could also be challenged.

Moreover, the issuance of a patent, while presumed valid and enforceable, is not conclusive as to its validity or its enforceability and it may not provide us with adequate proprietary protection or competitive advantages against competitors with similar products. Competitors may also be able to design around our patents. Other parties may develop and obtain patent protection for more effective technologies, designs or methods. We may not be able to prevent the unauthorized disclosure or use of our technical knowledge or trade secrets by consultants, vendors, former employees and current employees.

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.

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 (“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, which became effective in March 2013. The Leahy-Smith Act and its implementation may 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.

We may not have identified all patents, published applications or published literature that affect our business either by blocking our ability to commercialize our products or potential products, by preventing the patentability of one or more aspects of our products or potential products to us or our licensors, or by covering the same or similar technologies that may affect our ability to market our products and potential products. For example, we (or the licensor of a product or potential product to it) may not have conducted a patent clearance search sufficient to identify potentially obstructing third party patent rights. Moreover, patent applications in the United States are maintained in confidence for up to 18 months after their filing. In some cases, however, patent applications remain confidential in the U.S. Patent and Trademark Office, or the USPTO, for the entire time prior to issuance as a U.S. patent. Patent applications filed in countries outside of the United States are not typically published until at least 18 months from their first filing date. Similarly, publication of discoveries in the scientific or patent literature often lags behind actual discoveries. We cannot be certain that we or our licensors were the first to invent, or the first to file, patent applications covering our products. We also may not know if our competitors filed patent applications for technology covered by our pending applications or if we were the first to invent the technology that is the subject of our patent applications. Competitors may have filed patent applications or received patents and may obtain additional patents and proprietary rights that block or compete with our 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.

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

We cannot be certain that the legal steps we are taking are sufficient to protect our trademark and patent 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 or patent rights, which could result in disruptive and expensive litigation. Challenges to our trademarks or patents could result in significant costs related to the prosecution or defense of the registrations of our trademarks or patents or rebranding if we need to abandon or modify a trademark or patent.

Even if we have or obtain trademarks and patents covering our products, we may still be prevented from making, using, selling, offering for sale, or importing our products or technologies because of the trademark and patent rights of others. Others may have filed, and in the future may file, trademark or patent applications covering technologies or products that are similar or identical to ours. These filings could materially affect our ability to develop or sell our products. Because trademark and patent applications can take many years to issue and are not published for a period of time after filing, there may be currently pending applications unknown to us that may later result in issued trademarks or patents that our products or technologies may infringe. These trademark and patent applications may have priority over trademark and patent applications filed by us.

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.

Obtaining and maintaining patent protection depends on compliance with various procedures and other requirements, and our patent protection could be reduced or eliminated in case of non-compliance with these requirements.

Periodic maintenance fees, renewal fees, annuity fees and various other governmental fees on patents and/or applications will be due to the relevant patent agencies in several stages over the lifetime of the patents and/or applications. The relevant patent agencies require compliance with a number of procedural, documentary, fee payment and other provisions during the patent application process. In many cases, an inadvertent lapse can be cured by payment of a late fee or by other means in accordance with the applicable rules. However, there are situations in which the failure to comply with the relevant requirements can result in the abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. In such an event, our competitors might be able to use our technologies and know-how which could have a material adverse effect on our business, prospects, financial condition and results of operation.

Risks Related to Our Common Stock

We previously identified and remediated a material weakness in our internal control over financial reporting. If we are unable to 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 of December 31, 2022, management had identified, and during 2023 remediated, a material weakness specifically relating to deficiencies in its internal controls over the review process relating to third-party valuations. While the Company has made improvements to the design of its internal controls, there can be no assurance that future material weaknesses will not be identified. The occurrence of, or failure to remediate, a material weakness 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 SEC or other regulatory authorities, shareholder lawsuits, a loss of investor confidence and damage to our reputation.

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. Consequently, shareholders' ability to achieve a return on their investment will depend on appreciation in the price of our common stock.

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. As of December 31, 2024, there were 17,452,824 shares of common stock outstanding, 760,866 shares of common stock reserved for issuance upon the exercise of warrants, 342,888 shares of common stock reserved for issuance upon the exercise of pre-funded warrants, 1,091,000 shares of common stock reserved for issuance upon the exercise of options under our equity incentive plan, and 100,000 shares of common stock reserved for issuance upon the vesting of restricted stock units under our equity incentive plan. 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 our shares to raise capital to finance its operations.

Prior to February 17, 2017, we were a consolidated subsidiary of our 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 our common stock. Lineage has been periodically selling shares of our common stock from its holdings and has announced its intention to continue to sell our shares. The sale of such shares could have a depressing effect on the market value of our common stock and the prices at which we can sell our own shares of common stock to raise capital to support our operations.

We are a “smaller reporting company” under the SEC’s disclosure rules and have elected to comply with the reduced disclosure requirements applicable to smaller reporting companies.

As a smaller reporting company, we have elected to adopt the accommodations for scaled-back disclosure in our SEC filings, resulting in less information about our Company being available compared to other public companies. We are also a non-accelerated filer and are not required to comply with the auditor attestation requirements of Section 404(b) of the Sarbanes-Oxley Act of 2002. Our internal controls over financial reporting will not receive the level of review provided by the process relating to the auditor attestation included in annual reports of issuers that are subject to these requirements.

We cannot predict if investors will find our common stock less attractive because we are not required to comply with more robust disclosure or the auditor attestation requirements. If investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and trading prices may be negatively affected.

Item 1B. Unresolved Staff Comments.

Not applicable.

Item 1C. Cybersecurity.

We develop and maintain a cyber risk management program designed to identify, assess, manage, mitigate and respond to cybersecurity threats. The program is one component of our enterprise risk management system. The technical, administrative and physical controls underlying our program are based on nationally recognized practices and standards for cybersecurity.

Trusted partners are an important part of our cyber risk management program. We partner with leading cybersecurity advisors and service providers to conduct periodic risk assessments and to monitor and maintain the performance and effectiveness of security controls used in our environment.

In addition, we maintain processes to assess and manage risks relating to third-party service providers, including based on the nature of the engagement with the third party and based on the information and information systems to which the third party will have access. We conduct due diligence before onboarding new service providers and maintain ongoing evaluations to ensure compliance with our security standards.

The Audit Committee of the Board of Directors (the “Audit Committee”) oversees our management of enterprise risks, including cybersecurity risks. Members of the management team, including our IT director and General Counsel, brief the Audit Committee on the effectiveness of risk management efforts on at least a semi-annual basis. In addition, these risks are reviewed by the Board of Directors at least annually.

Our cyber risk management program helps mitigate risks that could have a material adverse effect on our business, financial condition, results or operations, cash flows or reputation. See “Risk Factors – Risks Related to Our Business Operations – *Security breaches and other disruptions could compromise our information and expose us to liability, and could cause our business and reputation to suffer.*”

Item 2. Properties.

Our principal executive and administrative offices are located in Irvine, California, under a lease arrangement. The Irvine lease includes approximately 26,800 square feet of rentable space and expires on October 31, 2027. Effective in September 2023, we entered into a sublease agreement with a subtenant to initially sublet approximately 13,400 square feet of rentable space. In June 2025, the portion of

the Irvine lease that is subleased will automatically increase to include the remaining portion of the premises, which consists of approximately 13,400 square feet of additional rentable space for a term that will continue to the expiration of the Irvine lease on October 31, 2027. The sublease agreement is subject and subordinate to the Irvine lease.

We operate a CLIA-certified laboratory and have additional office space in Nashville, Tennessee, under lease arrangements. The Nashville leases include 10,681 square feet of rentable space and expires in January 2027. We also have a research and development facility in Göttingen, Germany.

See Note 6 to our consolidated financial statements included elsewhere in this Report for additional information regarding our lease arrangements and properties.

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 pending litigation or proceedings. See Note 6 to our consolidated financial statements included elsewhere in this Report for additional information regarding commitments and contingencies.

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 17, 2025, we had approximately 182 holders of record of our common stock. This number does not include shareholders whose shares of our common stock are held in “street name” in accounts with securities broker-dealers or other financial institutions or fiduciaries.

Recent Sales of Unregistered Securities

None.

Repurchases

None.

Item 6. [RESERVED]

Not applicable.

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 consolidated financial statements for the years ended December 31, 2024 and 2023 included elsewhere in this Report, 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 under Risk Factors in Part I, Item 1A of this Report. For additional information, refer to the section above entitled “Cautionary Note Regarding Forward-Looking Statements.” The following discussion should be read in conjunction with our consolidated financial statements and the related notes thereto provided under Part IV, Item 15(a)(1) of this Report.

Overview

We are a pioneering diagnostics technology company. Our mission is to democratize access to novel molecular diagnostic testing to improve patient outcomes.

We do this primarily by developing molecular diagnostic test kits that empower our customers to run their own tests to participate in the patient-care value chain, which is counter-positioned with the central laboratory model. Our decentralized approach also puts testing in the hands of researchers to enable more studies, which inspires innovation, which we believe, can improve standards of care while also creating demand for more testing. We develop tests that measure both established biomarkers as well as pioneer the adoption of new and more effective biomarkers.

We believe that combining innovative science with a simple, but disruptive, business model can create enormous value. This model is designed to empower doctors to reduce uncertainty to make better decisions to save lives as well as enable researchers to measure biomarkers to inspire innovation.

Our customer institutions are hospitals, transplant centers, and labs. The decision to deploy our tests on behalf of patients or research studies supports front line doctors, including surgeons, nephrologists and oncologists, as well as researchers, pathologists, lab directors, medical directors, department heads, lab managers, and chief medical officers.

Our operating premise is that democratizing access to testing to foster scientific innovation and better treatments ultimately reduces the cost of care, while expanding access and improving outcomes.

At the heart, we are a science-driven organization that champions scientific integrity and inquiry. We employ world-renowned scientists who generate intellectual property in our strategic target markets. We have built and acquired an intellectual property portfolio that we believe will enable us to gain share in well-established clinical and research markets.

Our current intellectual property comprises three general areas: 1) organ transplant, 2) oncology therapy selection and 3) oncology therapy monitoring. Within these categories, we have developed or are in the process of developing LDTs that can be run at our Nashville, Tennessee lab, kitted RUO tests, and kitted clinical tests that can be run by local labs.

Our primary near-term strategic market is organ transplant. Oncocyte’s molecular diagnostic tests are designed to help the industry to better address one of the leading challenges in the transplantation market – which is the body’s potential to reject the donor organ. We do this by detecting early evidence of graft organ damage in the blood through assessing a known biomarker known as donor-derived cell-free DNA. GraftAssureCore (Kidney), for example, can find donor kidney damage up to 11 months sooner than other protocols. GraftAssureCore is analytically and clinically validated in three major solid organ transplant types (kidney, liver and heart) by peer reviewed international publications. We received a positive coverage decision from MoIDx for GraftAssureCore (Kidney) in August of 2023, and it became commercially available for ordering in January 2024 through our CLIA laboratory in Nashville, Tennessee. GraftAssureCore (Kidney) is now broadly available to transplant professionals upon request. In December 2024, we confirmed Medicare reimbursement for also monitoring certain high-risk patients, that is, those with newly developed donor-specific antibodies.

In July 2024, we began to commercialize the technology underlying GraftAssureCore (Kidney) by distributing its sister product, GraftAssureIQ, which is intended to be sold and used for research purposes and is labeled as RUO. We expect to distribute our RUO production through a mix of direct sales, partnering and distribution agreements, and licensing. We have entered into a global strategic partnership agreement with Bio-Rad to collaborate in the development and the commercialization of RUO and IVD kitted transplant products for clinical use (see Note 10, “Collaborative Arrangements,” to our consolidated financial statements included elsewhere in this Report for additional information).

Under strict regulatory rules, our kitted tests may not be used in a clinical treatment setting until they have attained IVD clearance from the FDA in the U.S. and In Vitro Diagnostic Medical Devices Regulation approval in the European Union. As such, we are working with these regulatory bodies to attain such clearance and approval, as applicable, supporting future distribution and higher sales of our products for clinical use.

We also have a laboratory and pharma services lab, certified under the CLIA and accredited by the CAP, in Nashville, Tennessee, and a research and development lab in Göttingen, Germany. Our innovation centers in Nashville and Germany employ world-renowned research scientists who, we believe, are leaders in their fields.

Our secondary strategic market is in the field of oncology – namely through diagnostic tests that can measure and predict which patients will best respond to certain types of therapies, as well as provide efficacy monitoring for therapies. For example, we are continuing to develop 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, and triple negative breast cancer. A kitted research product format of the underlying technology began proof-of-concept development in 2023. The application of immunotherapy is a global problem, so we expect partnering opportunities for each of our products as they reach clinical maturity. We also expect to begin commercializing our oncology product line, which includes DetermaIO, over the next 15 months.

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, nor 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 expect that our operating expenses will continue to increase if we successfully complete the development of DetermaIO and commercialize this test.

We also perform other assay development and clinical testing services for pharmaceutical and biotechnology companies through our Pharma Services operations.

We believe that the experience of our team with diverse technologies through our Pharma Services activities, strong scientific integrity regarding evidence generation and innovation mentality, alongside our flexibility in operations and regulatory strategy, will drive our success, differentiate us from our competition, and are foundational to our future. We are focusing on executing the technology priorities discussed herein, which have evolved to reflect our operations and strategic vision.

Recent Developments

At-The-Market Facility

On August 9, 2024, we entered into a sales agreement with a sales agent, pursuant to which the Company may offer and sell from time to time up to an aggregate of \$7.5 million of shares of our common stock, through the sales agent through an at-the-market facility (the “August 2024 Offering”). As of December 31, 2024, we received net proceeds from the sale of such shares of approximately \$1.7 million. See Note 7, “Common Stock – August 2024 Offering,” to our consolidated financial statements included elsewhere in this Report for additional information. On February 8, 2025, the Company terminated this sales agreement. As a result, the Company may not make any further sales pursuant to such at-the-market facility. See Note 14, “Subsequent Events,” to our consolidated financial statements included elsewhere in this Report for additional information.

February 2025 Offering

On February 10, 2025, we consummated a registered direct offering and concurrent private placement of our securities to certain accredited investors (the “February 2025 Offering”). The aggregate gross proceeds from the February 2025 Offering were approximately \$29.1 million. See Note 14, “Subsequent Events – Private Placement Transaction” and “Subsequent Events – Registered Direct Offering,” to our consolidated financial statements included elsewhere in this Report for additional information.

Results of Operations

Summary Results of Operations

	Years Ended December 31,			
	2024	2023	\$ Change	% Change
	(In thousands, except percentage change values)			
Net revenue	\$ 1,881	\$ 1,503	\$ 378	25 %
Cost of revenues	1,053	1,002	51	5 %
Cost of revenues – amortization of acquired intangibles	88	88	—	—
Research and development	9,839	9,294	545	6 %
Sales and marketing	3,944	2,795	1,149	41 %
General and administrative	10,204	11,182	(978)	(9)%
Change in fair value of contingent consideration	(4,275)	(5,762)	1,487	(26)%
Impairment losses	41,900	6,757	35,143	520 %
Impairment loss on held for sale assets	169	1,283	(1,114)	(87)%
Loss from operations	(61,041)	(25,136)	(35,905)	143 %
Total other income, net	378	281	97	35 %
Loss from continuing operations	(60,663)	(24,855)	(35,808)	144 %
Loss from discontinued operations (Note 13)	—	(2,926)	2,926	(100)%
Net loss	\$ (60,663)	\$ (27,781)	\$ (32,882)	118 %

Results of Operations – Year Ended December 31, 2024 Compared with the Year Ended December 31, 2023

Total net revenue increased to \$1.9 million for the year ended December 31, 2024, as compared to \$1.5 million in the comparable prior period from Pharma Services as further discussed below. Future Pharma Services revenue is expected to be impacted as a result of our shift in strategic focus on commercializing our transplant kitted tests, and deploying our sales personnel toward signing new hospital research laboratory customers.

Loss from continuing operations was \$60.7 million for the year ended December 31, 2024, compared to \$24.9 million for the comparable prior period. The loss from continuing operations expanded by \$35.8 million mainly due to impairment charges for certain in-process research and development (discussed below), the change in fair value of contingent consideration, and certain other changes in operating expenses from continuing operations as follows:

- Pharma Services revenue increased by \$392,000. Although we had a decrease in the number of contracts performed during the period, we earned revenue from one existing customer in the amount of approximately \$1.5 million during the fourth quarter of 2024. See below for additional information.
- Cost of revenues increased by \$51,000, primarily related to labor and allocated overhead associated with performing our Pharma Services. See below for additional information.
- Cost of revenues - amortization of acquired intangibles was unchanged, and relates to noncash amortization of acquired intangible assets such as our customer relationship intangible assets acquired as part of the Insight merger.
- Research and development expenses increased by \$545,000, as we continue development of GraftAssureCore, GraftAssureIQ, GraftAssureDx, DetermaIO and DetermaCNI. The main drivers of the increase were personnel-related expenses and facilities costs, partially offset by depreciation and amortization, stock-based compensation and severance costs (see below for additional details).
- Sales and marketing expenses increased by \$1.1 million, primarily attributable to continued ramp up in sales, marketing and advertising activities related to the transplant business, as well as supporting the commercialization efforts within oncology. The main drivers of the increase were personnel-related expenses, depreciation and amortization, and other expenses, which are primarily comprised of travel and entertainment, partially offset by facilities costs and stock-based compensation (see below for additional details).
- General and administrative expenses decreased by \$978,000, primarily due to decreases in facilities costs, stock-based compensation and severance costs, partially offset by personnel-related expenses and professional fees. See below for additional details.

- Change in fair value of contingent consideration was a gain of \$4.3 million in 2024 compared to a gain of \$5.8 million in 2023. This change was due to changes in the fair value model inputs and revised estimates on if and when future payouts will occur. See below for additional information.
- The current year impairment losses relate to our in-process research and development intangible assets. During the fourth quarter of 2024, it was determined that our DetermaIO and DetermaCNI intangible assets were impaired by \$41.9 million (see Note 5 to our consolidated financial statements included elsewhere in this Report for additional information). The prior year impairment losses related to two asset impairments, including in-process research and development intangible assets of \$5.0 million (see Note 5 to our consolidated financial statements included elsewhere in this Report for additional information) and leasehold improvements of \$1.8 million (see Note 4 to our consolidated financial statements included elsewhere in this Report for additional information).
- Impairment loss on held for sale assets relates to various agreements to sell laboratory equipment and the subsequent fair value adjustments. See Note 2, “Assets Held for Sale and Discontinued Operations,” to our consolidated financial statements included elsewhere in this Report for additional information.
- Total other income, net increased by \$97,000, primarily due to additional interest income and miscellaneous income in 2024 compared to 2023. See below for additional information.

Revenues

The following table shows our service revenues:

	Years Ended December 31,			
	2024	2023	\$ Change	% Change
	(In thousands, except percentage change values)			
Pharma Services	\$ 1,859	\$ 1,467	\$ 392	27 %
Laboratory Developed Test Services	22	36	(14)	(39)%
Total	\$ 1,881	\$ 1,503	\$ 378	25 %

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. 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 Laboratory Developed Test Services revenue. Refer to Note 2, “Revenue Recognition – Pharma Services Revenue” and “Disaggregation of Revenues and Concentrations of Credit Risk,” to our consolidated financial statements included elsewhere in this Report for additional information.

Laboratory Developed Test Services generally relate to payments received from sales prior to the Razor Sale Transaction. We generated revenue from performing DetermaRx tests on clinical samples through orders received from physicians, hospitals, and other healthcare providers. For all payers other than Medicare, we 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, we have recognized revenue upon payment. Refer to Note 2, “Revenue Recognition – Laboratory Developed Test Services,” to our consolidated financial statements included elsewhere in this Report for additional information.

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, 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 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 is as follows:

	Years Ended December 31,			
	2024	2023	\$ Change	% Change
	(In thousands, except percentage change values)			
Personnel-related expenses	\$ 4,352	\$ 3,586	\$ 766	21 %
Depreciation and amortization	1,043	1,264	(221)	(17)%
Stock-based compensation	810	1,238	(428)	(35)%
Laboratory supplies and expenses	1,826	1,676	150	9 %
Facilities and insurance	1,337	740	597	81 %
Professional fees, legal, and outside services	510	515	(5)	(1)%
Severance	—	149	(149)	(100)%
Other	(41)	96	(137)	(143)%
Clinical trials	2	30	(28)	(93)%
Total	\$ 9,839	\$ 9,294	\$ 545	6 %
% of Net Revenue	523 %	618 %		(95)%

We expect to continue to incur a significant amount of research and development expenses for the foreseeable future. We will continue development of GraftAssureCore, GraftAssureIQ, GraftAssureDx, DetermaIO and DetermaCNI. 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 laboratory in 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.

We intend to pursue a clinical trial in conjunction with our IVD submission in 2025, supporting our transplant products. We also may commence 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 is as follows:

	Years Ended December 31,			
	2024	2023	\$ Change	% Change
	(In thousands, except percentage change values)			
Personnel-related expenses	\$ 2,691	\$ 1,880	\$ 811	43 %
Depreciation and amortization	121	2	119	5950 %
Stock-based compensation	174	241	(67)	(28)%
Facilities and insurance	122	202	(80)	(40)%
Professional fees, legal, and outside services	195	163	32	20 %
Marketing and advertising	257	187	70	37 %
Other	384	120	264	220 %
Total	\$ 3,944	\$ 2,795	\$ 1,149	41 %
% of Net Revenue	210 %	186 %		24 %

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 GraftAssureCore, GraftAssureIQ, GraftAssureDx and DetermaCNI, 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 is as follows:

	Years Ended December 31,			
	2024	2023	\$ Change	% Change
	(In thousands, except percentage change values)			
Personnel-related expenses and board fees	\$ 3,957	\$ 3,461	\$ 496	14 %
Depreciation and amortization	242	249	(7)	(3)%
Stock-based compensation	769	1,249	(480)	(38)%
Facilities and insurance	1,626	2,435	(809)	(33)%
Professional fees, legal, and outside services	3,289	3,117	172	6 %
Severance	—	441	(441)	(100)%
Other	321	230	91	40 %
Total	\$ 10,204	\$ 11,182	\$ (978)	(9)%
% of Net Revenue	542 %	744 %		(202)%

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 elsewhere 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 and Chronix acquisition dates to the reporting periods being presented, with the subsequent changes in fair value recorded as part of our consolidated results from operations for such periods. See above Results of Operations explanation for additional information.

Other Income and Expenses

Other income and expenses are primarily comprised of interest income and expense, and gains/losses from marketable equity securities, which were sold in 2023 (see Note 2, “Marketable Equity Securities,” to our consolidated financial statements included elsewhere in this Report). Interest income is earned from money market funds we hold for capital preservation. Interest expense was incurred mainly from our financing lease obligations (see Note 6 to our consolidated financial statements included elsewhere in this Report) and insurance financing activity.

Income Taxes

We did not record any provision or benefit for income taxes for the years ended December 31, 2024 and 2023, as we had a full valuation allowance for the periods presented (see Note 12 to our consolidated financial statements included elsewhere in this Report).

A valuation allowance is provided when it is more-likely-than-not that some portion of the deferred tax assets will not be realized. We established a full valuation allowance for all periods presented due to the uncertainty of realizing future tax benefits from our net operating loss carry-forwards and other deferred tax assets.

Inflation

Although historically not significant to our results of operations, financial condition and cash flows, we may experience inflationary pressures, primarily in personnel costs, with certain laboratory supplies and from inventory costs related to certain raw materials. The extent of any future impacts from inflation on our business and our results of operations will be dependent upon how long elevated inflation levels persist and the extent to which the rate of inflation were to increase, if at all, neither of which we are able to predict. If elevated levels of inflation were to persist or if the rate of inflation were to accelerate, the purchasing power of our cash and cash equivalents may be diminished, our expenses could increase faster than anticipated and we may utilize our capital resources sooner than expected. Further, given the complexities of the reimbursement landscape in which we operate, our payers may be unwilling or unable to increase reimbursement rates to compensate for inflationary impacts. As such, the effects of inflation may adversely impact our results of operations, financial condition and cash flows.

Liquidity and Capital Resources

Our foreseeable material cash requirements as of December 31, 2024, are recognized as liabilities or generally are otherwise described in Note 6, “Commitments and Contingencies,” to our consolidated financial statements included elsewhere in this Report. Cash requirements are generally derived from our operating and investing activities including expenditures for working capital, human capital, equipment purchases, business development, investments in intellectual property, and business combinations. Our office lease obligations (net of sublease payments) and financing lease obligations, and contingent consideration obligations are further described in Note 6 and Note 3, respectively, to our consolidated financial statements included elsewhere in this Report. Historically, we have not entered into any off-balance sheet arrangements. As of December 31, 2024 and 2023, we had unrecognized tax benefits totaling \$1.1 million and \$2.3 million, respectively (see Note 12, “Income Taxes,” to our consolidated financial statements included elsewhere in this Report).

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 \$350.5 million as of December 31, 2024. At December 31, 2024, we had \$8.6 million of cash and cash equivalents. On February 10, 2025, we raised substantial additional capital as discussed below. We expect to continue to incur operating losses and negative cash flows for the near future. Although it is difficult to predict our liquidity requirements, based on the going concern evaluation discussed in Note 1 to our consolidated financial statements included elsewhere in this Report, management believes that it will have sufficient cash to meet its projected operating requirements for at least the next twelve months following the issuance of these consolidated financial statements.

On April 3, 2023, we entered into an agreement with certain members of our Board of Directors, and several institutional and accredited investors, including Broadwood Partners, L.P., our largest shareholder, relating to their purchase of an aggregate of up to 2,278,121 shares of our common stock at an offering price of \$7.08 per share to board members and \$6.03 per share to the other investors participating in the offering (see Note 7 to our consolidated financial statements included elsewhere in this Report). The offering was 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 us. We used approximately \$1.1 million of the net proceeds to immediately redeem an aggregate of 1,064 shares of our Series A Redeemable Convertible Preferred Stock.

On April 15, 2024, we consummated a private placement of our securities to certain accredited investors (the “April 2024 Offering”). The resulting net proceeds were approximately \$9.9 million, after deducting offering expenses of \$538,000 and deducting \$5.4 million for the redemption of all remaining shares of our Series A Redeemable Convertible Preferred Stock. These net proceeds are inclusive of an investment from Bio-Rad (see Note 9 to our consolidated financial statements included elsewhere in this Report), our global strategic partner. See Note 7, “Common Stock – April 2024 Offering,” to our consolidated financial statements included elsewhere in this Report for additional information.

On August 1, 2024, we filed a shelf registration statement on Form S-3, pursuant to which we registered for sale up to \$100.0 million of any combination of our common stock, preferred stock, warrants and/or units from time to time and at prices and on terms that we may determine (the “Primary Shelf Registration Statement”). On August 9, 2024, we entered into a sales agreement with a sales agent, pursuant to which we may offer and sell from time to time up to an aggregate of \$7.5 million of shares of our common stock, registered on the Primary Shelf Registration Statement, pursuant to the August 2024 Offering. As of December 31, 2024, we received net proceeds from the sale of such shares of approximately \$1.7 million. See Note 7, “Common Stock – August 2024 Offering,” to our consolidated financial statements included elsewhere in this Report for additional information. On February 8, 2025, the Company terminated this sales agreement. As a result, the Company may not make any further sales pursuant to such sales agreement. See Note 14, “Subsequent Events,” to our consolidated financial statements included elsewhere in this Report for additional information.

On October 4, 2024, we consummated a private placement of our securities to certain accredited investors (the “October 2024 Offering”). The gross proceeds from the October 2024 Offering were approximately \$10.2 million. After deducting placement agent fees and expenses and offering expenses payable by the Company of \$836,000, the resulting net proceeds were approximately \$9.4 million. See Note 7, “Common Stock – October 2024 Offering,” to our consolidated financial statements included elsewhere in this Report for additional information.

On February 10, 2025, we consummated the February 2025 Offering. The aggregate gross proceeds from the February 2025 Offering were approximately \$29.1 million. After deducting offering expenses payable by the Company of \$480,000, the resulting net proceeds were approximately \$28.7 million. See Note 14, “Subsequent Events – Private Placement Transaction” and “Subsequent Events – Registered Direct Offering,” to our consolidated financial statements included elsewhere in this Report for additional information.

We expect that our general operating expenses will be commensurate with the market opportunity 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 with the timelines and uncertainty for attaining the Medicare reimbursement approvals that will be essential for the successful commercialization of additional 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.

On April 5, 2024, we entered into a global strategic partnership agreement with Bio-Rad to collaborate in the development and the commercialization of RUO and IVD kitted transplant products. On November 8, 2024, Oncocyte and Bio-Rad entered into a memorandum of understanding with respect to such agreement to establish additional activities to be performed by each party pursuant to such agreement. See Note 10, “Collaborative Arrangements,” to our consolidated financial statements included elsewhere in this Report for additional information.

In addition to sales and marketing expenses, we will incur expenses from leasing and improving our offices and laboratory facilities in Nashville, Tennessee. During the third quarter of 2023, we entered into a sublease arrangement for our main office in Irvine, California. In January 2024, we expanded our Nashville facility by adding one new office lease and renewing and extending our existing leases. During 2024, we added five financing leases for certain laboratory equipment to be used in our operations. See Note 6, “Commitments and Contingencies,” to our consolidated financial statements included elsewhere in this Report for additional leasing information.

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 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 our collaborative arrangement for the development and the commercialization of RUO and IVD kitted transplant products, or delays in obtaining regulatory approval to distribute our products for clinical use, or delays in the development of, or in obtaining reimbursement coverage from Medicare for DetermalO and other future laboratory 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 long-term financing will be available on favorable terms, if at all.

See Note 1 and Note 7 to our consolidated financial statements included elsewhere in this Report for additional information about our liquidity discussion and equity offerings, respectively.

Cash Used in Operations

During the year ended December 31, 2024, our total research and development expenses were \$9.8 million, our sales and marketing expenses were \$3.9 million, and our general and administrative expenses were \$10.2 million. We also incurred \$1.1 million in total cost of revenues, including \$88,000 for amortization of intangible expenses. Consolidated net loss for the period was \$60.7 million, and our consolidated net cash used in operating activities amounted to \$20.7 million. Our cash used in operating activities during 2024 did not include the following noncash items: \$1.6 million in depreciation and amortization expenses, \$1.8 million in stock-based compensation, \$160,000 in other equity compensation expenses, \$4.3 million gain from change in fair value of contingent consideration, \$41.9 million loss from intangible asset impairments, and \$169,000 impairment loss on held for sale assets. Net changes in operating assets and liabilities for the period were \$1.3 million as an additional use of cash.

During the year ended December 31, 2023, our total research and development expenses were \$9.3 million, our sales and marketing expenses were \$2.8 million, and our general and administrative expenses were \$11.2 million. We also incurred \$1.1 million in total cost of revenues, including \$88,000 for amortization of intangible expenses. Consolidated net loss for the period was \$27.8 million, of which \$2.9 million was from discontinued operations, and our consolidated net cash used in operating activities amounted to \$23.3 million. Our cash used in operating activities during 2023 did not include the following noncash items: \$1.7 million in depreciation and amortization expenses, \$2.8 million in stock-based compensation, \$5.8 million gain from change in fair value of contingent consideration, \$6.8 million loss from asset impairments, \$1.5 million loss related to discontinued operations, \$1.3 million loss on disposal and held for sale assets, \$127,000 in other equity compensation expenses, and \$61,000 in losses from marketable equity securities. Net changes in operating assets and liabilities were \$4.0 million as an additional use of cash.

Cash Used in Investing Activities

During the year ended December 31, 2024, net cash used in investing activities was \$512,000, primarily from cash paid for construction in progress and purchase of furniture and equipment.

During the year ended December 31, 2023, net cash used in investing activities was \$932,000, primarily from cash sold in discontinued operations, partially offset by proceeds from the sale of marketable equity securities and equipment.

Cash Provided by Financing Activities

During the year ended December 31, 2024, net cash provided by financing activities was \$20.4 million from \$26.0 million of net cash proceeds from the April 2024 Offering, the August 2024 Offering and the October 2024 Offering, partially offset by the redemption of our remaining Series A Preferred Stock of \$5.4 million and repayments of financing lease obligations of \$201,000.

During the year ended December 31, 2023, net cash provided by financing activities was \$12.2 million, attributable to the \$13.4 million of net cash proceeds from the sale of shares of common stock, partially offset by redemption of Series A Redeemable Convertible Preferred Stock of \$1.1 million and repayments of financing lease obligations of \$117,000.

Critical Accounting Estimates

Our consolidated financial statements are prepared in conformity with GAAP. In preparing these financial statements, we make assumptions, judgments and estimates that involve a significant level of estimation uncertainty and have had or are reasonably likely to have a material impact on our financial condition or results of operations. We base our assumptions, judgments and estimates on historical experience and various other factors that we believe to be reasonable under the circumstances. Actual results could differ materially from these estimates under different assumptions or conditions. On a regular basis, we evaluate our assumptions, judgments and estimates and make changes accordingly.

We believe that of the significant accounting policies discussed in Note 2 to our consolidated financial statements included elsewhere in this Report, the following accounting policies involve a significant level of estimation uncertainty and require our most difficult, subjective or complex assumptions, judgments and estimates:

- Going Concern Assessment;
- Contingent Consideration Liabilities;
- Intangible Assets;
- Impairment of Long-Lived Assets;
- Revenue Recognition and Allowance for Credit Losses;
- Stock-Based Compensation; and
- Income Taxes.

Going Concern Assessment

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 (the “look-forward period”). As part of this assessment, based on conditions that are known and reasonably knowable to us, we consider various scenarios, forecasts, projections and estimates, including stress tests, 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. For additional information, refer to Note 1 to our consolidated financial statements included elsewhere in this Report.

Contingent Consideration Liabilities

Contingent consideration is 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 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 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. During the years ended December 31, 2024 and 2023, we recorded gains of \$4.3 million and \$5.8 million, respectively, related to the fair value of contingent consideration. As of December 31, 2024 and 2023, total contingent consideration liabilities were \$37.9 million and \$42.2 million, respectively. For additional information, refer to Note 3 to our consolidated financial statements included elsewhere in this Report.

Intangible Assets

We consider various factors and risks for potential impairment of IPR&D intangible assets, including the current legal and regulatory environment and the competitive landscape. Adverse clinical trial results, significant delays or inability to obtain LCD from the Centers for Medicare and Medicaid Services 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.

During the first quarter of 2023, due to changes in management and our economic condition, management shifted our business strategy to direct efforts on fewer studies and to transition from tests that are LDTs to RUO sales. Due to the change in strategy, our long range plan forecasts were updated and anticipated future benefits derived from our assets. The change in strategy represent a significant indicator for change in value of our long-lived assets. The original IPR&D balances were reassessed based on the updated long range plan, using the multi-period excess earnings method (“MPEEM”) approach, the results of the valuation noted that the carrying value of certain oncology related IPR&D intangible assets was greater than the fair market value. We recorded an impairment of approximately \$5.0 million as of March 31, 2023. During the fourth quarter of 2024, the IPR&D balances were reassessed using the MPEEM approach and the results of the valuations noted that the carrying values of certain oncology related IPR&D intangible assets were greater than the fair market values. We recorded a total impairment of \$41.9 million as of December 31, 2024. For additional information, refer to Note 5 to our consolidated financial statements included elsewhere in this Report.

Impairment of Long-Lived Assets

We assess the impairment of long-lived assets, which consists primarily of long-lived intangible assets, right-of-use assets, 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. 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. During the years ended December 31, 2024 and 2023, we recognized impairment losses on held for sale assets of \$169,000 and \$1.3 million, respectively. For additional information, refer to Note 2, “Assets Held for Sale and Discontinued Operations,” to our consolidated financial statements included elsewhere in this Report.

Revenue Recognition and Allowance for Credit Losses

Pharma Services

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, we have 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, 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 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.

We establish an allowance for credit losses 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 condition, reasonable and supportable forecast that affect the collectability of the reported amount, and historical experience. We continuously monitor collections and payments from customers and maintains a provision for estimated credit losses and uncollectible accounts, if any, based upon its historical experience and any specific customer collection issues that have been identified. Amounts determined to be uncollectible are written off against the credit loss reserve accounts. As of December 31, 2024 and 2023, we had an allowance for credit losses of \$16,000 and \$5,000, respectively, related to Pharma Services.

Stock-Based Compensation

We recognize compensation expense related to share-based payment awards made to employees, board directors and other non-employees based on estimated fair values. We estimate the fair value of 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. For grants with market-based and time-based vesting conditions, the fair value is estimated using the Monte Carlo simulation model, which includes the estimated period to achievement of the performance and market conditions, which are subject to the achievement of the market-based goals established by us and continued employment. We utilize the Black-Scholes option pricing model for determining the fair value of standard time-based 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. We estimate the expected volatility using our own stock price volatility for a period equal to the expected term of the options. The expected term of options granted is based on our own experience. The risk-free rate is based on the U.S. Treasury rates in effect during the corresponding period of grant. Key inputs and assumptions may change as we continue to develop our 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. During the years ended December 31, 2024 and 2023, we recognized total stock-based compensation of \$1.8 million and \$2.8 million, respectively. For additional information, refer to Note 8 to our consolidated financial statements included elsewhere in this Report.

Income Taxes

We account for income taxes in accordance with Accounting Standards Codification 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. For additional information, refer to Note 12, "Income Taxes," to our consolidated financial statements included elsewhere in this Report.

Item 7A. Quantitative and Qualitative Disclosures about Market Risk.

Under the 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.

The financial statements and related financial information required to be filed hereunder are indexed under [Item 15](#) of this report and are incorporated herein by reference.

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

The Audit Committee, as a matter of good governance, invited several registered public accounting firms to participate in an evaluation process to consider a potential audit firm rotation. As a result of this process, the Audit Committee approved the engagement of Marcum LLP as the Company's independent registered public accounting firm for the fiscal year ending December 31, 2023.

The Company dismissed WithumSmith+Brown, PC ("Withum") as independent registered public accounting firm of the Company on September 29, 2023. Withum's report on the Company's consolidated financial statements as of and for the fiscal years ended December 31, 2021 and December 31, 2022, did not contain an adverse opinion or a disclaimer of opinion and was not qualified or modified as to uncertainty, audit scope or accounting principles.

During the fiscal years ended December 31, 2021 and December 31, 2022, and the subsequent interim period through June 30, 2023, there were (i) no “disagreements” as that term is defined in Item 304(a)(1)(iv) of Regulation S-K, between the Company and Withum on any matter of accounting principles or practices, financial statement disclosure or auditing scope or procedure, which disagreements, if not resolved to the satisfaction of Withum, would have caused Withum to make reference to the subject matter of the disagreement in their reports on the financial statements for such years, and (ii) no “reportable events” as that term is defined in Item 304(a)(1)(v) of Regulation S-K, except for the material weaknesses related to the failure to 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, which material weaknesses were remediated prior to June 30, 2023, as reported in the Company’s Quarterly Report on Form 10-Q for the quarterly period ended June 30, 2023.

The Company requested that Withum furnish a letter addressed to the SEC stating whether or not it agrees with the statements made herein. Withum’s letter dated October 5, 2023 has been incorporated herein by reference under Exhibit 16.1 in Item 15 below.

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, 2024. 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 principal executive officer and our principal financial officer, as appropriate to allow timely decisions regarding required disclosure.

Management’s Annual 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 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.

Our management conducted an assessment of the effectiveness of our internal control over financial reporting as of December 31, 2024 based on the criteria set forth in the Internal Control Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission. Based on the assessment, our management has concluded that our internal control over financial reporting was effective as of December 31, 2024.

Exemption from Attestation Report of Independent Registered Public Accounting Firm

This Report does not include an attestation report of our independent registered public accounting firm regarding internal control over financial reporting. Management’s report was not subject to attestation by our independent registered public accounting firm pursuant to the rules of the SEC that permit us to provide only Management’s Annual Report because we are a non-accelerated filer.

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting that occurred during the fourth quarter ended December 31, 2024 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information

- (a) None.
- (b) None.

Item 9C. Disclosure Regarding Foreign Jurisdictions That Prevent Inspections

Not applicable.

PART III

Item 10. Directors, Executive Officers and Corporate Governance.

Board of Directors

The board of directors (the “Board”) is currently composed of four members. Directors are elected at our annual meeting of stockholders and serve until the earlier of the next annual meeting of stockholders or their resignation, removal or death.

Below is a list of the names, ages as of March 17, 2025, and positions of the individuals who currently serve as our Directors:

Name	Age	Director Since	Position
Joshua Riggs	43	2023	President and Chief Executive Officer and Director
Andrew Arno	65	2015	Chairman of the Board of Directors
Andrew J. Last	65	2015	Director
Louis E. Silverman	66	2023	Director

Director Biographies

Information concerning our directors is set forth below. The biographical description of each director includes the specific experience, qualifications, attributes and skills that led the Board to conclude that such person should serve as a director.

Joshua Riggs, 43, joined our Board and began serving as our President and Chief Executive Officer in February 2023. Mr. Riggs previously served as our Interim Chief Executive Officer from December 2022 to February 2023, the Company’s General Manager, Transplant from July 2022 to December 2022, and the Company’s Senior Director Business Development from August 2020 until September 2022. From January 2015 to August 2020, Mr. Riggs was the founder and principal of Intelliger Consulting, an organization devoted to consumer driven healthcare, and from January 2016 to July 2020, he was a principal at Bethesda Group, LLC, a boutique consulting group focused on helping small and mid-stage diagnostic companies and investment groups move emerging diagnostic content and platforms to market. Mr. Riggs received a BA in Interdisciplinary Studies from Adelphi University and an MBA from the University of Mississippi. We believe Mr. Riggs is qualified to serve on our Board because of his previous leadership experiences and involvement with all aspects of the Company’s business and operations.

Andrew Arno, 65, joined our Board in June 2015 and was appointed Chairman of the Board in May 2022. Mr. Arno has over 30 years of experience handling a wide range of corporate and financial matters, primarily including work as an investment banker and strategic advisor to emerging growth companies. Since October 2023, he has served as a Managing Member of Unterberg Legacy Capital, LLC, a merchant bank and multi-family office. He previously served, from 2015 to 2023, as Vice Chairman of Special Equities Group, LLC, a privately held investment banking firm affiliated with Dawson James Securities Inc., and previously with Bradley Woods & Co. Ltd., and Chardan Capital Markets, LLC. From 2013 until 2015, Mr. Arno served as Managing Director of Emerging Growth Equities, an investment banking firm, and was previously President of LOMUSA Limited, an investment banking firm. From 2009 to 2012, Mr. Arno served as Vice Chairman and Chief Marketing Officer of Unterberg Capital, LLC, an investment advisory firm that he co-founded. He was also Vice Chairman and Head of the Equity Capital Markets division of Merriman Capital LLC, an investment banking firm, and served on the board of the parent company, Merriman Holdings, Inc. Mr. Arno currently serves on the boards of directors of XXII Century Group (XXII), a biotechnology company, Smith Micro Software, Inc. (SMSI), a software company, Catheter Precision, Inc. (VTAK), a medical device company and Independa Inc., a privately held software companies. Mr. Arno also serves as Chairman of the Board of Directors of ComHear Inc., a privately held audio technology R&D company. Mr. Arno previously served as a director of Asterias Biotherapeutics, Inc. from August 2014 until it was acquired by Lineage Cell Therapeutics, Inc. (LCTX) in March 2019. Mr. Arno received a BS degree from George Washington University. We believe Mr. Arno is qualified to serve on our Board because of his financial expertise and his experience as a director on other public company boards.

Andrew J. Last, 65, joined our Board in December 2015. Dr. Last shares with our Board his many years of senior management experience commercializing products internationally in the genomics and life-sciences industries. Since 2023, Dr. Last has served on the Board of CellChorus Inc., a technology company that applies artificial intelligence to visually evaluate the performance of immune cells over time. From 2019 to 2024, Dr. Last served as Executive Vice President and Chief Operating Officer of Bio-Rad Laboratories, Inc., a global leader in developing, manufacturing, and marketing a broad range of innovative products for the life science research and clinical diagnostic markets. From December 2017 to April 2019, Dr. Last served as Chief Commercial Officer at Berkeley Lights Inc., a digital cell biology company focused on enabling and accelerating the rapid development and commercialization of biotherapeutics and other cell-based products, and as Chief Operating Officer of Intrexon Corporation, a company using synthetic biology to focus on programming biological systems to alleviate disease, remediate environmental challenges, and provide sustainable food and industrial chemicals from August 2016 to December 2017. From 2010 to 2016, Dr. Last was Executive Vice President and Chief Operating Officer of Affymetrix, a biotechnology company. Before joining Affymetrix, Dr. Last served as Vice President, Global and Strategic Marketing of BD Biosciences and as General Manager of Pharmingen from 2004 to 2010. From 2002 to 2004, Dr. Last held management positions at Applied Biosystems, Inc., including as Vice President and General Manager from 2003 to 2004 and Vice President of Marketing 2002 to 2003. Earlier in his career, he served in a variety of management positions at other companies, including Incyte Genomics and Monsanto. Dr. Last holds PhD and MS degrees with specialization in Agrochemical Chemicals and Bio-Aeronautics, respectively, from Cranfield University, and a BS degree in Biological Sciences from the University of Leicester in the United Kingdom. We believe Dr. Last is qualified to serve on our Board because of his extensive experience holding senior leadership positions within other biopharmaceutical companies and his many years of experience commercializing products in the genomics and life-sciences industries.

Louis E. Silverman, 66, joined our Board in November 2022 and previously served as the Lead Independent Director of the Company from February 2023 to July 2024. Since February 2014, Mr. Silverman has served as the Chairperson and Chief Executive Officer of privately held Hicuity Health, Inc. (formerly known as Advanced ICU Care, Inc.), a health care services company providing remote patient monitoring services to hospitals. From 2014 to 2022, Mr. Silverman served as a director on the board of directors of STAAR Surgical Company, which designs, develops, manufactures, and sells implantable lenses for the eye and companion delivery systems used to deliver the lenses into the eye. From June 2012 through February 2014, Mr. Silverman served as a consultant and board advisor for private equity investors and others regarding health care technology and health care technology service companies, and health care services portfolio investments. From September 2009 through June 2012, Mr. Silverman was Chief Executive Officer of Marina Medical Billing Services, Inc., a revenue cycle management company serving ER physicians nationally. From September 2008 through August 2009, Mr. Silverman served as President and Chief Executive Officer of Qualcomm-backed health care start-up LifeComm. From August 2000 through August 2008, Mr. Silverman served as the President and Chief Executive officer of Quality Systems, Inc., a publicly traded developer of medical and dental practice management and patient records software. From 1993 through 2000, he served in multiple positions, including Chief Operations Officer, of CorVel Corporation, a publicly traded national managed care services/technology company. Mr. Silverman earned a BA from Amherst College and an MBA from Harvard Business School. We believe Mr. Silverman is qualified to serve on our Board because of his extensive experience holding senior leadership and board positions with other public and private companies.

Executive Officers

Below is a list of the names, ages as of March 17, 2025, positions, and a brief account of the business experience of the individuals who serve as our executive officers.

Name	Age	Position
Joshua Riggs	43	President and Chief Executive Officer and Director
James Liu	30	Vice President Accounting, Controller, Treasurer and Principal Accounting Officer
Andrea James	43	Chief Financial Officer

Executive Officer Biographies

The principal occupation and business experience for at least the past five years for our executive officers is as follows:

Joshua Riggs biographical information can be found in the section titled “Item 10. Directors, Executive Officers and Corporate Governance – Director Biographies” and is incorporated by reference herein.

James Liu, 30, was appointed Vice President Accounting, Controller, Treasurer and Principal Accounting Officer of the Company on March 10, 2025, and previously served as the Company’s Senior Director, Controller, Principal Accounting Officer and interim Principal Financial Officer from August 2023 until March 2025. Mr. Liu previously served as Controller and Principal Accounting Officer of the Company since September 2022, after serving as Interim Controller from July 2022 to September 2022 and Manager of Securities and Exchange Commission Reporting and Compliance from July 2021 to July 2022. Prior to that, Mr. Liu was the Accounting Manager of Acacia Research Corporation from November 2020 to July 2021, and Senior Accountant at Gatekeeper Systems, Inc. (“Gatekeeper Systems”) from August 2019 to November 2020. Prior to joining Gatekeeper Systems, Mr. Liu served as Senior Assurance Associate at BDO USA, LLP from October 2016 to August 2019. Mr. Liu holds a BASc degree from the University of California, San Diego, and is a Certified Public Accountant.

Andrea James, 43, has served as the Chief Financial Officer of the Company since June 17, 2024. Previously, Ms. James joined Axon Enterprise in September 2017 as Vice President of Investor Relations. In May 2019, she was promoted to Vice President of Corporate Strategy & Investor Relations. In July 2020, she was promoted to Senior Vice President of Corporate Strategy & Investor Relations. In September 2022, she was promoted to Chief Communications Officer, reporting to the chief financial officer and maintaining her responsibility for investor relations. Ms. James concluded full-time employment at Axon on December 31, 2023, and continued to work as an advisor to Axon through May 2024, to ensure a smooth transition. Previously, Ms. James consulted in a strategic investor relations role for Tesla, Inc., and served as a vice president and senior research analyst for Dougherty & Company (now Colliers Securities), an investment bank, where she researched emerging technologies on behalf of institutional investors. Ms. James holds a B.S. in Computer Information Systems from American University, with a dual-minor in Applied Physics and Communications. She holds an M.S. in Journalism from Northwestern University.

There is no arrangement or understanding between any of the directors or officers identified above and any other person pursuant to which he was selected as a director or officer. None of the directors or officers identified above is, or has been, a participant in any transaction involving the Company, and is not a participant in any proposed transaction with the Company, in each case, required to be disclosed pursuant to Item 404(a) of Regulation S-K, other than as described in the “Certain Relationships and Related Transactions, and Director Independence” section below.

Director Independence

Our Board has reviewed the materiality of any relationship that each of our directors has with the Company, either directly or indirectly. Based upon this review, our Board has determined that the following directors are “independent directors” as defined by The Nasdaq Stock Market:

Louis E. Silverman
Andrew J. Last
Andrew Arno

Board Committees

Our Board has an Audit Committee, a Compensation Committee, and a Nominating/Corporate Governance Committee.

- The Audit Committee consists of Andrew J. Last (Chair), Andrew Arno and Louis E. Silverman.
- The Compensation Committee consists of Louis E. Silverman (Chair), Andrew Last and Andrew Arno.
- The Nominating/Corporate Governance Committee consists of Andrew Arno (Chair), Louis E. Silverman and Andrew J. Last.

Audit Committee

The purpose of the Audit Committee is to recommend the engagement of our independent registered public accountants, to review their performance and the plan, scope, and results of the audit, and to review and approve the fees we pay to our independent registered public accountants. The Audit Committee also will review our accounting and financial reporting procedures and controls. The Audit Committee has a written charter that requires the members of the Audit Committee to be directors who are independent in accordance with the applicable Nasdaq Rules and Rule 10A-3 under the Exchange Act. A copy of the Audit Committee Charter has been posted on our internet website and can be found at www.Oncocyte.com.

All members of our Audit Committee meet the requirements for financial literacy under the applicable rules and regulations of the SEC and Nasdaq. Our Board has determined that each of Andrew J. Last and Louis E. Silverman is an audit committee financial expert as defined under the applicable rules of the SEC and has the requisite financial sophistication under the applicable rules and regulations of Nasdaq. All of the members of our Audit Committee are independent directors as defined under the applicable rules and regulations of the SEC and Nasdaq.

Compensation Committee

The Compensation Committee oversees our compensation and employee benefit plans and practices, including executive compensation arrangements and incentive plans and awards of stock options and other equity-based awards under our equity plans, including the Oncocyte Corporation Amended and Restated 2018 Equity Incentive Plan (as amended and restated, the “Incentive Plan”). The Compensation Committee will determine or recommend to the Board the terms and amount of executive compensation and grants of equity-based awards to executives, key employees, consultants, and independent contractors. The Chief Executive Officer may make recommendations to the Compensation Committee concerning executive compensation and performance, but the Compensation Committee makes its own determination or recommendation to the Board with respect to the amount and components of compensation, including salary, bonus and equity awards to executive officers, generally taking into account factors such as company performance, individual performance, and compensation paid by peer group companies. A copy of the Compensation Committee Charter has been posted on our internet website and can be found at www.Oncocyte.com.

Oncocyte may engage compensation consultants from time to time to provide advice to management and the Compensation Committee, including with regard to market survey information and competitive market trends in employee, executive and directors’ compensation programs.

Nominating/Corporate Governance Committee

The purpose of the Nominating/Corporate Governance Committee is to recommend to the Board individuals qualified to serve as directors and on committees of the Board, and to make recommendations to the Board on issues and proposals regarding corporate governance matters. The Nominating/Corporate Governance Committee also oversees compliance with, and all requests for waivers of, our Code of Ethics, and under our Interested Persons Transaction Policy reviews for approval transactions between us and our executive officers, directors, and stockholders who beneficially own 5% or more of our outstanding shares of common stock.

The Nominating/Corporate Governance Committee will consider nominees for election as directors proposed by stockholders, provided that they notify the Nominating/Corporate Governance Committee of the nomination in proper written form, either by personal delivery or by United States registered mail, to our corporate Secretary at our principal executive offices no earlier than the close of business on the 120th calendar day and no later than the close of business on the 90th calendar day prior to the anniversary date of the immediately preceding annual meeting of stockholders. If the current year’s annual meeting is called for a date that is more than 30 days before or more than 60 days after the anniversary of the immediately preceding annual meeting of stockholders, notice must be received not later than the close of business on the 10th calendar day following the day on which we first make a public announcement of the date of the annual meeting of stockholders. To be in proper written form, the notice from a stockholder must include the information required by our bylaws. A copy of the Nominating/Corporate Governance Committee Charter has been posted on our internet website and can be found at www.Oncocyte.com.

The Board and the Nominating/Corporate Governance Committee have not set any specific minimum qualifications that a prospective nominee would need in order to be nominated to serve on the Board. Rather, in evaluating any new nominee or incumbent director, the Nominating/Corporate Governance Committee will consider whether the particular person has the knowledge, skills, experience, and expertise needed to manage our affairs in light of the skills, experience, and expertise of the other members of the Board as a whole. The Committee will also consider whether a nominee or incumbent director has any conflicts of interest with Oncocyte that might conflict with our Code of Ethics or that might otherwise interfere with their ability to perform their duties in a manner that is in the best interest of Oncocyte and its stockholders. The Committee will also consider whether including a prospective director on the Board will result in a Board composition that complies with (a) applicable state corporate laws, (b) applicable federal and state securities laws, and (c) the rules of the SEC and each stock exchange on which our shares are listed.

The Board and the Nominating/Corporate Governance Committee have not adopted specific policies with respect to a particular mix or diversity of skills, experience, expertise, perspectives, and background that nominees should have. However, the present Board was assembled with a focus on attaining a Board comprised of people with substantial experience in bioscience, the pharmaceutical or diagnostic industry, corporate management, and finance. The Board believes that this interdisciplinary approach best suits our needs at this particular stage, as we work to develop and commercialize diagnostic tests.

Board Leadership Structure

Our leadership structure bifurcates the roles of Chief Executive Officer and Chairman of the Board. Andrew Arno currently serves as Chairman of the Board, and serves as a liaison between the Board and our Chief Executive Officer. The Chairman of the Board also interfaces with our other non-management directors with respect to matters such as the members and chairs of Board committees, other corporate governance matters, and strategic planning.

Our Board believes this division of responsibility is an effective approach for addressing the risks we face and increasing management accountability and improving the ability of the Board to monitor whether management's actions are in the best interests of the Company and its stockholders. All of our Board committees are comprised of only independent directors. All Board committees are chaired by independent directors who report to the full Board whenever necessary. We believe this leadership structure helps facilitate efficient decision-making and communication among our directors and fosters efficient Board functioning at meetings.

The Board's Role in Risk Management

The Board has an active role, as a whole, in overseeing management of the risks of our business. The Board regularly reviews information regarding our credit, liquidity, and operations, as well as the risks associated with our research and development activities, regulatory compliance with respect to the operation of our CLIA laboratories, and our plans to expand our business. The Audit Committee provides oversight of our financial reporting processes and the annual audit of our financial statements. In addition, the Nominating/Corporate Governance Committee reviews and must approve any business transactions between Oncocyte and its executive officers, directors, and stockholders who beneficially own 5% or more of our outstanding shares of common stock.

Involvement in Certain Legal Proceedings

None of our directors or executive officers has been involved in any of the following events during the past ten years:

- any bankruptcy petition filed by or against any business of which such person was a general partner or executive officer either at the time of the bankruptcy or within two years prior to that time;
- any conviction in a criminal proceeding or being subject to a pending criminal proceeding (excluding traffic violations and other minor offenses);
- being subject to any order, judgment, or decree, not subsequently reversed, suspended or vacated, of any court of competent jurisdiction, permanently or temporarily enjoining, barring, suspending or otherwise limiting his or her involvement in any type of business, securities or banking activities; or
- being found by a court of competent jurisdiction (in a civil action), the SEC or the Commodity Futures Trading Commission to have violated a federal or state securities or commodities law, and the judgment has not been reversed, suspended, or vacated.

Family Relationships

There are no family relationships among our directors or executive officers.

Delinquent Section 16(a) Reports

Section 16(a) of the Exchange Act requires our directors and executive officers and each person who owns more than ten percent of a registered class of our equity securities (collectively, "Reporting Persons") to file with the SEC initial reports of ownership and reports of changes in ownership of our Common Stock and our other equity securities. Reporting Persons are required by SEC regulation to furnish us with copies of all Section 16(a) forms that they file. Based solely on the Company's review of the copies of the forms received by it during the fiscal year ended December 31, 2024 and written representations that no other reports were required, the Company believes that each person who, at any time during such fiscal year, was a director, officer or beneficial owner of more than ten percent of the Company's common stock complied with all Section 16(a) filing requirements during such fiscal year.

Code of Business Conduct and Ethics

We have adopted a Code of Business Conduct and Ethics (“Code of Ethics”) that applies to our principal executive officer, our principal financial officer and accounting officer, our other executive officers, and our directors. The purpose of the Code of Ethics is to deter wrongdoing and to promote the conduct of all Oncocyte business in accordance with high standards of integrity, including, among other things: (i) compliance with applicable governmental laws, rules, and regulations; (ii) honest and ethical conduct, including the ethical handling of actual or apparent conflicts of interest; (iii) the prompt internal reporting of any suspected violations of the Code of Ethics to appropriate persons or through Oncocyte’s Compliance Hotline/Helpline; (iv) complete cooperation in the investigation of reported violations and the provision of truthful, complete and accurate information; and (v) accountability for adherence to the Code of Ethics. A copy of our Code of Ethics has been posted on our internet website and can be found at www.Oncocyte.com. We intend to disclose any future amendments to certain provisions of our Code of Ethics, and any waivers of those provisions granted to our principal executive officers, principal financial officer, principal accounting officer or controller or persons performing similar functions, by posting the information on our website within four business days following the date of the amendment or waiver.

Insider Trading Policy and Hedging Transactions

We have adopted an Insider Trading Policy that prohibits our employees, including our officers, directors, and their designees from engaging in short sales of Oncocyte securities (sales of securities that are not then owned), including a “sale against the box” (a sale with delayed delivery), or other hedging or monetization transactions with respect to Oncocyte securities, including, but not limited to, through the use of financial instruments such as exchange funds, prepaid variable forwards, equity swaps, puts, calls, collars, forwards and other derivative instruments.

Clawback Policy

In November 2023, we adopted a Clawback Policy to create greater accountability for our executive officers and employees. Under the policy, if we are required to prepare an accounting restatement of our financial statements due to material noncompliance with any financial reporting requirement under the securities laws, we will require reimbursement or forfeiture of any incentive compensation that exceeds the amount of incentive compensation that would have otherwise been received had it been determined on the restated performance metrics and/or restated financial statements received by executive officers and certain other employees during the three completed fiscal years immediately preceding the date on which the Company is required to prepare an accounting restatement.

Our Board believes the adoption of our Clawback Policy is consistent with our executive compensation philosophy and objectives, and in furtherance of the Board’s intention to follow sound corporate governance practices.

Item 11. Executive Compensation.

Smaller Reporting Company

We are a “smaller reporting company” as defined in the rules and regulations of the SEC. As a smaller reporting company we may take advantage of specified reduced disclosure and other requirements that are otherwise applicable, in general, to public companies that are not smaller reporting companies. Accordingly, this Report includes reduced disclosure about our executive compensation arrangements.

Summary Compensation Table

The following table shows compensation awarded to, paid to or earned by, (1) the Company’s principal executive officer, (2) the Company’s most highly compensated executive officer other than the principal executive officer and (3) up to two individuals who would have qualified as one of the Company’s two most highly compensated executive officers other than the principal executive officer but for the fact that the individual was not serving as an executive officer of the Company at the end of the last completed fiscal year; during the fiscal years ended December 31, 2024 and 2023 (collectively, the “Named Executive Officers”).

Name and Principal Position	Year	Salary	Bonus	Stock Awards ⁽¹⁾	Option Awards ⁽¹⁾	All Other Compensation ⁽²⁾	Total
Joshua Riggs	2024	\$ 385,018	\$ 166,400	\$ —	\$ 209,709	\$ 24,950	\$ 786,077
President and Chief Executive Officer ⁽³⁾	2023	\$ 339,846	\$ 117,000	\$ —	\$ 220,284	\$ 47,780	\$ 724,910
Andrea James	2024	\$ 175,165	\$ 72,800	\$ 173,000	\$ 330,000	\$ 7,898	\$ 758,863
Chief Financial Officer ⁽⁷⁾	2023	\$ —	\$ —	\$ —	\$ —	\$ —	\$ —
James Liu	2024	\$ 204,457	\$ 63,900	\$ —	\$ 23,301	\$ 12,270	\$ 303,928
Senior Director, Controller and Principal Accounting Officer	2023	\$ 191,360	\$ 52,900	\$ —	\$ 44,681	\$ 15,572	\$ 304,513
Ekkehard Schütz	2024	\$ 370,356	\$ 166,800	\$ —	\$ 81,554	\$ 14,858	\$ 633,568
Chief Science Officer	2023	\$ 242,028	\$ 132,700	\$ —	\$ 165,892	\$ 34,547	\$ 575,167

- (1) Option awards granted under our 2010 Employee Stock Option Plan (the “Option Plan”) or under our Incentive Plan are valued at the aggregate grant date fair value, as if all options were fully vested and exercisable at the date of grant. Amounts shown in this column do not reflect dollar amounts actually received by our Named Executive Officers. Instead, these amounts reflect the aggregate grant date fair value of each stock option granted, computed in accordance with the provisions of FASB ASC Topic 718. For stock options that have performance-based (sometimes referred to as milestone-based) vesting conditions, compensation is shown in the tables in the same manner as Oncocyte recorded stock-based compensation expense for the grant on the basis of the estimated probability that the vesting condition will be met or the determination that the condition has been met. We used the Black-Scholes Pricing Model to compute option fair values based on applicable exercise and stock prices, an expected option term, volatility assumptions, and risk-free interest rates. Our Named Executive Officers will only realize compensation upon exercise of the stock options and to the extent the trading price of our common stock is greater than the exercise price of such stock options at the time of exercise.

Time-based stock awards consist entirely of restricted stock units (“RSUs”) and are valued in the table at the aggregate grant date fair value based on the closing price of Oncocyte common stock as quoted on the applicable trading market as if the stock awards were fully vested. Beginning on February 7, 2023, our common stock began trading on the Nasdaq Capital Market under the symbol “OCX.” Previously, our common stock traded under the same symbol on The Nasdaq Global Market since March 8, 2021, and prior to that, on the NYSE American. For stock awards that have performance-based (sometimes referred to as milestone-based) vesting conditions, compensation is shown in the tables in the same manner as Oncocyte recorded stock-based compensation expense for the grant on the basis of the estimated probability that the vesting condition will be met or the determination that the condition has been met. The fair value of the stock awards was measured using Black-Scholes option-pricing model assuming that performance goals will be achieved for the performance-based stock awards, and the Monte Carlo simulation model for the market-based vesting conditions.

- (2) Other compensation consists primarily of employer contributions to employee accounts under our 401(k) plan. See *Executive Employment Agreements, Change of Control Provisions and Separation Payments – Separation Payments* for more information.
- (3) In December 2022, Mr. Riggs was appointed Interim President and Chief Executive Officer and was later appointed President and Chief Executive Officer in February 2023.
- (4) In May 2024, Mr. Riggs was granted 90,000 stock options exercisable at an exercise price of \$2.76 per share.
- (5) In January 2023, Mr. Riggs was granted 12,874 stock options exercisable at an exercise price of \$9.26 per share. In June 2023, Mr. Riggs was granted 17,500 stock options exercisable at an exercise price of \$4.26 per share. In August 2023, Mr. Riggs was granted 40,000 stock options exercisable at an exercise price of \$3.34 per share. Mr. Riggs was also granted 5,821 stock options in February 2023, exercisable at an exercise price of \$7.80 per share, that were deemed earned in 2022.
- (6) Includes \$56,880 in cash and 5,821 stock options exercisable at an exercise price of \$7.80 per share.
- (7) Ms. James was appointed as the Company’s Chief Financial Officer on June 17, 2024.

- (8) In June 2024, Ms. James was granted 100,000 RSUs.
- (9) In June 2024, Ms. James was granted 200,000 stock options exercisable at an exercise price of \$2.76 per share.
- (10) In May 2024, Mr. Liu was granted 10,000 stock options exercisable at an exercise price of \$2.76 per share.
- (11) In January 2023, Mr. Liu was granted 2,853 stock options exercisable at an exercise price of \$9.26 per share. In February 2023, Mr. Liu was granted 8,482 stock options exercisable at an exercise price of \$3.11 per share.
- (12) In May 2024, Dr. Schütz was granted 35,000 stock options exercisable at an exercise price of \$2.76 per share.
- (13) In January 2023, Dr. Schütz was granted 12,873 stock options exercisable at an exercise price of \$9.26 per share. In February 2023, Dr. Schütz was granted 6,044 stock options exercisable at an exercise price of \$7.80 per share. In August 2023, Dr. Schütz was granted 20,000 stock options exercisable at an exercise price of \$3.34 per share.

Employment Agreements

Joshua Riggs

We entered into an amended and restated employment agreement dated as of June 6, 2023, effective as of May 1, 2023, and as amended on July 13, 2023 (as amended, the “Riggs Employment Agreement”) with Mr. Riggs, related to his services with the Company.

The Riggs Employment Agreement provides for (i) a base salary of \$360,000 per annum (pro-rated for partial years), (ii) a target bonus opportunity of fifty percent (50%) of Mr. Riggs’ base salary, and (iii) eligibility to participate in employee benefit programs and plans offered by the Company. On May 30, 2024, Board approved increases to the annual base salary of Mr. Riggs from \$360,000 to \$400,000, effective May 20, 2024. On March 4, 2025, the Board approved an increase to the annual base salary of Mr. Riggs from \$400,000 to \$420,000, effective March 10, 2025.

Pursuant to the Riggs Employment Agreement, on June 9, 2023, Mr. Riggs received options to purchase 350,000 shares of Company common stock (the “CEO Options”) under the Incentive Plan. The CEO Options have an exercise price per share equal to \$2.76 and expire 10 years from the date of grant. The vesting of the CEO Options is as follows: 25% of the options vested on June 9, 2024, and the balance of the options vested or will vest thereafter in thirty-six (36) substantially equal monthly installments, subject to Mr. Riggs’ continued employment with the Company and compliance with any restrictive covenants by which he is bound on each applicable vesting date.

In the event Mr. Riggs’ employment is terminated by the Company without Cause (as defined in the Riggs Employment Agreement) (excluding due to death or disability) or by Mr. Riggs for Good Reason (as defined in the Riggs Employment Agreement), in addition to any accrued but unpaid base salary and any other vested benefits (the “Accrued Obligations”), subject to the execution of a release of claims and Mr. Riggs’ continued compliance with any restrictive covenants by which he may be bound, Mr. Riggs will be entitled to receive: (i) an amount equal to twelve (12) months of Mr. Riggs’ base salary, payable at Company’s sole discretion either (x) in a lump sum on the first payroll date following the sixtieth (60th) day following the date of termination or (y) in twelve (12) equal monthly installments during the twelve (12) months following the date of termination; (ii) a pro-rated annual bonus based for the year of termination based on actual performance; (iii) reimbursement of health care premiums for up twelve (12) months following the date of termination; and (iv) accelerated vesting of the next vesting tranche of any outstanding time-based equity awards. In the event Mr. Riggs’ employment is terminated due to death, by the Company due to Disability (as defined in the Riggs Employment Agreement) or for Cause, or by Mr. Riggs’ without Good Reason, Mr. Riggs will receive the Accrued Obligations.

The Riggs Employment Agreement also contains customary restrictive covenants, including restrictions related to non-solicitation, competitive activities, non-publicity, non-disparagement and cooperation. In addition, in connection with entering into the Riggs Employment Agreement, Mr. Riggs also entered into (i) an employee confidential information and inventions assignment agreement, and (ii) the Company’s standard form indemnification agreement for officer and directors of the Company.

On March 9, 2025, the Board approved a one-time grant under the Incentive Plan of \$600,000 of RSUs to Mr. Riggs, subject to a maximum of 200,000 RSUs, which shall have a grant date of the second full trading day after the release of the Company’s financial results for the quarter and fiscal year ended December 31, 2024, with one-fourth of the RSUs shall vest on each of the first, second, third and fourth anniversaries of the effective date of grant, subject to continuous service through the applicable vesting date.

Ekkehard Schütz

During 2024, the annual salary of Dr. Schütz, our Chief Science Officer was \$378,025. On March 4, 2025, the Board approved an increase to the annual base salary of Dr. Schütz from \$378,025 to \$396,926, effective March 10, 2025. In addition, Dr. Schütz previously entered into a Managing Director Service Agreement with our wholly owned German subsidiary, Chronix Biomedical GmbH (“Chronix Germany”), relating to his services as Managing Director of Chronix Germany (the “Managing Director Service Agreement”). Pursuant to the Managing Director Service Agreement, Dr. Schütz is eligible for (i) a base salary of €315,000 per annum, and (ii) a target bonus opportunity of forty percent (40%) of base salary.

Either party may terminate the Managing Director Service Agreement upon 6 months’ prior written notice. In addition, the agreement will terminate automatically when Dr. Schütz reaches the age at which he becomes entitled to a regular old age pension payable the German statutory pension scheme, or if Dr. Schütz becomes unable to work in general or specifically unable to exercise his profession. The Managing Director Service Agreement also contains certain restrictive covenants, including a two-year non-compete following the termination of the agreement. During this two-year period, Dr. Schütz will receive monthly compensation equal to 50% of latest contractual benefits. The Managing Director Service Agreement also provides for the assignment to Chronix of Dr. Schütz’s inventions and intellectual property rights.

On March 9, 2025, the Board approved a one-time grant under the Incentive Plan of \$360,000 of RSUs to Dr. Schütz, subject to a maximum of 120,000 RSUs, which shall have a grant date of the second full trading day after the release of the Company’s financial results for the quarter and fiscal year ended December 31, 2024, with one-fourth of the RSUs shall vest on each of the first, second, third and fourth anniversaries of the effective date of grant, subject to continuous service through the applicable vesting date.

Andrea James

Ms. James, our Chief Financial Officer, entered into an employment agreement with the Company (the “James Employment Agreement”), effective June 17, 2024. Pursuant to the terms of the James Employment Agreement, Ms. James will receive an initial annual base salary of \$325,000 (such annual base salary, as may be adjusted by the Board from time to time, the “Base Salary”) and will be eligible to receive an initial annual cash bonus, targeted at 50% of the Base Salary (such target, as may be adjusted by the Board from time to time, the “Annual Bonus”). On March 4, 2025, the Board approved an increase to the annual base salary of Andrea James from \$325,000 to \$341,250, effective March 10, 2025.

If Ms. James’s employment is terminated by the Company without Cause (as defined in the James Employment Agreement), or Ms. James resigns from the Company with Good Reason (as defined in the James Employment Agreement), the Company shall: (a) pay Ms. James all accrued but unpaid Base Salary and any vacation or paid time off accrued, (b) any vested benefits to which Ms. James or her estate may be entitled to under the Company’s benefit plan’s or applicable law, (c) an amount equal to 12-months of the Base Salary, (d) pay Ms. James an amount equal to a pro-rated portion of the Annual Bonus, (d) reimbursement for an amount equal to the monthly portion of the premium cost of participation in such group health plan that the Company paid for immediately prior to the date of termination for a period of up to 12 months, (e) with respect to each outstanding time-based equity award, if any, accelerated vesting of the next trench of time-based equity that would have vested had Ms. James remained employed through the next applicable vesting date, and (f) with respect to the Performance Equity Award (as defined below), accelerated time vesting of any options that are performance vested as of the date of termination.

In connection with Ms. James’ appointment as Chief Financial Officer, the Board approved the following grants to Ms. James: (a) an Option (as defined in the Incentive Plan) to purchase 200,000 shares of the Company’s Common Stock (the “Stock Option Grant”), and (b) an award of 100,000 Restricted Stock Units (as defined in the Incentive Plan) (the “Performance Equity Grant”). Both the Stock Option Grant and the Performance Equity Grant was subject to stockholder approval of an amendment to the Incentive Plan, increasing the total number of shares of Common Stock available for grant of awards under the Incentive Plan, which was obtained on October 11, 2024.

On March 4, 2025, the Board approved a one-time bonus of \$25,000 to Ms. James to be paid in cash or RSUs under the Incentive Plan, at the discretion of Ms. James, in recognition of her achievements and contributions to the Company since becoming Chief Financial Officer of the Company in June 2024. If Ms. James elects to receive such bonus in RSUs, such RSUs shall (i) have a grant date of the second full trading day after the release of the Company’s financial results for the quarter and fiscal year ended December 31, 2024, and (ii) vest immediately on the effective date of grant.

On March 9, 2025, the Board approved a one-time grant under the Incentive Plan of \$360,000 of RSUs to Ms. James, subject to a maximum of 120,000 RSUs, which shall have a grant date of the second full trading day after the release of the Company’s financial results for the quarter and fiscal year ended December 31, 2024, with one-fourth of the RSUs shall vest on each of the first, second, third and fourth anniversaries of the effective date of grant, subject to continuous service through the applicable vesting date.

Outstanding Equity Awards at 2024 Fiscal Year End

The following table summarizes certain information concerning stock options and other equity awards granted by us under the Option Plan and the Incentive Plan held as of December 31, 2024, by our Named Executive Officers:

Name	Option Awards				Stock Awards			
	Number of Securities Underlying Unexercised Options Exercisable	Number of Securities Underlying Unexercised Options Unexercisable ⁽¹⁾	Option Exercise Price	Option Expiration Date	Number of shares or units of stock that have not vested	Market value of shares of units of stock that have not vested	Equity incentive plan awards: Number of unearned shares, units or other rights that have not vested	Equity incentive plan awards: Market or payout value of unearned shares, units or other rights that have not vested
Joshua Riggs	(2) 6,250	(2) —	\$ 26.60	July 22, 2030	—	—	—	—
	(3) 2,394	(3) 105	\$ 106.80	February 25, 2031	—	—	—	—
	(4) 1,124	(4) 375	\$ 27.80	March 24, 2032	—	—	—	—
	(5) 322	(5) 177	\$ 23.40	May 3, 2032	—	—	—	—
	(6) 12,499	(6) —	\$ 9.20	December 7, 2032	—	—	—	—
	(7) 4,291	(7) 8,582	\$ 9.26	January 17, 2033	—	—	—	—
	(8) 3,557	(8) 2,263	\$ 7.80	February 24, 2033	—	—	—	—
	(9) 6,563	(9) 10,936	\$ 4.26	June 9, 2033	—	—	—	—
	(10) —	(10) 40,000	\$ 3.34	August 15, 2033	—	—	—	—
	(11) —	(11) 90,000	\$ 2.76	May 20, 2034	—	—	—	—
Andrea James	(12) —	(12) 200,000	\$ 2.87	October 11, 2034	100,000	⁽¹⁾ ₍₃₎ \$ 173,000	—	—
James Liu	(14) 427	(14) 73	\$ 23.00	March 15, 2032	—	—	—	—
	(15) 84	(15) 29	\$ 27.80	March 24, 2032	—	—	—	—
	(16) 2,112	(16) 1,638	\$ 17.74	September 20, 2032	—	—	—	—
	(17) 951	(17) 1,902	\$ 9.26	January 17, 2033	—	—	—	—
	(18) 2,474	(18) 6,008	\$ 3.11	October 10, 2033	—	—	—	—
	(19) —	(19) 10,000	\$ 2.76	May 20, 2034	—	—	—	—
Ekkehard Schütz	(20) 11,456	(20) 1,043	\$ 109.20	April 16, 2031	—	—	—	—
	(21) 3,281	(21) 1,094	\$ 23.00	March 15, 2032	—	—	—	—
	(22) 2,187	(22) —	\$ 22.60	May 11, 2032	—	—	—	—
	(23)			January 17,				

4,292)	8,582	\$	9.26	2033	—	—	—	—
	(
	2				February 24,				
	4				2033				
3,695)	2,349	\$	7.80		—	—	—	—

	(2 5)	20,000	\$	3.34	August 15, 2033	—	—	—	—
	(2 6)	35,000	\$	2.76	May 20, 2034	—	—	—	—

- (1) Except as otherwise indicated below, one quarter of the options shall vest upon completion of 12 full months of continuous employment measured from the date of grant, and the balance of the options will vest in 36 equal monthly installments commencing on the first anniversary of the date of grant, based upon the completion of each month of continuous employment.
- (2) The date of grant was July 22, 2020.
- (3) The date of grant was February 25, 2021.
- (4) The date of grant was March 24, 2022.
- (5) The date of grant was May 3, 2022.
- (6) The options vested on December 7, 2023.
- (7) The options vested, or will vest, (i) one-third on January 17, 2024, (ii) one-third on January 17, 2025, and (iii) one-third on January 17, 2026.
- (8) The date of grant was February 24, 2023.
- (9) The date of grant was June 9, 2023.
- (10) The date of grant was August 15, 2023. The options vest subject to the achievement by Oncocyte of pre-defined product and regulatory goals.
- (11) The date of grant was May 20, 2024.
- (12) The date of grant was June 20, 2024.
- (13) The date of grant was June 20, 2024. The RSUs vest subject to the achievement by Oncocyte of pre-defined goals related to market capitalization.
- (14) The date of grant was March 15, 2022.
- (15) The date of grant was March 24, 2022.
- (16) The date of grant was September 20, 2022.
- (17) The options vested, or will vest, (i) one-third on January 17, 2024, (ii) one-third on January 17, 2025, and (iii) one-third on January 17, 2026.
- (18) The date of grant was October 10, 2023.
- (19) The date of grant was May 20, 2024.
- (20) The date of grant was April 16, 2021.
- (21) The date of grant was March 15, 2022.
- (22) The options vest subject to the achievement by Oncocyte of pre-defined product and regulatory goals in 2022. 50% of the options vested on December 31, 2023, and the remaining options were cancelled.
- (23) The options vested, or will vest, (i) one-third on January 17, 2024, (ii) one-third on January 17, 2025, and (iii) one-third on January 17, 2026.

- (24) The date of grant was February 24, 2023.
- (25) The options vest subject to the achievement by Oncocyte of pre-defined product and regulatory goals.
- (26) The date of grant was May 20, 2024.

The Oncocyte Corporation 2018 Equity Incentive Plan

The Incentive Plan was approved by our stockholders on August 27, 2018 (the “Effective Date”) for an aggregate of 250,000 shares of common stock, as adjusted for the Company’s 1-for-20 reverse stock split effective on July 24, 2023 (the “Reverse Stock Split”). On July 17, 2019, our stockholders approved the first Amendment to the Incentive Plan to increase the total number of shares of common stock issuable under the Incentive Plan to a total of 550,000 shares of common stock (as adjusted for the Reverse Stock Split). On July 24, 2021, our stockholders approved the second Amendment to the Incentive Plan to increase the total number of shares of common stock issuable under the Incentive Plan to a total of 1,050,000 shares of common stock (as adjusted for the Reverse Stock Split). On October 11, 2024, our stockholders approved an amendment and restatement of the Incentive Plan, to among other things, to increase the total number of shares of common stock issuable under the Incentive Plan to 2,300,000 shares of common stock.

As of March 17, 2025, we had 1,031,165 shares of common stock available for future issuance under the Incentive Plan.

We have adopted the Incentive Plan that permits us to grant awards, consisting of stock options, the grant or sale of restricted stock (“Restricted Stock”), the grant of stock appreciation rights (“SARs”), and the grant of restricted stock units (“RSUs”), for up to a total of 2,300,000 shares of our common stock. The Incentive Plan also permits Oncocyte to issue such other securities as our Board or the Compensation Committee administering the Incentive Plan may determine. Awards of stock options, Restricted Stock, SARs, and RSUs (“Awards”) may be granted under the Incentive Plan to Oncocyte employees, directors, and consultants. The purposes of the Incentive Plan are to (a) enable the Company to attract and retain the types of employees, consultants and directors who will contribute to the Company’s long-range success; (b) provide incentives that align the interests of employees, consultants and directors with those of the shareholders of the Company; and (c) promote the success of the Company’s business.

Awards may vest and thereby become exercisable or have restrictions on forfeiture lapse on the date of grant or in periodic installments or upon the attainment of performance goals, or upon the occurrence of specified events. Vesting of an Award after the date of grant may be accelerated only in the limited circumstances specified in the Incentive Plan. In the case of the acceleration of vesting of any performance-based Award, acceleration of vesting shall be limited to actual performance achieved, pro rata achievement of the performance goal(s) on the basis for the elapsed portion of the performance period, or a combination of actual and pro rata achievement of performance goals.

No Awards may be granted under the Incentive Plan more than ten years after the date upon which the Incentive Plan was adopted by our Board, and no options or SARs granted under the Incentive Plan may be exercised after the expiration of ten years from the date of grant.

Subject to the terms of the Incentive Plan, the Incentive Plan shall be administered by the Board or such committee of the Board as is designated by the Board to administer the Plan (the “Committee”). Membership on the Committee shall be limited to “non-employee directors” in accordance with Rule 16b-3 under the Securities Exchange Act of 1934, as amended. The Committee may delegate certain duties to one or more officers of the Company as provided in the Incentive Plan. The Committee will determine the persons to whom awards are to be made, determine the type, size and terms of awards, construe and interpret the Incentive Plan, and exercise its discretion to make any other determinations that it believes necessary for the administration of the Incentive Plan.

Stock Options

Options granted under the Incentive Plan may be either “incentive stock options” within the meaning of Section 422(b) of the Internal Revenue Code of 1986, as amended (the “Code”), or “non-qualified” stock options that do not qualify incentive stock options. Incentive stock options may be granted only to our employees and employees of our subsidiaries. The exercise price of stock options granted under the Incentive Plan must be equal to the fair market of our common stock on the date the option is granted. In the case of an optionee who, at the time of grant, owns more than 10% of the combined voting power of all classes of our capital stock, the exercise price of any incentive stock option must be at least 110% of the fair market value of our common stock on the grant date, and the term of the option may be no longer than five years. The aggregate fair market value of our common stock (determined as of the grant date of the option) with respect to which incentive stock options become exercisable for the first time by an optionee in any calendar year may not exceed \$100,000.

The exercise price of an option may be payable in cash or in shares of our common stock having a fair market value equal to the exercise price, or in a combination of cash and common stock, or other legal consideration for the issuance of stock as our Board or the Committee may approve.

Generally, options will be exercisable only while the optionee remains an employee, director or consultant, or during a specific period thereafter, but in the case of the termination of an employee, director, or consultant's services due to death or disability, the period for exercising a vested option shall be extended to the earlier of 12 months after termination or the expiration date of the option.

Restricted Stock and Restricted Stock Units

In lieu of granting options, we may enter into purchase agreements with employees under which they may purchase or otherwise acquire RSUs subject to such vesting, transfer, and repurchase terms, and other restrictions. The price at which Restricted Stock may be issued or sold will be not less than 100% of fair market value. Employees or consultants, but not executive officers or directors, who purchase Restricted Stock may be permitted to pay for their shares by delivering a promissory note or an installment payment agreement that may be secured by a pledge of their Restricted Stock. Restricted Stock may also be issued for services actually performed by the recipient prior to the issuance of the Restricted Stock. Unvested Restricted Stock for which we have not received payment may be forfeited, or we may have the right to repurchase unvested shares upon the occurrence of specified events, such as termination of employment.

Subject to the restrictions set with respect to the particular Award, a recipient of Restricted Stock generally shall have the rights and privileges of a stockholder upon vesting, including the right to vote the Restricted Stock and the right to receive dividends; provided that, any cash dividends and stock dividends with respect to the Restricted Stock shall be withheld for the recipient's account, and interest may be credited on the amount of the cash dividends withheld. The cash dividends or stock dividends so withheld and attributable to any particular share of Restricted Stock (and earnings thereon, if applicable) shall be distributed to the recipient in cash or, at the discretion of our Board or the Committee, in shares of our common stock having a fair market value equal to the amount of such dividends, if applicable, upon the release of restrictions on the Restricted Stock and, if the Restricted Stock is forfeited, the recipient shall have no right to the dividends.

The terms and conditions of a grant of RSUs shall be determined by our Board or the Committee. No shares of our common stock shall be issued at the time an RSU is granted. A recipient of RSUs shall have no voting rights with respect to the RSUs. Upon the expiration of the restrictions applicable to an RSU, we will either issue to the recipient, without charge, one share of our common stock per RSU or cash in an amount equal to the fair market value of one share of our common stock.

At the discretion of our Board or the Committee, each RSU (representing one share of our common stock) may be credited with cash and stock dividends paid in respect of one share ("Dividend Equivalents"). Dividend Equivalents shall be withheld for the recipient's account, and interest may be credited on the amount of cash Dividend Equivalents withheld. Dividend Equivalents credited to a recipient's account and attributable to any particular RSU (and earnings thereon, if applicable) shall be distributed in cash or in shares of our common stock having a fair market value equal to the amount of the Dividend Equivalents and earnings, if applicable, upon settlement of the RSU. If a RSU is forfeited, the recipient shall have no right to the related Dividend Equivalents.

SARs

An SAR is the right to receive, upon exercise, an amount payable in cash or shares, or a combination of shares and cash, equal to the number of shares subject to the SAR that is being exercised, multiplied by the excess of (a) the fair market value of a common share on the date the SAR is exercised, over (b) the exercise price specified in the SAR Award agreement. SARs may be granted either as free-standing SARs or in tandem with options. No SAR may be exercised later than 10 years after the date of grant.

The exercise price of an SAR shall not be less than 100% of the fair market value of one share of common stock on the date of grant. An SAR granted in conjunction with an option shall have the same exercise price as the related option, shall be transferable only upon the same terms and conditions as the related option, and shall be exercisable only to the same extent as the related option; provided, however, that the SAR by its terms shall be exercisable only when the fair market value per share exceeds the exercise price per share of the SAR or related option. Upon any exercise of an SAR granted in tandem with an option, the number of shares for which the related option shall be exercisable shall be reduced by the number of shares for which the SAR has been exercised. The number of shares for which an SAR issued in tandem with an option shall be exercisable shall be reduced by the number of shares for which the related option has been exercised.

Stock Appreciation Rights

A Stock Appreciation Right (or SAR) is the right to receive, upon exercise, an amount payable in cash or shares, or a combination of shares and cash, equal to the number of shares subject to the SAR that is being exercised, multiplied by the excess of (a) the fair market value of a share of our common stock on the date the SAR is exercised, over (b) the exercise price specified in the award agreement related to the SAR. SARs may be granted either as free-standing SARs or in tandem with options. No SAR may be exercised later than 10 years after the date of grant.

The exercise price of an SAR shall not be less than 100% of the fair market value of one share of our common stock on the date of grant. An SAR granted in conjunction with an option shall have the same exercise price as the related option, shall be transferable only upon the same terms and conditions as the related option, and shall be exercisable only to the same extent as the related option; provided, however, that the SAR by its terms shall be exercisable only when the fair market value per share exceeds the exercise price per share of the SAR or related option. Upon any exercise of an SAR granted in tandem with an option, the number of shares for which the related option shall be exercisable shall be reduced by the number of shares for which the SAR has been exercised. The number of shares for which an SAR issued in tandem with an option shall be exercisable shall be reduced by the number of shares for which the related option has been exercised.

Repricing Prohibition

The Incentive Plan prohibits any modification of the purchase price or exercise price of an outstanding option or other Award if the change would effect a “repricing” without stockholder approval. As defined in the Incentive Plan, “repricing” means a reduction in the exercise price of an outstanding option or SAR or cancellation of an “underwater” or “out-of-the-money” Award in exchange for other Awards or cash. An “underwater” or “out-of-the-money” Award is defined to mean an Award for which the exercise price is less than the “fair market value” of our common stock. The fair market value is generally determined by the closing price per share of our common stock on The Nasdaq Stock Market LLC or any other national securities exchange or inter-dealer quotation system on which our common stock is traded.

Share Recycling

Shares subject to an Award shall that is canceled, forfeited or expires prior to exercise or realization, either in full or in part, shall again be made available for issuance or delivery under the Incentive Plan. This provision is designed to limit the number of shares that Oncocyte asks for, and incentivize the company to be prudent in its management of both employees and shares.

Adjustments Upon Changes in Stock

In the event of changes in the outstanding common stock or in the capital structure of the Company by reason of any stock or extraordinary cash dividend, stock split, reverse stock split, an extraordinary corporate transaction such as any recapitalization, reorganization, merger, consolidation, combination, exchange, or other relevant change in capitalization occurring after the grant date of any award, awards granted under the Incentive Plan and any award agreements, including the exercise price of stock options and Stock Appreciation Rights and the number of shares of common stock subject to such stock options, Stock Appreciation Rights, or stock awards, the maximum number of shares of common stock subject to all awards available under the Incentive Plan, and the maximum number of shares of common stock with respect to which any one person may be granted awards during any period under the Incentive Plan will be equitably adjusted or substituted, as to the number, price or kind of a share of common stock or other consideration subject to such awards to the extent necessary to preserve the economic intent of such award.

Term

The Incentive Plan will terminate automatically on July 2, 2028, which is ten years from the date the Incentive Plan was originally approved by our Board. No Award shall be granted pursuant to the Incentive Plan after such date, but Awards theretofore granted may extend beyond that date.

Amendment of Plan

The Board at any time, and from time to time, may amend or terminate the Incentive Plan. However, except with respect to adjustments upon changes in common stock and subject to applicable law, no amendment shall be effective unless approved by the shareholders of the Company to the extent shareholder approval is necessary to satisfy any applicable laws.

Clawback

Notwithstanding any other provisions in the Incentive Plan, any award which is subject to recovery under any law, government regulation or stock exchange listing requirement, will be subject to such deductions and clawback as may be required to be made pursuant to such law, government regulation or stock exchange listing requirement (or any policy adopted by the Company pursuant to any such law, government regulation or stock exchange listing requirement).

Federal Income Tax Consequence of Participation in the Incentive Plan

The following is a brief summary of certain federal income tax consequences relating to the transactions described under the Incentive Plan as set forth below. This summary does not purport to address all aspects of federal income taxation and does not describe any potential state, local, or foreign tax consequences. This discussion is based upon provisions of the Code and the applicable treasury regulations issued thereunder, and judicial and administrative interpretations under the Code and treasury regulations, all as in effect as of the date hereof, and all of which are subject to change (possibly on a retroactive basis) or different interpretation.

Laws Affecting Deferred Compensation

In 2004, Section 409A was added to the Code to regulate all types of deferred compensation. If the requirements of Section 409A of the Code are not satisfied, deferred compensation and earnings thereon will be subject to tax as it vests, plus an interest charge at the underpayment rate plus 1% and a 20% penalty tax. Certain performance awards, stock options, SARs, restricted stock units, and certain types of restricted stock are subject to Section 409A of the Code.

Incentive Stock Options

Under Section 422(a) of the Code, the grant and exercise of an incentive stock option pursuant to the Incentive Plan is entitled to the benefits of Section 421(a) of the Code. Under Section 421(a), an optionee will not be required to recognize income at the time the option is granted or at the time the option is exercised, except to the extent that the optionee is subject to the alternative minimum tax. If the applicable holding periods described below are met, when the shares of stock received upon exercise of an incentive stock option are sold or otherwise disposed of in a taxable transaction, the option holder will recognize compensation income (taxed as a long-term capital gain), for the taxable year in which disposition occurs, in an amount equal to the excess of the fair market value of our common stock at the time of such disposition over the amount paid for the shares.

We will not be entitled to any business expense deduction with respect to the grant or exercise of an incentive stock option, except in connection with a disqualifying disposition as discussed below. No portion of the amount received by the optionee upon the sale of our common stock acquired through the exercise of an incentive stock option will be subject to withholding for federal income taxes, or be subject to FICA or state disability taxes, except in connection with a disqualifying disposition.

In order for a participant to receive the favorable tax treatment provided in Section 421(a) of the Code, Section 422 requires that the participant make no disposition of the option shares within two years from the date the option was granted, nor within one year from the date the option was exercised and the shares were transferred to the participant. In addition, the participant must, with certain exceptions for death or disability, be an employee of Oncocyte (or of a parent or subsidiary of Oncocyte, as defined in Section 424(e) and (f) of the Code, or a corporation, or parent or subsidiary thereof, issuing or assuming the option in a merger or other corporate reorganization transaction to which Section 424(a) of the Code applies) at all times within the period beginning on the date of the grant of the option and ending on a date within three months before the date of exercise. In the event of the death of the participant, the holding periods will not apply to a disposition of the option or option shares by the participant's estate or by persons receiving the option or shares under the participant's will or by intestate succession.

If a participant disposes of stock acquired pursuant to the exercise of an incentive stock option before the expiration of the holding period requirements set forth above, the participant will realize, at the time of the disposition, ordinary income to the extent the fair market value of our common stock on the date the shares were purchased exceeded the purchase price. The difference between the fair market value of our common stock on the date the shares were purchased and the amount realized on disposition is treated as long-term or short-term capital gain or loss, depending on the participant's holding period of the shares of our common stock. The amount treated as ordinary income may be subject to the income tax withholding requirements of the Code and FICA withholding requirements. The participant will be required to reimburse us, either directly or through payroll deduction, for all withholding taxes that we are required to pay on behalf of the participant. At the time of the disposition, we will be allowed a corresponding business expense deduction under Section 162 of the Code to the extent of the amount of the participant's ordinary income. We may adopt procedures to assist us in identifying such deductions, and may require a participant to notify us of his or her intention to dispose of any such shares.

Regardless of whether a participant satisfies the requisite holding period for his or her option and shares, the participant may be subject to the alternative minimum tax with respect to the amount by which the fair market value of our common stock acquired exceeded the exercise price of the option on the date of exercise.

Other Options

The Incentive Plan also permits us to grant options that do not qualify as incentive stock options. These “non-qualified” stock options may be granted to employees or non-employees, such as persons performing consulting or professional services for us. An Incentive Plan participant who receives a non-qualified option will not be taxed at the time of receipt of the option, provided that the option does not have an ascertainable value or an exercise price below fair market value of our common stock on the date of grant, but the participant will be taxed at the time the option is exercised.

The amount of taxable income that will be earned upon exercise of a non-qualified option will be the difference between the fair market value of our common stock on the date of the exercise and the exercise price of the option. We will be allowed a business expense deduction to the extent of the amount of the participant’s taxable income recognized upon the exercise of a non-qualified option. Because the option holder is subject to tax immediately upon exercise of the option, there are no applicable holding periods for the stock. The option holder’s tax basis in our common stock purchased through the exercise of a non-qualified option will be equal to the exercise price paid for the stock plus the amount of taxable gain recognized upon the exercise of the option. The option holder may be subject to additional tax on sale of the stock if the price realized exceeds his or her tax basis.

SARs; Restricted Stock; and RSUs

A recipient of an SAR will not recognize taxable income upon the grant of the SAR. The recipient of the SAR will recognize ordinary income upon exercise of the SAR in an amount equal to the difference between the fair market value of the shares and the exercise price on the date of exercise. Any gain or loss recognized upon any later disposition of the shares generally will be a capital gain or loss.

A recipient of a Restricted Stock Award will not have taxable income upon the grant, unless the Restricted Stock is then vested, or unless the recipient elects under Section 83(b) of the Code to be taxed at the time of grant. Otherwise, upon vesting of the shares, the recipient will recognize ordinary income equal to the fair market value of the shares at the time of vesting less the amount paid for such shares, if any. Any gain or loss recognized upon any later disposition of the shares generally will be a capital gain or loss.

A recipient of an RSU does not recognize taxable income when the Award is granted. When a vested RSU (and dividend equivalents, if any) is settled and distributed, the participant will recognize ordinary income equal to the amount of cash or the fair market value of shares received, less the amount paid for the RSU, if any.

Federal Tax Withholding

Any ordinary income realized by a participant upon the granting, vesting, exercise, or conversion of an award under the Incentive Plan, as applicable, is subject to withholding of applicable federal, state, and local income tax and to withholding of the participant’s share of any tax under the Federal Insurance Contribution Act and the Federal Unemployment Tax Act. To satisfy our federal income tax withholding requirements, we will have the right to require, as a condition to delivery of any certificate for shares of our common stock or the registration of the shares in the participant’s name, that the participant remit to us an amount sufficient to satisfy those withholding requirements. Alternatively, we may withhold a portion of the shares (valued at fair market value) that otherwise would be issued to the participant to satisfy all or part of the withholding tax obligations or may, if we consent, accept delivery of shares (that the participant has not acquired from us within six months prior to the date of exercise) with an aggregate fair market value that equals or exceeds the required tax withholding payment. Withholding does not represent an increase in the participant’s total income tax obligation since it is fully credited toward his or her tax liability for the year. Additionally, withholding does not affect the participant’s tax basis in the shares. Compensation income realized and tax withheld will be reflected on Forms W-2 supplied by the Company to employees no later than January 31 of the succeeding year. Deferred compensation that is subject to Section 409A of the Code will be subject to certain federal income tax withholding and reporting requirements.

Tax Consequences to the Company

To the extent that a participant recognizes ordinary income in the circumstances described above, we will be entitled to a corresponding deduction provided that, among other things, the income meets the test of reasonableness, is an ordinary and necessary business expense, is not an “excess parachute payment” within the meaning of Section 280G of the Code, and is not disallowed by the \$1,000,000 limitation on certain executive compensation under Section 162(m) of the Code discussed below. While deductibility of executive compensation for federal income tax purposes is among the factors the Board and Committee considers when structuring executive compensation arrangements, it is not the sole or primary factor considered. The Company retains the flexibility to authorize compensation that may not be deductible if we believe it is in the best interests of the Company.

Million Dollar Deduction Limit and Other Tax Matters

We may not deduct compensation of more than \$1,000,000 that is paid to “covered employees” (as defined in Section 162(m) of the Code), which include (i) an individual (or, in certain circumstances, his or her beneficiaries) who, at any time during the taxable year, is either our principal executive officer or principal financial officer; (ii) an individual who is among our three highest compensated officers for the taxable year (other than an individual who was either our principal executive officer or principal financial officer at any time during the taxable year); or (iii) anyone who was a covered employee for purposes of Section 162(m) of the Code for any tax year beginning on or after January 1, 2017. This limitation on deductions (x) only applies to compensation paid by a publicly-traded corporation (and not compensation paid by non-corporate entities) and (z) may not apply to certain types of compensation, such as qualified performance-based compensation that is payable pursuant to a written, binding contract that was in effect as of November 2, 2017, so long as the contract is not materially modified after that date.

To the extent that compensation is payable pursuant to a prior plan award granted on or before November 2, 2017, and if the Company determines that Section 162(m) of the Code will apply to any such awards, the Company intends that the terms of those awards will not be materially modified and will be constructed so as to constitute qualified performance-based compensation and, as such, will be exempt from the \$1,000,000 limitation on deductible compensation.

If an individual’s rights under the Incentive Plan are accelerated as a result of a change in control and the individual is a “disqualified individual” under Section 280G of the Code, then the value of any such accelerated rights received by such individual may be included in determining whether or not such individual has received an “excess parachute payment” under Section 280G of the Code, which could result in (i) the imposition of a 20% federal excise tax (in addition to federal income tax) payable by the individual on the value of such accelerated rights, and (ii) the loss by us of a corresponding compensation deduction on such amounts.

Employment Benefits Plans

401(k) Plan

The Company has a defined contribution retirement plan in which all employees are eligible to participate. This plan is intended to qualify under Section 401(k) of the Code so that contributions by employees and by the Company to the plan and income earned on plan contributions are not taxable to employees until withdrawn or distributed from the plan, and so that contributions, including employee salary deferral contributions, will be deductible by the Company when made. The Company currently provides contributions under this plan based on the employee’s compensation, subject to statutory limits.

Director Compensation Program

Directors and members of committees of our Board who are salaried employees of Oncocyte are entitled to receive compensation as employees but are not compensated for serving as directors or attending meetings of our Board or committees of our Board. All directors are entitled to reimbursements for their out-of-pocket expenses incurred in attending meetings of our Board or committees of our Board.

In 2024, non-employee directors, other than the Chairman of our Board, received an annual fee of \$77,177 in cash for their service on our Board for the full year. Our Chairman received an annual cash fee of \$87,177 for his service as Chairman of the Board and for his service on our Board. In addition to cash fees, non-employee directors received options to purchase 30,000 shares of common stock under the Incentive Plan and no restricted stock units under the Incentive Plan. Our Chairman received options to purchase an additional 50,000 shares of common stock under the Incentive Plan and no additional restricted stock units under the Incentive Plan.

Fees earned or paid in cash are paid in quarterly installments, and the stock options and restricted stock units will vest one year from the date of grant, subject to the non-employee director’s continued service as a director of Oncocyte or a subsidiary from the date of grant until the vesting date or, if earlier, until the next annual meeting of shareholders. The options will expire if not exercised ten years from the date of grant.

The following table summarizes certain information concerning the compensation paid during the past fiscal year to each of the persons who served as directors during the year ended December 31, 2024, and who were not our employees on the date the compensation was earned.

Name	Fees Earned or Paid in Cash	Stock Awards	Option Awards ⁽¹⁾	Non-Equity Incentive Plan Compensation	Nonqualified Deferred Compensation Earnings	All Other Compensation	Total
Andrew Arno	\$ 87,177	\$ —	\$ 120,789	\$ —	\$ —	\$ —	\$ 207,966
Alfred D. Kingsley ⁽²⁾	\$ 18,375	\$ —	\$ —	\$ —	\$ —	\$ —	\$ 18,375
Andrew J. Last	\$ 77,177	\$ —	\$ 74,187	\$ —	\$ —	\$ —	\$ 151,364
Louis E. Silverman	\$ 77,177	\$ —	\$ 74,187	\$ —	\$ —	\$ —	\$ 151,364

- (1) Equity awards granted will vest and become exercisable one year from the date of grant, subject to the non-employee director's continued service as a director of Oncocyte or a subsidiary from the date of grant until the vesting date or, if earlier, until the next annual meeting of shareholders, but must be reported here at the aggregate grant date fair value, as if all options were fully vested and exercisable at the date of grant. Values are computed in accordance with FASB Accounting Standards Codification (ASC) Topic 718, *Compensation - Stock Compensation*. We used the Black-Scholes Pricing Model to compute option fair values based on applicable exercise and stock prices, an expected option term, volatility assumptions, and risk-free interest rates.
- (2) Mr. Kingsley no longer serves on the Board as of April 25, 2024, because he unexpectedly passed away.

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

Equity Compensation Plan Information

The following table sets forth additional information, as of December 31, 2024, about our common stock that may be issued upon the exercise of options and other rights under all of our compensation plans and agreements (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⁾
Equity compensation plans approved by security holders	246	\$ 40.77	1,026
Equity compensation plans not approved by security holders	—	\$ —	—
Total	246	\$ 40.77	1,026

- (1) Includes both the Incentive Plan and our expired Employee Stock Option Plan. The Option Plan expired in 2020 and no further equity awards may be granted under the Option Plan.
- (2) All shares remaining available for future issuance are under the Incentive Plan.

Security Ownership of Certain Beneficial Owners and Management

The following table sets forth information regarding beneficial ownership of our common stock as of March 17, 2025 (i) by each person who is known by us to beneficially own more than 5% of our common stock; (ii) by each of our named executive officers and directors; and (iii) by all of our Named Executive Officers and directors as a group. Unless otherwise indicated in the following table, the address for each person named in the table is: 1185 Avenue of the Americas, New York, NY 10036.

Name and Address of Beneficial Owner	Amount and Nature of Beneficial Ownership ⁽¹⁾	Percent of Class ⁽²⁾
5% Stockholders		
Broadwood Partners, L.P. ⁽³⁾	11,560,350	40.21 %

PATRICK W SMITH TTEE THE SMITH IRREVOCABLE TRUST U/A DTD 05/01/2015 ⁽⁴⁾	3,258,485	11.39	%
AWM Investment Company, Inc. ⁽⁵⁾	2,860,314	9.99	%
Bio-Rad Laboratories, Inc. ⁽⁶⁾	2,764,078	9.66	%
Named Executive Officers and Directors			
Joshua Riggs ⁽⁷⁾	47,554	*	
Andrea James ⁽⁸⁾	151,231	*	
James Liu ⁽⁹⁾	8,245	*	
Ekkehard Schütz ⁽¹⁰⁾	51,928	*	
Andrew Arno ⁽¹¹⁾	118,589	*	
Andrew J. Last ⁽¹²⁾	23,685	*	
Louis E. Silverman ⁽¹³⁾	8,588	*	
All directors and executive officers as a group	409,819	1.43	%

* Less than one percent.

- (1) Beneficial ownership is determined in accordance with the rules of the SEC and generally includes voting or investment power with respect to securities. Each of the beneficial owners listed above has direct ownership of and sole voting power and investment power with respect to the shares set forth in the above table.
- (2) A total of 28,599,285 shares of our Common Stock are considered to be outstanding pursuant to SEC Rule 13d-3(d)(1) as of March 17, 2025.
- (3) Based on information available to the Company and the Schedule 13D/A filed jointly with the SEC on February 10, 2025, by Broadwood Partners, L.P. ("Broadwood"), Broadwood Capital, Inc. ("Broadwood Capital") and Neal C. Bradsher. Represents (i) 11,410,100 shares of common stock directly owned by Broadwood, (ii) warrants to purchase 150,093 shares of common stock directly owned by Broadwood, (iii) 157 shares of common stock directly owned by Neal C. Bradsher.
- (4) Based on information available to the Company, the Schedule 13G/A filed with the SEC on December 27, 2024, jointly by PATRICK W SMITH TTEE THE SMITH IRREVOCABLE TRUST U/A DTD 05/01/2015 (the "Trust") and Patrick W. Smith and the Form 4 filed by Mr. Smith on February 11, 2025. Represents 3,258,485 shares of common stock held by the Trust. Mr. Smith, the sole trustee of the Trust, may be deemed to beneficially own the shares of common stock owned by the Trust. The address for the Trust and Mr. Smith is 11445 E. Via Linda Suite 2-411, Scottsdale, AZ 85259.
- (5) Based on information available to the Company and the Schedule 13G/A filed with the SEC on February 14, 2025, by AWM Investment Company, Inc. ("AWM"). Represents (i) 497,249 shares of common stock held by Special Situations Cayman Fund, L.P. ("Cayman"), (ii) 77,434 shares of common stock issuable upon exercise of certain pre-funded warrants (subject to a 9.99% beneficial ownership limitation) held by Cayman, (iii) 475,030 shares of common stock issuable upon exercise of certain pre-funded warrants (subject to a 9.99% beneficial ownership limitation) held by Cayman, (iv) 32,833 shares of common stock issuable upon exercise of certain warrants (subject to a 9.99% beneficial ownership limitation) held by Cayman, (v) 1,744,288 shares of common stock held by Special Situations Fund III QP, L.P. ("SSFQP"), (vi) 265,454 shares of common stock issuable upon exercise of certain pre-funded warrants (subject to a 9.99% beneficial ownership limitation) held by SSFQP, (vii) 1,717,774 shares of common stock issuable upon exercise of certain pre-funded warrants (subject to a 9.99% beneficial ownership limitation) held by SSFQP, (viii) 117,261 shares of common stock issuable upon exercise of certain warrants (subject to a 9.99% beneficial ownership limitation) held by SSFQP, (ix) 195,431 shares of common stock held by Special Situations Private Equity Fund, L.P. ("SSPE"), (x) 18,762 shares of common stock issuable upon exercise of certain warrants (subject to a 9.99% beneficial ownership limitation) held by Special Situations Private Equity Fund, L.P. ("SSPE"), (xi) 292,374 shares of common stock issuable upon exercise of certain pre-funded warrants (subject to a 9.99% beneficial ownership limitation) held by SSPE, (xii) 390,862 shares of common stock held by Special Situations Life Sciences Fund, L.P. ("SSLS"), (xiii) 18,762 shares of common stock issuable upon exercise of certain warrants (subject to a 9.99% beneficial ownership limitation) held by SSLS, and (xiv) 584,748 shares of common stock issuable upon exercise of certain pre-funded warrants (subject to a 9.99% beneficial ownership limitation) held by SSLS.

AWM is the investment adviser to Cayman, SSFQP, SSPE and SSLs (collectively, the “Funds”) and has sole voting and dispositive power over the securities held by the Funds. David Greenhouse and Adam Stettner are the principal owners of AWM. Through their control of AWM, Messrs. Greenhouse and Stettner share voting and investment control over the portfolio securities of each of Cayman and SSFQP. Messrs. Greenhouse and Stettner disclaim any beneficial ownership of the reported shares other than to the extent of any pecuniary interest in each of them may have therein. The principal place of business for each of AWM, Cayman, SSFQP, SSPE, and SSLs is 527 Madison Avenue, Suite 2600, New York, NY 10022.

- (6) Based on information available to the Company and the Schedule 13G/A filed with the SEC on March 4, 2025, by Bio-Rad Laboratories, Inc. (“Bio-Rad”). Represents 2,764,078 shares of common stock held by Bio-Rad.
- The shares of common stock are directly owned by Bio-Rad Laboratories, Inc. (“Bio-Rad”). The address of the principal business office of Bio-Rad is 1000 Alfred Nobel Dr., Hercules, CA 94547.
- (7) Amount consists of (i) 3,505 shares of common stock and (ii) 44,049 shares of common stock issuable upon exercise of certain stock options held by Mr. Riggs that were vested as of March 17, 2025 or will vest within 60 days thereafter.
- (8) Amount consists of 151,231 shares of common stock held by Ms. James.
- (9) Amount consists of 8,245 shares of common stock issuable upon exercise of certain stock options held by Mr. Liu that were vested as of March 17, 2025 or will vest within 60 days thereafter.
- (10) Amount consists of (i) 20,647 shares of common stock and (ii) 31,281 shares of common stock issuable upon exercise of certain stock options held by Mr. Schütz that were vested as of March 17, 2025 or will vest within 60 days thereafter.
- (11) Amount consists of (i) 81,554 shares of common stock held by Mr. Arno, (ii) 7,804 shares of common stock held by JBA Investments LLC (“JBA”), (iii) 7,804 shares of common stock held by MJA Investments LLC (“MJA”), and (iv) 21,426 shares of common stock issuable upon exercise of certain stock options held by Mr. Arno that were vested as of March 17, 2025 or will vest within 60 days thereafter.
- Mr. Arno is the Manager of each of JBA and MJA and has shared voting and dispositive power over the securities held by JBA and MJA.
- (12) Amount consists of (i) 4,509 shares of common stock and (ii) 19,176 shares of common stock issuable upon exercise of certain stock options held by Mr. Last that were vested as of March 17, 2025 or will vest within 60 days thereafter.
- (13) Amount consists of (i) 1,564 shares of common stock and (ii) 7,024 shares of common stock issuable upon exercise of certain stock options held by Mr. Silverman that were vested as of March 17, 2025 or will vest within 60 days thereafter.

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

Transactions with Related Persons

SEC rules require us to disclose any transaction or currently proposed transaction in which we are a participant and in which any related person has or will have a direct or indirect material interest involving an amount that exceeds the lesser of \$120,000 or one percent (1%) of the average of the Company’s total assets as of the end of last two completed fiscal years. A related person is any executive officer, director, nominee for director, or holder of 5% or more of the Company’s common stock, or an immediate family member of any of those persons.

Our Board has adopted a Related Person Transaction Policy to assist us in identifying, reviewing and approving or rejecting related person transactions. Under the policy, any related person transaction proposed to be entered by the Company must be reviewed, approved or ratified by the Nominating/Corporate Governance Committee of the Board, as described in the policy. The related person transaction may be approved or ratified only if the Nominating/Corporate Governance Committee determines that, under all of the circumstances, the transaction is in, or is not in conflict with, the best interests of the Company.

Certain Sales of Equity Securities

On April 3, 2023, the Company entered into that certain securities purchase agreement, by and among the Company and certain accredited investors, including Broadwood Partners, L.P. (“Broadwood”), a beneficial holder of 5% or more of the Company’s outstanding shares of common stock, certain funds and accounts managed by PVI (collectively, “Pura Vida”), a beneficial holder of 5% or more of the Company’s outstanding shares of common stock, and entities affiliated with AWM Investment Company, Inc. (collectively, “AWM”), a beneficial holder of 5% or more of the Company’s outstanding shares of common stock, and certain individuals, including our Chairman, Andrew Arno and former director John Peter Gutfreund (and certain of their affiliated parties) pursuant to which, the Company issued and sold in a registered direct offering an aggregate of 2,274,709 shares of common stock at an offering price of: (i) \$6.03 to investors who were not considered to be “insiders” of the Company pursuant to the Nasdaq Listing Rules (“Insiders”), and (ii) \$7.08 to Insiders (the “Registered Direct Offering”). Pursuant to the Registered Direct Offering, the Company sold an aggregate of (i) 1,341,381 shares of common stock to Broadwood at a price per share equal to \$6.03, for a total purchase price equal to \$8,093,361.84, (ii) 33,150 shares of common stock to Pura Vida at a price per share equal to \$6.03, for a total purchase price equal to \$200,013.84, (iv) 472,354 shares of common stock to AWM a price per share equal to \$6.03, for a total purchase price equal to \$2,849,999.92, (v) 21,162 shares of common stock to Mr. Arno and his affiliated parties at a price per share equal to \$7.08, for a total purchase price equal to \$150,000.51, and (vi) 85,250 shares of common stock to Mr. Gutfreund at a price per share equal to \$7.08, for a total purchase price equal to \$604,252.00.

On April 5, 2023, the Company used a portion of the net proceeds from the Registered Direct Offering to redeem 588.23529 shares of Series A Preferred Stock then-held by Mr. Gutfreund for a total purchase price equal to \$618,672.34.

On April 11, 2024, the Company entered into a securities purchase agreement, by and among the Company and certain investors, including Broadwood, entities affiliated with AWM, Bio-Rad Laboratories, Inc. (“Bio-Rad”), which our director, Andrew Last is the Executive Vice President and Chief Operating Officer of Bio-Rad, and certain individuals, including our Chairman Andrew Arno, pursuant to which, the Company issued and sold in a private placement (the “April 2024 Private Placement”) an aggregate of 5,076,900 shares of common stock and pre-funded warrants with an exercise price of \$0.0001 per share, to purchase up to 342,888 shares of common stock (“Pre-Funded Warrants”). The purchase price for one share of common stock was \$2.9164 and the purchase price for one Pre-Funded Warrant was \$2.9163. Certain Insiders subscribed for 42,373 shares of common stock sold in the April 2024 Private Placement, at a purchase price equal to \$2.95 per share of common stock. Pursuant to the April 2024 Private Placement, the Company sold an aggregate of (i) 2,420,000 shares of common stock to Broadwood at a price per share equal to \$2.9164, for a total purchase price equal to \$7,057,688, (ii) 342,889 shares of common stock at a price per share equal to \$2.9164 and 342,889 Pre-Funded Warrants to entities affiliated with AWM for a total purchase price equal to \$2,000,000.04, (iii) 1,200,109 shares of common stock to Bio-Rad at a price per share equal to \$2.9164, for a total purchase price equal to \$3,499,997.89, (iv) 33,898 shares of common stock to Mr. Arno at a price per share equal to \$2.95, for a total purchase price equal to \$100,000.00.

On October 2, 2024, the Company entered into a securities purchase agreement, by and among the Company and certain investors including: Unterberg Legacy Capital, LLC (“Unterberg”), which Andy Arno, a director of the Company, is beneficiary of an individual retirement account that is a managing member of Unterberg; Broadwood; Bio-Rad; AWM; Pura Vida; a certain affiliate of Patrick W. Smith, a 5% beneficial owner of the Company’s outstanding shares of common stock; Ekkehard Schuetz, the Company’s Chief Science Officer; and Andrea James, the Company’s Chief Financial Officer, which provided for the issuance and sale in a private placement (the “October 2024 Private Placement”) of an aggregate of 3,461,138 shares of common stock a purchase price of \$2.948 or \$2.97 to certain Insiders. The gross proceeds to the Company from the October 2024 Private Placement were approximately \$10.2 million, before deducting placement agent fees and expenses and estimated offering expenses payable by the Company. Pursuant to the October 2024 Private Placement, the Company issued and sold an aggregate of (i) 1,315,339 shares of common stock to Broadwood at a price per share equal to \$2.948, for a total purchase price equal to \$3,877,619.38, (ii) 310,83 shares of common stock to Bio-Rad at a price per share equal to \$2.948, for a total purchase price equal to \$916,342.78, (iii) 275,000 shares of common stock to AWM at a price per share equal to \$2.948, for a total purchase price equal to \$810,700.00, (iv) 169,606 shares of common stock to Pura Vida at a price per share equal to \$2.948, for a total purchase price equal to \$500,000.00, (v) 3,367 shares of common stock to Mr. Schuetz, at a price per share equal to \$2.97, for a total purchase price equal to \$10,000.00, (vi) 33,670 shares of common stock to Ms. James at a price per share equal to \$2.97, for a total purchase price equal to \$100,000.00, (vii) 678,426 shares of common stock to Mr. Smith at a price per share equal to \$2.948 for a total purchase price equal to \$2,000,000.00, and (viii) 33,921 shares of common stock to Unterberg at a price per share equal to \$2.948 for a total purchase price equal to \$100,000.00.

On February 7, 2025, the Company entered into a securities purchase agreement (the “PIPE Purchase Agreement”), by and among the Company and certain investors including, Broadwood, Unterberg, Bio-Rad, AWM, an affiliate of Patrick A. Smith, Pura Vida, Andrea James and Ekkehard Schuetz, pursuant to which, the Company issued and sold in a private placement (the “February 2025 Private Placement”) an aggregate of 7,536,708 shares of common stock and pre-funded warrants with an exercise price of \$0.0001 per share, to purchase up to 3,069,925 shares of common stock (“Pre-Funded Warrants”). The purchase price for one share of common stock was \$2.05 and the purchase price for one Pre-Funded Warrant was \$2.0499. Pursuant to the February 2025 Private Placement, the Company sold an aggregate of (i) 4,505,488 shares of common stock to Broadwood, for a total purchase price equal to \$9,236,250, (ii) 922,758 shares of common stock to Bio-Rad, for a total purchase price equal to \$1,891,654, (iii) Pre-Funded Warrants to purchase 3,069,925 shares of common stock to AWM, for a total purchase price equal to \$6,293,346, (iv) 1,077,600 shares of common stock to Mr. Smith, for a total purchase price equal to \$2,209,080, (v) 292,683 shares of common stock to Pura Vida for a total purchase price equal to \$600,000, (vi) 97,561 shares of common stock to Ms. James, for a total purchase price equal to \$200,000, (vii) 12,195 shares of common stock to Mr. Schuetz, for a total purchase price equal to \$25,000, and (viii) 36,585 shares of common stock to Unterberg, for a total purchase price equal to \$75,000.

Concurrently with the execution and delivery of the PIPE Purchase Agreement, on February 7, 2025, the Company entered into a securities purchase agreement, by and among the Company and certain investors including Broadwood, Bio-Rad, AWM and an affiliate of Patrick A. Smith, pursuant to which, the Company issued and sold in a registered direct offering (the “February 2025 Registered Direct Offering”) an aggregate of 3,609,755 shares of common stock at a price per share equal to \$2.05. Pursuant to the February 2025 Registered Direct Offering, the Company issued and sold an aggregate of (i) 660,207 shares of common stock to Broadwood, for a total purchase price equal to \$1,353,424, (ii) 330,376 shares of common stock to Bio-Rad, for a total purchase price equal to \$667,271, (iii) 2,052,026 shares of common stock to AWM, for a total purchase price equal to \$4,206,653, and (iv) 385,814 shares of common stock to an affiliate of Mr. Smith, for a total purchase price equal to \$790,919.

Other Transactions with Bio-Rad Laboratories, Inc.

During the years ended December 31, 2023 and December 31, 2024, we purchased \$581,000 and \$538,000 in laboratory equipment, respectively, and incurred \$375,000 and \$413,000 in laboratory related expenses from Bio-Rad, respectively. During 2024, the Company also made finance lease payments of \$217,000 under four laboratory equipment leases from Bio-Rad with a remaining financing lease liability of \$796,000 as of December 31, 2024. As of December 31, 2024, Oncocyte’s accounts payable due to Bio-Rad was \$638,000. One of our directors, Andrew Last, served as the Executive Vice President and Chief Operating Officer of Bio-Rad before retiring on September 6, 2024.

On April 5, 2024, the Company entered into that certain Collaboration Agreement with Bio-Rad to collaborate in the development and the commercialization of research use only and in vitro diagnostics kitted transplant products using Bio-Rad’s ddPCR instruments and reagents (the “Collaboration Agreement”). Pursuant to the Collaboration Agreement, Bio-Rad agreed to purchase in the Company’s next subsequent private placement of its securities, shares of the Company’s common stock equal to 9.99% of the total number of shares of common stock issued and outstanding immediately after the closing of such investment, provided that the total purchase price would not exceed \$3,500,000 unless Bio-Rad chose to exceed such limit (the “Bio-Rad Investment”). In satisfaction of such Bio-Rad Investment, Bio-Rad purchased shares of the Company’s common stock pursuant to the October 2024 Private Placement, as further described herein. In addition, pursuant to the Collaboration Agreement, the Company agreed to pay to Bio-Rad a single digit royalty payment based on a percentage of the Company’s net sales under the Collaboration Agreement, and Bio-Rad has an option to have the exclusive right to promote, market and sell certain kits worldwide subject to certain conditions. If such options are exercised, subject to certain conditions as set forth in the Collaboration Agreement, Bio-Rad has agreed to purchase additional shares of the Company’s common stock, at the then-current market price per share, up to a specified maximum aggregate purchase price. Dr. Last, the Company’s director, recused himself from all Board discussions related to the Collaboration Agreement and the Bio-Rad Investment.

Director Independence

See “Directors, Executive Officers and Corporate Governance - Director Independence” and “Directors, Executive Officers and Corporate Governance - Board Committees” above.

Item 14. Principal Accountant Fees and Services.

Independent Registered Public Accounting Firm

On October 10, 2023, the Audit Committee dismissed WithumSmith+Brown, PC (“Withum”) as the Company’s independent registered public accounting firm. The Audit Committee, effective as of October 10, 2023, appointed Marcum LLP (Auditor ID #688) (“Marcum”) as the Company’s independent registered public accounting firm for the Company’s fiscal year ended December 31, 2023.

Audit and Non-Audit Fees

The Company engaged Withum as its independent auditors from July 19, 2021, to October 10, 2023. The Company engaged Marcum from October 8, 2023, to present. The following table presents fees for professional audit services rendered by Withum and Marcum, as applicable during the fiscal years ended December 31, 2024 and 2023:

	2024		2023	
Audit fees ⁽¹⁾	\$	159,650	\$	175,000
Audit related fees ⁽²⁾		231,432		-
Tax fees ⁽³⁾		90,713		138,083
All other fees ⁽⁴⁾		-		-
Total	\$	481,795	\$	313,083

- (1) Audit Fees consist of fees billed by Marcum for professional services rendered for the audit of our annual financial statements included in our Annual Report on Form 10-K, and review of the interim financial statements included in our Quarterly Reports on Form 10-Q, as applicable, and services that are normally provided by our independent registered public accountants in connection with statutory and regulatory filings or engagements.
- (2) Audit-Related Fees consist of fees billed by Marcum for assurance and related services that are reasonably related to the performance of the audit or review of our consolidated financial statements and are not reported under "Audit Fees." This category includes fees related to non-routine SEC filings.
- (3) Tax Fees consist of fees for professional services billed by Moss Adams, LLP rendered in connection with the preparation of consolidated and subsidiary federal and state income tax returns, and tax related provision work, research, compliance and consulting.
- (4) There were no other fees for the years ended December 31, 2024 and 2023.

Policy on Audit Committee Pre-Approval of Audit and Permissible Non-Audit Services of Independent Public Accountant

Consistent with SEC policies regarding auditor independence, the Audit Committee has responsibility for appointing, setting compensation and overseeing the work of our independent registered public accounting firm. In recognition of this responsibility, the Audit Committee has established a policy to pre-approve all audit and permissible non-audit services provided by our independent registered public accounting firm. Other than de minimis services incidental to audit services, non-audit services shall generally be limited to tax services such as advice and planning and financial due diligence services. All fees for such non-audit services must be approved by the Audit Committee, except to the extent otherwise permitted by applicable SEC regulations. The Audit Committee may delegate to one or more designated members of the Audit Committee the authority to grant pre-approvals, provided such approvals are presented to the Audit Committee at a subsequent meeting. During 2024 and 2023, all of the fees paid to Marcum and Withum, as applicable, were approved by the Audit Committee.

PART IV

Item 15. Exhibits and Financial Statement Schedules.

(a)(1) Financial Statements.

The following consolidated financial statements of Oncocyte are filed as part of this Report:

	Page
<u>Report of Independent Registered Public Accounting Firm</u> (PCAOB ID 688)	F-1
<u>Consolidated Balance Sheets</u>	F-3
<u>Consolidated Statements of Operations</u>	F-4
<u>Consolidated Statements of Comprehensive Loss</u>	F-5
<u>Consolidated Statements of Series A Redeemable Convertible Preferred Stock and Shareholders' Equity</u>	F-6
<u>Consolidated Statements of Cash Flows</u>	F-7
<u>Notes to Consolidated Financial Statements</u>	F-8

(a)(2) Financial Statement Schedules.

Financial statement schedules are omitted because they are not applicable or the required information is shown in the Financial Statements or the Notes thereto.

(a)(3) Exhibits.

Refer to Item 15(b) below.

(b) Exhibits. The following exhibits are either filed herewith or incorporated herein by reference:

Exhibit Numbers	Exhibit Description
2.1	<u>Agreement and Plan of Merger, dated January 10, 2020, by and 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)</u>
2.2	<u>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)</u>
2.3	<u>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)</u>
2.4	<u>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)</u>
2.5	<u>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)</u>
2.6	<u>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)</u>
3.1	<u>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)</u>

- 3.2 [Certificate of Amendment of Articles of Incorporation of Oncocyte Corporation, as filed with the Secretary of State of the State of California on July 24, 2023 \(Incorporated by reference to Oncocyte Corporation's Current Report on Form 8-K filed with the Securities and Exchange Commission on July 24, 2023\).](#)
- 3.3 [Certificate of Determination of Preferences, Rights and Limitations of Series A Convertible Preferred Stock \(Incorporated by reference to Oncocyte Corporation's Current Report on Form 8-K filed with the Securities and Exchange Commission on April 13, 2022\).](#)
- 3.4 [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 [Silicon Valley Bank Warrant \(Incorporated by reference to Oncocyte Corporation's Annual Report on Form 10-K filed with the Securities and Exchange Commission on February 27, 2017\).](#)
- 4.3 [Warrant to Purchase Common Stock, dated October 17, 2019, between Oncocyte Corporation and Silicon Valley Bank \(Incorporated by Reference to Oncocyte Corporation's Current Report on Form 8-K filed with the Securities and Exchange Commission on October 21, 2019\).](#)
- 4.4 [Form of Common Stock Warrant \(Incorporated by reference to Oncocyte Corporation's Current Report on Form 8-K filed with the Securities and Exchange Commission on April 19, 2022\).](#)
- 4.5 [Form of Pre-Funded Warrant \(Incorporated by reference to Oncocyte Corporation's Current Report on Form 8-K filed with the Securities and Exchange Commission on April 12, 2024\).](#)
- 4.6 [Form of Pre-Funded Warrant \(Incorporated by reference to Oncocyte Corporation's Current Report on Form 8-K filed with the Securities and Exchange Commission on February 10, 2025\).](#)
- 4.7* [Description of Securities](#)
- 10.1# [2010 Stock Option Plan \(Incorporated by reference to Oncocyte Corporation's Form 10 12\(g\) filed with the Securities and Exchange Commission on October 7, 2015\).](#)
- 10.2# [2017 Amendment to 2010 Stock Option Plan \(Incorporated by reference to Registration Statement on Form S-8, File Number 333-219109 filed with the Securities and Exchange Commission on June 30, 2017\).](#)
- 10.3# [Form of 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\).](#)
- 10.4# [Form of 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\).](#)
- 10.5# [Amended and Restated 2018 Equity Incentive Plan \(Incorporated by reference to Oncocyte Corporation's Current Report on Form 8-K filed with the Securities and Exchange Commission on October 15, 2024\).](#)
- 10.6# [Form of 2018 Equity Incentive Plan Employee Stock Option Agreement \(Incorporated by reference to Oncocyte Corporation's Current Report on Form 8-K filed with the Securities and Exchange Commission on August 29, 2018\).](#)
- 10.7# [Form of 2018 Equity Incentive Plan Non-Employee Director Stock Option Agreement \(Incorporated by reference to Oncocyte Corporation's Current Report on Form 8-K filed with the Securities and Exchange Commission on August 29, 2018\).](#)
- 10.8# [Form of 2018 Equity Incentive Plan Restricted Stock Unit Agreement \(Incorporated by reference to Oncocyte Corporation's Current Report on Form 8-K filed with the Securities and Exchange Commission on August 29, 2018\).](#)

- 10.9# [Oncocyte Corporation Change in Control and Severance Plan \(Incorporated by Reference to Annual Report on Form 10-K Filed with the Securities and Exchange Commission on March 26, 2020\)](#)
- 10.10# [Form of Change in Control and Severance Agreement \(Incorporated by Reference to Annual Report on Form 10-K Filed with the Securities and Exchange Commission on March 26, 2020\)](#)
- 10.11# [Amended and Restated Employment Agreement, dated June 6, 2023, by and between Oncocyte Corporation and Joshua Riggs \(Incorporated by reference to Oncocyte Corporation's Current Report on Form 8-K filed with the Securities and Exchange Commission on June 9, 2023\)](#)
- 10.12# [Amendment to Amended and Restated Employment Agreement, dated July 13, 2023, by and between Oncocyte Corporation and Joshua Riggs \(Incorporated by reference to Oncocyte Corporation's Current Report on Form 8-K filed with the Securities and Exchange Commission on July 14, 2023\)](#)
- 10.13 [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\)](#)
- 10.14 [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\)](#)
- 10.15 [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\)](#)
- 10.16 [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\)](#)
- 10.17 [Loan and Security Agreement, dated February 21, 2017, by and between Oncocyte Corporation and Silicon Valley Bank \(Incorporated by reference to Oncocyte Corporation's Annual Report on Form 10-K filed with the Securities and Exchange Commission on February 27, 2017\)](#)
- 10.18+ [First Amendment to Loan and Security Agreement, dated October 17, 2019, between Oncocyte Corporation and Silicon Valley Bank \(Incorporated by reference to Oncocyte Corporation's Current Report on Form 8-K filed with the Securities and Exchange Commission on October 21, 2019\)](#)
- 10.19 [Loan Deferral Agreement, dated April 2, 2020, by and between Oncocyte Corporation and Silicon Valley Bank \(Incorporated by Reference to Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission on May 12, 2020\)](#)
- 10.20 [Office Lease Agreement, dated December 23, 2019, as amended between Oncocyte Corporation and Cushing Ventures, LLC \(Incorporated by reference to Oncocyte Corporation's Current Report on Form 8-K filed with the Securities and Exchange Commission on December 27, 2019\)](#)
- 10.21 [Amendment to and Waiver of Right to Extend Original Lease, dated as of December 26, 2024, effective as of January 2, 2025, by and among Oncocyte Corporation, Induce Biologics USA, Inc. and Cushing Ventures, LLC \(Incorporated by reference to Oncocyte Corporation's Current Report on Form 8-K filed with the Securities and Exchange Commission on January 8, 2025\)](#)
- 10.22 [Sublease Agreement, dated August 8, 2023, by and between Oncocyte Corporation and Induce Biologics USA, Inc. \(Incorporated by reference to Oncocyte Corporation's Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission on November 9, 2023\)](#)
- 10.23 [Lease Agreement for Suite 103, dated January 1, 2024, between Insight Genetics, Inc. and MPC Holdings, LLC \(Incorporated by reference to Oncocyte Corporation's Annual Report on Form 10-K filed with the Securities and Exchange Commission on April 16, 2024\)](#)
- 10.24 [Lease Agreement for Suite 410, dated January 1, 2024, between Insight Genetics, Inc. and MPC Holdings, LLC \(Incorporated by reference to Oncocyte Corporation's Annual Report on Form 10-K filed with the Securities and Exchange Commission on April 16, 2024\)](#)

- 10.25 [Lease Agreement for Suite 510, dated January 1, 2024, between Insight Genetics, Inc. and MPC Holdings, LLC \(Incorporated by reference to Oncocyte Corporation's Annual Report on Form 10-K filed with the Securities and Exchange Commission on April 16, 2024\)](#)
- 10.26 [Form of Subscription Agreement between Oncocyte Corporation and Certain Investors \(Incorporated by Reference to Current Report on Form 8-K filed with the Securities and Exchange Commission on April 28, 2020\)](#)
- 10.27 [Subscription Agreements, dated January 20, 2021, between Oncocyte Corporation and the Investors Named Therein \(Incorporated by Reference to Current Report on Form 8-K filed with the Securities and Exchange Commission on January 21, 2021\)](#)
- 10.28 [Form of Securities Purchase Agreement dated April 13, 2022, by and among Oncocyte Corporation and certain investors \(Incorporated by reference to Oncocyte Corporation's Current Report on Form 8-K filed with the Securities and Exchange Commission on April 13, 2022\)](#)
- 10.29 [Securities Purchase Agreement, dated April 3, 2023, by and among Oncocyte Corporation and each purchaser identified on the signatures pages thereto \(Incorporated by reference to Oncocyte Corporation's Current Report on Form 8-K filed with the Securities and Exchange Commission on April 6, 2023\)](#)
- 10.30 [Securities Purchase Agreement, dated April 11, 2024, by and among the Company and the investors signatory thereto \(Incorporated by reference to Oncocyte Corporation's Current Report on Form 8-K filed with the Securities and Exchange Commission on April 12, 2024\)](#)
- 10.31 [Registration Rights Agreement, dated April 11, 2024, by and among the Company and the investors signatory thereto \(Incorporated by reference to Oncocyte Corporation's Current Report on Form 8-K filed with the Securities and Exchange Commission on April 12, 2024\)](#)
- 10.32# [Employment Agreement, dated May 20, 2024, by and between Oncocyte Corporation and Ekkehard Schütz \(Incorporated by reference to Oncocyte Corporation's Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission on August 8, 2024\)](#)
- 10.33# [Employment Agreement, dated June 17, 2024, by and between Oncocyte Corporation and Andrea James \(Incorporated by reference to Oncocyte Corporation's Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission on August 8, 2024\)](#)
- 10.34 [Sales Agreement, dated August 9, 2024, by and between the Oncocyte Corporation and Needham & Company, LLC \(Incorporated by reference to Oncocyte Corporation's Current Report on Form 8-K filed with the Securities and Exchange Commission on August 9, 2024\)](#)
- 10.35+ [Securities Purchase Agreement, dated October 2, 2024, by and among the Company and the investors signatory thereto \(Incorporated by reference to Oncocyte Corporation's Current Report on Form 8-K filed with the Securities and Exchange Commission on October 3, 2024\)](#)
- 10.36+ [Registration Rights Agreement, dated October 2, 2024, by and among the Company and the investors signatory thereto \(Incorporated by reference to Oncocyte Corporation's Current Report on Form 8-K filed with the Securities and Exchange Commission on October 3, 2024\)](#)
- 10.37+ [Collaboration Agreement, dated April 5, 2024, between the Company and Bio-Rad Laboratories, Inc. \(Incorporated by reference to Oncocyte Corporation's Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission on May 15, 2024\)](#)
- 10.38+ [Memorandum of Understanding, dated November 8, 2024, between the Company and Bio-Rad Laboratories, Inc. \(Incorporated by reference to Oncocyte Corporation's Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission on November 12, 2024\)](#)
- 10.39+ [Securities Purchase Agreement, dated February 7, 2025, by and among the Company and the investors signatory thereto \(Incorporated by reference to Oncocyte Corporation's Current Report on Form 8-K filed with the Securities and Exchange Commission on February 10, 2025\)](#)

10.40+	<u>Registration Rights Agreement, dated February 7, 2025, by and among the Company and the investors signatory thereto (Incorporated by reference to Oncocyte Corporation's Current Report on Form 8-K filed with the Securities and Exchange Commission on February 10, 2025)</u>
10.41+	<u>Securities Purchase Agreement, dated February 7, 2025, by and among the Company and the investors signatory thereto (Incorporated by reference to Oncocyte Corporation's Current Report on Form 8-K filed with the Securities and Exchange Commission on February 10, 2025)</u>
16.1	<u>Letter of WithumSmith+Brown, PC, dated October 5, 2023 (Incorporated by reference to Oncocyte Corporation's Current Report on Form 8-K filed with the Securities and Exchange Commission on October 5, 2023)</u>
19.1*	<u>Insider Trading Policy</u>
21	<u>Subsidiaries (Incorporated by reference to Oncocyte Corporation's Annual Report on Form 10-K filed with the Securities and Exchange Commission on April 12, 2023)</u>
23.1*	<u>Consent of Marcum LLP</u>
31.1*	<u>Certification of the Principal 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</u>
31.2*	<u>Certification of the Principal 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</u>
32.1**	<u>Certifications pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002</u>
97.1	<u>Oncocyte Corporation Clawback Policy (Incorporated by reference to Oncocyte Corporation's Annual Report on Form 10-K filed with the Securities and Exchange Commission on April 16, 2024)</u>
101.INS	Inline XBRL Instance Document – the instance document does not appear in the Interactive Data File because XBRL tags are embedded within the Inline XBRL document
101.SCH	Inline XBRL Taxonomy Extension Schema With Embedded Linkbase Documents
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

* Filed herewith.

** The certifications attached as Exhibit 32.1 that accompany this Report are not deemed filed with the SEC and are not to be incorporated by reference into any filing of Oncocyte under the Securities Act, or the Exchange Act, whether made before or after the date of this Report, regardless of any general incorporation language contained in any filing.

The referenced exhibit is a management contract, compensatory plan or arrangement.

+ Schedules have been omitted from this filing pursuant to Item 601(b) of Regulation S-K. The Company agrees to furnish supplementally a copy of any omitted schedule to the SEC upon its request; provided, however, that the Company may request confidential treatment pursuant to Rule 24b-2 of the Exchange Act for any schedule so furnished. Certain portions of this exhibit (indicated by “[*]” or “[**]”) have been omitted because they are both (i) not material and (ii) would be competitively harmful if publicly disclosed.

(c) Other financial statement schedules.

Not applicable.

Item 16. Form 10-K Summary.

Not applicable.

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.

ONCOCYTE CORPORATION

Date: March 24, 2025

By: /s/ Joshua Riggs

Joshua Riggs
President and Chief Executive Officer
(Principal Executive Officer)

Date: March 24, 2025

By: /s/ Andrea James

Andrea James
Chief Financial Officer
(Principal Financial 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.

<u>Signature</u>	<u>Title</u>	<u>Date</u>
<u>/s/ Joshua Riggs</u> JOSHUA RIGGS	President and Chief Executive Officer and Director (Principal Executive Officer)	March 24, 2025
<u>/s/ Andrea James</u> ANDREA JAMES	Chief Financial Officer (Principal Financial Officer)	March 24, 2025
<u>/s/ James Liu</u> JAMES LIU	Vice President Accounting, Controller, Treasurer and Principal Accounting Officer (Principal Accounting Officer)	March 24, 2025
<u>/s/ Andrew Arno</u> ANDREW ARNO	Director	March 24, 2025
<u>/s/ Andrew J. Last</u> ANDREW J. LAST	Director	March 24, 2025
<u>/s/ Louis E. Silverman</u> LOUIS E. SILVERMAN	Director	March 24, 2025

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Shareholders and Board of Directors of
Oncocyte Corporation

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Oncocyte Corporation (the “Company”) as of December 31, 2024 and 2023, the related consolidated statements of operations, comprehensive loss, Series A redeemable convertible preferred stock and shareholders’ equity and cash flows for each of the two years in the period ended December 31, 2024, and the related notes (collectively referred to as the “financial statements”). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2024 and 2023, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2024, in conformity with accounting principles generally accepted in the United States of America.

Change in Accounting Principle

As discussed in Note 2 to the financial statements, the Company has adopted Financial Accounting Standards Board (“FASB”) Accounting Standards Update (“ASU”) No. 2023-07, *Segment Reporting (Topic 280)—Improvements to Reportable Segment Disclosures*, and accordingly has modified its segment disclosures using the retrospective approach.

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's 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 audits to obtain reasonable assurance about whether the 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 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 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 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 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 financial statements and (2) involved our especially challenging, subjective, or complex judgments. The communication of critical audit matters does not alter in any way our opinion on the 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.

Contingent consideration – Fair valuation of contingent consideration liabilities

As described in Note 3 to the financial statements, the Company reported certain contingent consideration liabilities at their estimated fair value as of year-end. The Company used a discounted cash flow model, which is an income approach, in determining the fair value of the contingent consideration liabilities.

The principal considerations for our determination that the fair value of contingent consideration liabilities is a critical audit matter, are that there is significant judgment by management in estimating possible future payouts, the discount rate, and the likelihood of certain milestones being met. This in turn led to high degree of auditor judgment, subjectivity, and effort in performing audit procedures in evaluating audit evidence related to management's estimates and assumptions used in the valuation model. Furthermore, evaluating the related audit evidence required significant auditor judgment as the nature of the evidence is highly subjective, and audit effort involved the use of professionals with specialized skills and knowledge to assist in evaluating the audit evidence obtained.

Addressing the matter involved performing procedures and evaluating evidence in connection with forming our overall audit opinion on the financial statements. These procedures included (i) performing risk assessment procedures on management's own estimate, which included evaluating certain of their assumptions and the methodology used, (ii) developing an independent estimate of the fair value of contingent consideration using information from comparable companies and other sources, and (iii) involving the use of auditor-employed valuation specialists in assessing the estimate.

Intangible assets – Impairment evaluation for certain indefinite-lived intangible assets

As described in Note 5 to the financial statements, the Company identified indicators of impairment for its in-process research and development indefinite-lived intangible assets and accordingly performed an impairment evaluation. The Company used a multi-period excess earnings method, which is an income approach, to determine the fair value of the intangible assets in such evaluation.

The principal considerations for our determination that the impairment evaluation is a critical audit matter, are that there is significant judgment by management in estimating forecasted cash flows and assumptions such as the discount rate. This in turn led to high degree of auditor judgment, subjectivity, and effort in performing audit procedures in evaluating audit evidence related to management's estimates and assumptions used in the forecasted cash flows and valuation model. Furthermore, evaluating the audit evidence related to impairment evaluation required significant auditor judgment as the nature of the evidence is highly subjective, and the audit effort involved the use of professionals with specialized skills and knowledge to assist in evaluating the audit evidence obtained.

Addressing the matter involved performing procedures and evaluating evidence in connection with forming our overall audit opinion on the financial statements. These procedures included (i) performing risk assessment procedures on management's own estimate, which included evaluating certain of their assumptions and the methodology used, (ii) developing an independent estimate of the fair value of indefinite-lived intangible assets using information from comparable companies and other sources, and (iii) involving the use of auditor-employed valuation specialists in assessing the estimate.

/s/ Marcum LLP

Marcum LLP

We have served as the Company's auditor since 2023.

Costa Mesa, CA
March 24, 2025

ONCOCYTE CORPORATION
CONSOLIDATED BALANCE SHEETS
(In thousands, except per share data)

	December 31,	
	2024	2023
ASSETS		
CURRENT ASSETS		
Cash and cash equivalents	\$ 8,636	\$ 9,432
Accounts receivable, net of allowance for credit losses of \$16 and \$5, respectively	1,613	484
Inventories	410	—
Deferred financing costs	279	—
Prepaid expenses and other current assets	821	643
Assets held for sale	—	139
Total current assets	11,759	10,698
NONCURRENT ASSETS		
Right-of-use and financing lease assets, net	2,757	1,637
Machinery and equipment, net, and construction in progress	3,567	3,799
Intangible assets, net	14,607	56,595
Restricted cash	1,700	1,700
Other noncurrent assets	691	463
TOTAL ASSETS	\$ 35,081	\$ 74,892
LIABILITIES AND SHAREHOLDERS' (DEFICIT) EQUITY		
CURRENT LIABILITIES		
Accounts payable	\$ 2,279	\$ 953
Accrued compensation	1,939	1,649
Accrued royalties	1,116	1,116
Accrued expenses and other current liabilities	418	452
Right-of-use and financing lease liabilities, current	1,295	665
Current liabilities of discontinued operations (Note 13)	—	45
Contingent consideration liabilities, current	228	2,314
Total current liabilities	7,275	7,194
NONCURRENT LIABILITIES		
Right-of-use and financing lease liabilities, noncurrent	2,369	2,204
Contingent consideration liabilities, noncurrent	37,711	39,900
TOTAL LIABILITIES	47,355	49,298
Commitments and contingencies (Note 6)		
Series A Redeemable Convertible Preferred Stock, no par value; stated value \$1,000 per share; 5 shares issued and outstanding at December 31, 2023; aggregate liquidation preference of \$5,296 as of December 31, 2023	—	5,126
SHAREHOLDERS' (DEFICIT) EQUITY		
Preferred stock, no par value, 5,000 shares authorized; no shares issued and outstanding	—	—
Common stock, no par value, 230,000 shares authorized; 17,453 and 8,261 shares issued and outstanding at December 31, 2024 and 2023, respectively	338,244	310,295
Accumulated other comprehensive income	21	49
Accumulated deficit	(350,539)	(289,876)
Total shareholders' (deficit) equity	(12,274)	20,468
TOTAL LIABILITIES AND SHAREHOLDERS' (DEFICIT) EQUITY	\$ 35,081	\$ 74,892

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

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

	Years Ended December 31,	
	2024	2023
Net revenue	\$ 1,881	\$ 1,503
Cost of revenues	1,053	1,002
Cost of revenues – amortization of acquired intangibles	88	88
Gross profit	740	413
Operating expenses:		
Research and development	9,839	9,294
Sales and marketing	3,944	2,795
General and administrative	10,204	11,182
Change in fair value of contingent consideration	(4,275)	(5,762)
Impairment losses	41,900	6,757
Impairment loss on held for sale assets	169	1,283
Total operating expenses	61,781	25,549
Loss from operations	(61,041)	(25,136)
Other (expenses) income:		
Interest expense	(84)	(52)
Loss on marketable equity securities	—	(61)
Other income, net	462	394
Total other income, net	378	281
Loss from continuing operations	(60,663)	(24,855)
Loss from discontinued operations (Note 13)	—	(2,926)
Net loss	\$ (60,663)	\$ (27,781)
Net loss per share (Note 2):		
Net loss from continuing operations - basic and diluted	\$ (60,926)	\$ (25,797)
Net loss from discontinued operations - basic and diluted	\$ —	\$ (2,926)
Net loss attributable to common stockholders - basic and diluted	\$ (60,926)	\$ (28,723)
Net loss from continuing operations per share - basic and diluted	\$ (4.66)	\$ (3.37)
Net loss from discontinued operations per share - basic and diluted	\$ —	\$ (0.38)
Net loss attributable to common stockholders per share - basic and diluted	\$ (4.66)	\$ (3.75)
Weighted average shares outstanding - basic and diluted	13,071	7,651

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

ONCOCYTE CORPORATION
CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS
(In thousands)

	Years Ended December 31,	
	2024	2023
Net loss	\$ (60,663)	\$ (27,781)
Foreign currency translation adjustments	(28)	10
Comprehensive loss	<u>\$ (60,691)</u>	<u>\$ (27,771)</u>

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

ONCOCYTE CORPORATION
CONSOLIDATED STATEMENTS OF SERIES A REDEEMABLE CONVERTIBLE PREFERRED STOCK AND SHAREHOLDERS' (DEFICIT)
EQUITY
(In thousands)

	Year Ended December 31, 2024						
	Series A Redeemable Convertible Preferred Stock		Common Stock		Accumulated Other Comprehensive Income	Accumulated Deficit	Total Shareholders' Equity (Deficit)
	Shares	Amount	Shares	Amount			
Balance at December 31, 2023	5	\$ 5,126	8,261	\$ 310,295	\$ 49	\$ (289,876)	\$ 20,468
Net Loss	—	—	—	—	—	(60,663)	(60,663)
Foreign currency translation adjustment	—	—	—	—	(28)	—	(28)
Stock-based compensation	—	—	—	1,753	—	—	1,753
Vesting of bonus awards	—	—	—	52	—	—	52
Sale of common shares, net of financing costs	—	—	8,538	24,638	—	—	24,638
Sale of common shares under at-the-market transactions, net of financing costs	—	—	611	1,661	—	—	1,661
Shares issued upon vesting of RSUs	—	—	4	—	—	—	—
Shares issued for consultant services	—	—	39	108	—	—	108
Redemption of Series A redeemable convertible preferred stock	(5)	(5,389)	—	—	—	—	—
Accretion of Series A convertible preferred stock to redemption value	—	263	—	(263)	—	—	(263)
Balance at December 31, 2024	—	\$ —	17,453	\$ 338,244	\$ 21	\$ (350,539)	\$ (12,274)

	Year Ended December 31, 2023						
	Series A Redeemable Convertible Preferred Stock		Common Stock		Accumulated Other Comprehensive Income	Accumulated Deficit	Total Shareholders' Equity
	Shares	Amount	Shares	Amount			
Balance at December 31, 2022	6	\$ 5,302	5,932	\$ 294,929	\$ 39	\$ (260,676)	\$ 34,292
Cumulative change in accounting principle (Note 2)	—	—	—	—	—	(1,419)	(1,419)
Balance at January 1, 2023, as adjusted	6	5,302	5,932	294,929	39	(262,095)	32,873
Net loss	—	—	—	—	—	(27,781)	(27,781)
Foreign currency translation adjustment	—	—	—	—	10	—	10
Stock-based compensation	—	—	—	2,760	—	—	2,760
Vesting of bonus awards	—	—	—	91	—	—	91
Sale of common shares, net of financing costs	—	—	2,275	13,421	—	—	13,421
Deemed dividend on Series A redeemable convertible preferred stock	—	118	—	(118)	—	—	(118)
Shares issued upon vesting of RSUs	—	—	45	—	—	—	—
Shares issued for consultant services	—	—	9	36	—	—	36
Redemption of Series A redeemable convertible preferred stock	(1)	(1,118)	—	—	—	—	—
Accretion of Series A convertible preferred stock to redemption value	—	824	—	(824)	—	—	(824)
Balance at December 31, 2023	5	\$ 5,126	8,261	\$ 310,295	\$ 49	\$ (289,876)	\$ 20,468

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

ONCOCYTE CORPORATION
CONSOLIDATED STATEMENTS OF CASH FLOWS
(In thousands)

	Years Ended December 31,	
	2024	2023
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	\$ (60,663)	\$ (27,781)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization expense	1,476	1,592
Amortization of intangible assets	88	88
Stock-based compensation	1,753	2,760
Equity compensation for bonus awards and consulting services	160	127
Loss on marketable equity securities	—	61
Change in fair value of contingent consideration	(4,275)	(5,762)
Impairment losses	41,900	6,757
Loss on disposal of discontinued operations	—	1,521
Impairment loss on held for sale assets	169	1,283
Changes in operating assets and liabilities:		
Accounts receivable	(1,129)	109
Inventories	(410)	—
Prepaid expenses and other assets	(458)	784
Accounts payable and accrued liabilities	967	(4,757)
Lease assets and liabilities	(291)	(107)
Net cash used in operating activities	<u>(20,713)</u>	<u>(23,325)</u>
CASH FLOWS FROM INVESTING ACTIVITIES:		
Proceeds from sale of marketable equity securities	—	367
Proceeds from sale of equipment	4	354
Construction in progress and purchases of furniture and equipment	(516)	(281)
Cash sold in discontinued operations (Note 13)	—	(1,372)
Net cash used in investing activities	<u>(512)</u>	<u>(932)</u>
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from sale of common shares	26,012	13,848
Financing costs to issue common shares	(1,374)	(427)
Proceeds from sale of common shares under at-the-market transactions	1,802	—
Financing costs for at-the-market sales	(421)	—
Redemption of Series A redeemable convertible preferred shares	(5,389)	(1,118)
Repayment of financing lease obligations	(201)	(117)
Net provided by financing activities	<u>20,429</u>	<u>12,186</u>
NET CHANGE IN CASH, CASH EQUIVALENTS (INCLUDES DISCONTINUED OPERATIONS) AND RESTRICTED CASH	(796)	(12,071)
CASH, CASH EQUIVALENTS (INCLUDES DISCONTINUED OPERATIONS) AND RESTRICTED CASH, BEGINNING	11,132	23,203
CASH, CASH EQUIVALENTS AND RESTRICTED CASH, ENDING	<u>\$ 10,336</u>	<u>\$ 11,132</u>
SUPPLEMENTAL DISCLOSURE OF CASH FLOW INFORMATION		
Cash paid for interest	\$ 42	\$ 7
Cash paid for income taxes	\$ —	\$ —
SUPPLEMENTAL SCHEDULE OF NONCASH INVESTING AND FINANCING ACTIVITIES		
Construction in progress, machinery and equipment purchases included in accounts payable and accrued liabilities	\$ 570	\$ —
Accretion of Series A convertible preferred stock	\$ 263	\$ 824
Lease assets obtained in exchange for lease liabilities	\$ 1,202	\$ —

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

ONCOCYTE CORPORATION

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

1. Organization and Description of the Business

Oncocyte Corporation (“Oncocyte,” the “Company,” “we,” “our” or “us”), incorporated in 2009 in California, is a pioneering diagnostics technology company. Our mission is to democratize access to novel molecular diagnostic testing to improve patient outcomes. Our current intellectual property comprises three general areas: 1) organ transplant, 2) oncology therapy selection, and 3) oncology therapy monitoring. Within these categories, we have developed or are in the process of developing laboratory developed tests (“LDTs”) that can be run at our Nashville, Tennessee lab, kitted research use only (“RUO”) tests, and kitted clinical tests that can be run by local labs.

Razor Transactions

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 had developed and licensed to Oncocyte the lung cancer treatment stratification laboratory test that Oncocyte was commercializing as DetermaRx. On February 24, 2021, Oncocyte completed the purchase of all the remaining issued and outstanding shares of common stock of Razor. As a result of the purchase of the Razor common stock, Oncocyte became the sole shareholder of Razor.

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 constituted 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”).

On February 16, 2023, Oncocyte completed the Razor Sale Transaction (the “Razor Closing”). 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 allowed 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.

As a result of the divestiture of Razor, the Company has reflected the 2023 operations of Razor as a discontinued operation. See Note 13, “Discontinued Operations of Razor” for additional information.

Liquidity

Oncocyte has incurred operating losses and negative cash flows since inception and had an accumulated deficit of \$350.5 million as of December 31, 2024. Oncocyte expects to continue to incur operating losses and negative cash flows for the foreseeable future. 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, 2024, Oncocyte had \$8.6 million of cash and cash equivalents. On February 10, 2025, we raised substantial additional capital as discussed below.

Oncocyte received a positive coverage decision from MolDx for GraftAssureCore (Kidney) in August of 2023, and it became commercially available for ordering in January 2024 through Oncocyte’s Clinical Laboratory Improvements Amendment (“CLIA”) Laboratory in Nashville, Tennessee. GraftAssureCore (Kidney) is now broadly available to transplant professionals upon request. In July 2024, Oncocyte began to commercialize the technology underlying GraftAssureCore (Kidney) by distributing its sister product, GraftAssureIQ, which is intended to be sold and used for research purposes and is labeled as RUO. Oncocyte expects to distribute its RUO production through a mix of direct sales, partnering and distribution agreements, and licensing. In December 2024, we confirmed Medicare reimbursement for also monitoring certain high-risk patients, that is, those with newly developed donor-specific antibodies.

ONCOCYTE CORPORATION
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

In the field of oncology, Oncocyte is continuing to develop 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, and triple negative breast cancer. A kitted research product format of the underlying technology began proof-of-concept development in 2023. The application of immunotherapy is a global problem, so we expect partnering opportunities for each of our products as they reach clinical maturity. We also expect to begin commercializing our oncology product line, which includes DetermaIO, over the next 15 months.

On April 5, 2024, the Company entered into a global strategic partnership agreement with Bio-Rad Laboratories, Inc. (“Bio-Rad”) to collaborate in the development and the commercialization of RUO and in vitro diagnostic (“IVD”) kitted transplant products for clinical use. See Note 10, “Collaborative Arrangements” for additional information. On November 8, 2024, the Company and Bio-Rad entered into a memorandum of understanding with respect to such agreement to establish additional activities to be performed by each party pursuant to such agreement (see Note 10).

On April 15, 2024, the Company consummated a private placement of its securities to certain accredited investors (the “April 2024 Offering”). The resulting net proceeds were approximately \$9.9 million, after deducting offering expenses of \$538,000 and deducting \$5.4 million for the redemption of all remaining shares of the Company’s Series A Redeemable Convertible Preferred Stock. These net proceeds are inclusive of an investment from Bio-Rad (see Note 9), our aforementioned global strategic partner. See Note 7, “Common Stock – April 2024 Offering,” for additional information.

On August 1, 2024, the Company filed a shelf registration statement on Form S-3, pursuant to which it registered for sale up to \$100.0 million of any combination of its common stock, preferred stock, warrants and/or units from time to time and at prices and on terms that it may determine (the “Primary Shelf Registration Statement”). On August 9, 2024, the Company entered into a sales agreement with a sales agent, pursuant to which the Company may offer and sell from time to time up to an aggregate of \$7.5 million of shares of the Company’s common stock, registered on the Primary Shelf Registration Statement, through the sales agent through an at-the-market facility (the “August 2024 Offering”). As of December 31, 2024, net proceeds to the Company from the sale of such shares were approximately \$1.7 million. See Note 7, “Common Stock – August 2024 Offering,” for additional information. On February 8, 2025, the Company terminated this sales agreement. As a result, the Company may not make any further sales pursuant to such at-the-market facility. See Note 14, “Subsequent Events” for additional information.

On October 4, 2024, the Company consummated a private placement of its securities to certain accredited investors (the “October 2024 Offering”). The gross proceeds from the October 2024 Offering were approximately \$10.2 million. After deducting placement agent fees and expenses and offering expenses payable by the Company of \$836,000, the resulting net proceeds were approximately \$9.4 million. These net proceeds are inclusive of an investment from Bio-Rad (see Note 9), our aforementioned global strategic partner. See Note 7, “Common Stock – October 2024 Offering” for additional information.

On February 10, 2025, the Company consummated a registered direct offering and concurrent private placement of its securities to certain accredited investors (the “February 2025 Offering”). The aggregate gross proceeds from the February 2025 Offering were approximately \$29.1 million. After deducting offering expenses payable by the Company of \$480,000, the resulting net proceeds were approximately \$28.7 million. These net proceeds are inclusive of an investment from Bio-Rad (see Note 9), our aforementioned global strategic partner. See Note 14, “Subsequent Events – Private Placement Transaction” and “Subsequent Events – Registered Direct Offering” for additional information.

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 our collaborative arrangement for the development and the commercialization of RUO and IVD kitted transplant products, progress in obtaining regulatory approval to distribute our products for clinical use, and progress in the 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 Oncocyte's current stockholders. Oncocyte cannot assure that adequate long-term financing will be available on favorable terms, if at all.

ONCOCYTE CORPORATION

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

In accordance with Accounting Standards Codification (“ASC”) 205-40, *Going Concern*, we evaluated whether there are conditions and events, considered in the aggregate, that raise substantial doubt about our ability to continue as a going concern within one year after the date that the consolidated financial statements included in this Annual Report on Form 10-K (this “Report”) are issued. This evaluation initially does not take into consideration the potential mitigating effect of our plans that have not been fully implemented as of the date the consolidated financial statements included in this Report are issued. When substantial doubt exists under this methodology, we evaluate whether the mitigating effect of our plans sufficiently alleviates substantial doubt about our ability to continue as a going concern. The mitigating effect of our plans, however, is only considered if both (1) it is probable that the plans will be effectively implemented within one year after the date that such financial statements are issued, and (2) it is probable that the plans, when implemented, will mitigate the relevant conditions or events that raise substantial doubt about our ability to continue as a going concern within one year after the date that such financial statements are issued. In performing this analysis, we excluded certain elements of our operating plan that cannot be considered probable.

Although it is difficult to predict the Company’s liquidity requirements, based on the going concern evaluation discussed above, management believes that it will have sufficient cash to meet its projected operating requirements for at least the next twelve months following the issuance of these consolidated financial statements. The factors that previously raised substantial doubt about the Company’s ability to continue as a going concern in the prior year were resolved in part as a result of the February 2025 Offering described above. Accordingly, management has concluded that substantial doubt does not exist about the Company’s ability to continue as a going concern for a period of at least one year from the date of issuance of these consolidated financial statements. However, the Company anticipates that it will continue to generate operating losses and negative operating cash flows for the foreseeable future as it continues the development of its various programs and incurs additional costs associated with being a public company.

2. Summary of Significant Accounting Policies

Accounting Principles

The consolidated financial statements and accompanying notes are prepared on the accrual basis of accounting in accordance with U.S. generally accepted accounting principles (“GAAP”).

Principles of Consolidation and Basis of Presentation

On January 31, 2020, with the acquisition of Insight Genetics, Inc. (“Insight”) 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”), 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 April 15, 2021, with the 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, Chronix became a wholly-owned subsidiary of Oncocyte (the “Chronix Merger”), 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.

We have reflected the 2023 operations of Razor as discontinued operations. See Note 13 for further information. Amounts and disclosures throughout these notes to consolidated financial statements relate solely to continuing operations and exclude all discontinued operations, unless otherwise noted. Discontinued operations comprise activities that were disposed of or discontinued 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.

On July 24, 2023, the Company implemented a 1-for-20 reverse stock split of the outstanding shares of its common stock. The par value per share and the authorized number of shares of common stock and preferred stock were not adjusted as a result of the reverse stock split. All common stock share and per-share amounts for all periods presented in these consolidated financial statements have been adjusted to reflect the reverse stock split. The number of authorized shares of common stock remains at 230,000,000 shares.

ONCOCYTE CORPORATION
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

Reclassifications

Certain prior period amounts in the consolidated financial statements and notes to consolidated financial statements have been reclassified to conform to the current period presentation. Included in such prior period amounts are the contingent consideration liabilities, current balance of \$2.3 million, which was previously presented as accrued severance from acquisition on the consolidated balance sheet, and the same amount is reflected in the beginning balances of the Level 3 fair value roll forwards in Note 3, “Business Combinations and Contingent Consideration – Acquisition of Chronix Biomedical, Inc.” These changes had no impact on the previously reported consolidated financial condition, results of operations or cash flows.

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 and forecasted financial information, 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), the carrying value of any goodwill and other intangibles and related impairments, assumptions related to going concern assessments, revenue recognition, allowances for credit losses, allocation of direct and indirect expenses, useful lives associated with long-lived intangible and other 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 stock-based awards and other equity instruments. These assessments are made in the context of information reasonably available to Oncocyte. Actual results may differ materially from those estimates.

Segment Reporting

In accordance with ASC 280, *Segment Reporting*, Oncocyte’s management views its operations as one reportable segment that includes the research, development and commercialization of diagnostic tests, including molecular diagnostic services to pharmaceutical customers. See Note 11 for additional information.

Fair Value Measurements, Business Combinations and Contingent Consideration Liabilities

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. Such inputs reflect management’s best estimate of what market participants would use in pricing the asset or liability at the measurement date. Consideration is given to the risk inherent in the valuation technique and the risk inherent in the inputs to the model. Management estimates include certain pricing models, discounted cash flow methodologies and similar techniques that use significant unobservable inputs, including the entity’s own assumptions in determining fair value.

ONCOCYTE CORPORATION
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

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 as of the acquisition date based on prices quoted on the principal national securities exchange on which the shares traded. Oncocyte recognizes estimated fair values of the tangible assets and identifiable intangible assets acquired, including in-process research and development (“IPR&D”), and liabilities assumed, including any contingent consideration, as of the acquisition date. Goodwill is recognized as any amount of excess consideration transferred over the fair value of the tangible and identifiable intangible assets acquired net of the liabilities assumed. 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 recorded at fair value on a recurring basis, except for money market funds. These assets are measured at fair value using the period-end quoted market prices as a Level 1 input.

The carrying amounts of cash and cash equivalents, restricted cash, net accounts receivable, 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.

In accordance with GAAP, from time to time, the Company measures certain assets at fair value on a nonrecurring basis. The Company reviews the carrying value of intangibles, including IPR&D (see Note 5), and other long-lived assets for indications of impairment at least annually. Refer to related discussions of impairments below.

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 laboratory 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, which are carried at fair value based on Level 3 inputs on a recurring basis.

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 and additional Level 3 fair value disclosures.

Cash, Cash Equivalents and Restricted Cash

Oncocyte considers all highly liquid securities with original maturities of three months or less when purchased to be cash equivalents. For the periods presented, Oncocyte’s cash equivalents are comprised of investments in AAA rated money market funds that invest in first-tier only securities, which primarily include domestic commercial paper and securities issued or guaranteed by the U.S. government or its agencies. Restricted cash relates to a bank letter of credit required under our office lease arrangement, refer to Note 6 for additional information.

For cashflow reporting purposes, the Company combines the reported balance sheet amounts from cash and cash equivalents with restricted cash (noncurrent). As of December 31, 2024 and 2023, the aggregate amount of such ending balances were \$10.3 million and \$11.1 million, respectively, as presented on the consolidated statements of cash flows.

ONCOCYTE CORPORATION
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

Marketable Equity Securities

Oncocyte accounts for shares of public common stock it may hold as marketable equity securities in accordance with ASC 321-10, *Investments – Equity Securities*, as the shares have a readily determinable fair value quoted on national stock exchange. 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 or expense, and are reported as current assets in the consolidated balance sheet based on the closing trading price of the security as of the date being presented. During the fourth quarter of 2023, Oncocyte sold its remaining marketable equity securities for an aggregate realized loss of approximately \$1.4 million. During the year ended December 31, 2023, in connection with the sale, Oncocyte recorded the remaining loss on marketable equity securities of \$61,000.

Investments in 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 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 16, 2023, Oncocyte continues to own an equity interest Razor, however, based on the Razor transactions as discussed in Note 1, the remaining common stock held is accounted for at historical cost less impairment, which is currently zero.

Inventories

Inventories include raw materials, work-in-process and finished goods and are valued at the lower of cost or net realizable value. In September 2024, the Company capitalized certain initial RUO inventory costs in connection with its collaboration arrangement with Bio-Rad to develop and commercialize its GraftAssureIQ RUO kitted tests and eventual IVD kitted transplant testing products. See Note 10, “Collaborative Arrangements” for additional information. As of December 31, 2024, inventories were comprised of raw materials of \$207,000 and finished goods of \$203,000.

Assets Held for Sale and Discontinued Operations

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.

The Company has entered into various agreements to sell laboratory equipment. As a result, the Company classified the equipment as held for sale current assets in the consolidated balance sheets, as all the criteria of ASC subtopic 360-10, *Property, Plant, and Equipment* had been met. The equipment was written down to its fair value, less cost to sell, the remainder of which was \$139,000 as of December 31, 2023. During the fourth quarter of 2024, the Company placed the remaining equipment items back into service. During the years ended December 31, 2024 and 2023, the Company recorded an impairment loss on held for sale assets of \$169,000 and \$1.3 million, respectively, in the consolidated statements of operations.

ONCOCYTE CORPORATION
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

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 ASC Topic 205, *Presentation of Financial Statements*. Razor has been reflected as a discontinued operation in the 2023 consolidated financial statements. See Note 13, "Discontinued Operations of Razor" for additional information.

Property and Equipment

Machinery and equipment are stated at cost, less accumulated depreciation and amortization. Depreciation and amortization 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 amortizes 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.

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 coverage determination ("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.

Oncocyte does not have intangible assets with indefinite useful lives other than the acquired IPR&D discussed in Note 5, which as of December 31, 2024, has been partially impaired.

When applicable, 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 that it is more-likely-than-not that the carrying value of the associated reporting unit exceeds its fair value. 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 is considered to be the sole reporting unit and, therefore, goodwill is tested for impairment at the enterprise level, when applicable.

ONCOCYTE CORPORATION
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

In accordance with ASC 350, 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. When applicable, we test 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.

Long-Lived Intangible Assets

Long-lived intangible assets subject to amortization are stated at acquired cost, less accumulated amortization. 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 1 to 9 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. Long-lived intangible assets currently consist of acquired customer relationships with an estimated useful life of 5 years (see Note 5).

Impairment of Long-Lived Assets

Oncocyte's long-lived assets consist primarily of intangible assets, right-of-use assets for operating and financing leases, customer relationships, and machinery and equipment. If events or changes in circumstances indicate that the carrying amount of a long-lived 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 carrying value of the asset over its fair value, is recorded.

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 include office leases and related ROU lease liabilities, current and long-term, in the consolidated balance sheets. Financing leases include machinery and equipment and related financing lease liabilities, current and long-term, in the consolidated balance sheets (see "Property and Equipment" above for more information). Oncocyte discloses the amortization of our operating lease ROU assets and payments as a net amount in the consolidated statements of cash flows. Oncocyte has entered into various operating and financing leases in accordance with ASC 842 as further discussed in Note 6.

ONCOCYTE CORPORATION
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

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, 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. 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.

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. Based on the above guidance and, among other factors, the fact that our warrants cannot be cash settled under any circumstance but require share settlement, all of our outstanding warrants meet the equity classification criteria and have been classified as equity. Refer to Note 7 for details about our outstanding warrants.

Revenue Recognition

Pursuant to ASC 606, *Revenue from Contracts with Customers*, 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.

The following table presents consolidated revenues by service:

	Years Ended December 31,	
	2024	2023
	(In thousands)	
Pharma Services	\$ 1,859	\$ 1,467
Laboratory Developed Test Services	22	36
Total	\$ 1,881	\$ 1,503

ONCOCYTE CORPORATION
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

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 service of its Pharma Service offering as a single performance obligation. Offerings include services such as recurring fees for project management, fees for storage and handling, pass through expenses for shipping or calibration, training, proficiency, reproducibility tests, etc. 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 acknowledgment of completed services, and 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 other current assets as of the financial statement date. Amounts recorded in contract assets are reclassified to accounts receivable in Oncocyte's consolidated balance sheets when the customer is invoiced according to the billing schedule in the contract.

As of December 31, 2024 and 2023, Oncocyte had gross accounts receivable from Pharma Services customers of \$1.6 million and \$489,000, respectively.

Allowance for Credit Losses

Oncocyte establishes an allowance for credit losses 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 condition, 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. Oncocyte continuously monitors collections and payments from customers and maintains a provision for estimated credit losses and uncollectible accounts, if any, based upon its historical experience and any specific customer collection issues that have been identified. Amounts determined to be uncollectible are written off against the credit loss reserve accounts. As of December 31, 2024 and 2023, Oncocyte had an allowance for credit losses of \$16,000 and \$5,000, respectively, related to Pharma Services.

Laboratory Developed Test Services

Prior to the Razor Sale Transaction, Oncocyte generated 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 in (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 has billed 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 has recognized revenue upon payment because it has had insufficient history to reliably estimate payment patterns.

ONCOCYTE CORPORATION
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

As of December 31, 2024 and 2023, Oncocyte had no accounts receivable from Medicare and Medicare Advantage covered DetermaRx tests. Laboratory Developed Test Services revenue recorded during the years ended December 31, 2024 and 2023 was the result of payments received.

Allowance for Credit Losses

Oncocyte maintained an allowance for credit losses related to Laboratory Developed Test Services at an amount we estimated to be sufficient to provide adequate protection against losses resulting from extending credit to our customers. We based this allowance, in the aggregate, on historical collection experience, age of receivables and general economic conditions, as well as specific identification of uncollectible accounts. We initially established an allowance in 2022 in connection with remaining Medicare and Medicare Advantage account balances and continued to add to the allowance as appropriate. In the first quarter of 2023, in connection with the adoption of the new current expected credit loss model, the Company determined that the Medicare and Medicare Advantage accounts receivable net balance at December 31, 2022 of approximately \$1.4 million was uncollectible and should therefore be written-off. Accordingly, the Company recorded a cumulative-effect adjustment of such amount to the opening accumulated deficit balance as of January 1, 2023, as presented in the consolidated statement of shareholders' equity. The impact of recording such adjustment on our consolidated balance sheet as of January 1, 2023, was to reduce our net accounts receivable and increase our accumulated deficit balances by \$1.4 million. As of December 31, 2023, we had no allowance for credit losses related to Laboratory Developed Test Services. The 2023 allowance for credit losses activity included a beginning balance of \$154,000, no credit loss provisions, and the full write-off to an ending balance of zero as of December 31, 2023.

Licensing Revenue

Revenues that may be recognized include 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.

Disaggregation of Revenues and Concentrations of Credit Risk

The following table presents the percentage of consolidated revenues by service:

	Years Ended December 31,	
	2024	2023
Pharma Services	99 %	98 %
Laboratory Developed Test Services	1 %	2 %
Total	100 %	100 %

The following table presents the percentage of consolidated revenues generated by unaffiliated customers, based on the respective periods presented, that individually represented greater than ten percent of consolidated revenues:

	Years Ended December 31,	
	2024	2023
Pharma services - Company A	84 %	47 %
Pharma services - Company B	*	27 %
Pharma services - Company C	*	11 %

* Less than 10%

ONCOCYTE CORPORATION
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

The following table presents the percentage of consolidated revenues attributable to geographical locations, based on country of domicile:

	Years Ended December 31,	
	2024	2023
United States – Pharma Services	88 %	59 %
Outside of the United States – Pharma Services	11 %	39 %
United States – Laboratory Developed Test Services	1 %	2 %
Total	100 %	100 %

Refer to Note 11, “Segment Reporting” for additional information about geographical revenues and long-lived tangible assets.

Financial instruments that potentially subject the Company to concentrations of credit risk are cash and cash equivalents and accounts receivable. The Company places its cash equivalents primarily in highly rated money market funds. Cash and cash equivalents are also invested in deposits with certain financial institutions and may, at times, exceed federally insured limits. The Company has not experienced any significant losses on its deposits of cash and cash equivalents.

One Pharma Services customer individually represented approximately 97% of accounts receivable as of December 31, 2024. Two Pharma Services customers individually represented approximately 79% and 13% of accounts receivable as of December 31, 2023.

The Company had accounts payable to three vendors that represented approximately 37%, 28% and 14% of accounts payable as of December 31, 2024, and four vendors that represented approximately 32%, 21%, 12% and 11% of accounts payable as of December 31, 2023.

The Company has a concentration in the volume of business transacted with Bio-Rad, its global strategic partner. In 2024, the Company entered into an agreement with Bio-Rad to collaborate in the development and the commercialization of RUO and IVD kitted transplant products using Bio-Rad’s ddPCR instruments and reagents, pursuant to which it is dependent on Bio-Rad with respect to many of its ongoing operations and future target performance. See Note 9, “Related Party Transactions” and Note 10, “Collaborative Arrangements” for additional information.

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 Laboratory Developed Test Services, providing deliverables according to our licensing agreements, license fees due to third-parties, and amortization of acquired intangible assets such as the customer relationship intangible assets (see Note 5). Infrastructure expenses include depreciation of laboratory equipment, allocated rent costs, leasehold improvements, and allocated information technology costs for operations at Oncocyte’s CLIA laboratory in Tennessee. Costs associated with generating the revenues are recorded as the tests or services are performed regardless of whether revenue was recognized. Royalties or revenue share payments for licensed technology calculated as a percentage 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, 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 depreciation expense and 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. Certain research and development expenses are attributed to our global strategic collaboration arrangement with Bio-Rad for commercializing our RUO kitted test product. See Note 10, “Collaborative Arrangements” for additional information.

ONCOCYTE CORPORATION
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

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, depreciation expense, telecommunications, property taxes and insurance. During the years ended December 31, 2024 and 2023, Oncocyte's total advertising expenses were \$258,000 and \$190,000, respectively. Certain sales and marketing expenses are attributed to our global strategic collaboration arrangement with Bio-Rad for commercializing our RUO kitted test product. See Note 10, "Collaborative Arrangements" for additional information.

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, depreciation expense, telecommunications, property taxes and insurance. Certain general and administrative expenses are attributed to our global strategic collaboration arrangement with Bio-Rad for commercializing our RUO kitted test product. See Note 10, "Collaborative Arrangements" for additional information.

Stock-Based Compensation

Oncocyte recognizes compensation expense related to employee, Board of Director and other non-employee option grants and restricted stock grants in accordance with ASC 718, *Compensation – Stock Compensation*.

Oncocyte estimates the fair value of stock-based payment awards on the grant date and recognizes the resulting fair value over the requisite service period, which is generally a four-year vesting 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 time-based options granted under Oncocyte's equity plan. The fair value of each restricted stock unit ("RSU") or award ("RSA") is determined by the product of the number of units or shares granted and the grant date market price of the underlying common stock. 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 ratably on a straight-line basis over the requisite service period. Options have a maximum contractual term of ten years. Forfeitures are accounted for as they occur. Refer to Note 8 for additional information.

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. 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. Oncocyte estimates the expected volatility using its own stock price volatility 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.

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 "Income Taxes" below), 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.

Retirement Plan

Oncocyte has an employee savings and retirement plan under Section 401(k) of the Internal Revenue Code. The plan is a defined contribution plan in which eligible employees may elect to have a percentage of their compensation contributed to the plan, subject to certain guidelines issued by the Internal Revenue Service. During the years ended December 31, 2024 and 2023, Oncocyte's total contributions to the plan were \$318,000 and \$310,000, respectively.

ONCOCYTE CORPORATION
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

Collaborative Arrangements

The Company analyzes its collaboration arrangements to assess whether they are within the scope of ASC 808, *Collaborative Arrangements*, which includes determining whether such arrangements involve joint operating activities performed by parties that are both active participants in the activities and exposed to significant risks and rewards dependent on the commercial success of such activities. To the extent that the arrangement falls within the scope of ASC 808, the Company assesses whether the payments between the Company and its collaboration partner fall within the scope of other accounting literature. If the Company concludes that payments from the collaboration partner to the Company would represent consideration from a customer, the Company accounts for those payments within the scope of ASC 606. However, if the Company concludes that its collaboration partner is not a customer for certain activities and associated payments, the Company presents such payments as a reduction of research and development expense or general and administrative expense, based on where the Company presents the underlying expense. See Note 10, “Collaborative Arrangements” for additional information.

Income Taxes

Oncocyte and its subsidiaries will file a consolidated U.S. federal income tax return and combined California state return for the year ended December 31, 2024. 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.

Oncocyte did not record any provision or benefit for income taxes for the years ended December 31, 2024 and 2023, as Oncocyte had a full valuation allowance for the periods presented.

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. Oncocyte established a full valuation allowance for all periods presented due to the uncertainty of realizing future tax benefits from its net operating loss carry-forwards and other deferred tax assets.

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, 2024 and 2023. Oncocyte is not aware of any uncertain tax positions that could result in significant additional payments, accruals, or other material deviation as of December 31, 2024. Oncocyte is currently unaware of any tax issues under review. As of December 31, 2024 and 2023, the Company had unrecognized tax benefits totaling \$1.1 million and \$2.3 million, respectively. See Note 12 for additional information.

On June 27, 2024, California enacted SB-167, which suspends the use of California net operating loss and limits the use of California research tax credits to \$5.0 million each year for our fiscal years 2025-2027. On June 29, 2024, California enacted SB-175, which provides a refund mechanism for the incremental tax that was paid as a result of SB-167. The Company is evaluating the impact of the law changes but does not expect these law changes to have a material impact on the Company’s consolidated financial statements.

ONCOCYTE CORPORATION
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

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. The 2024 weighted average shares outstanding - basic in the following table includes the effects of pre-funded warrants that were issued in April 2024 (refer to Note 7, “Common Stock Purchase Warrants” for additional information). 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. On February 10, 2025, the Company consummated the February 2025 Offering that included the issuance of an aggregate of 11,146,463 shares of common stock of the Company and pre-funded warrants to purchase up to 3,069,925 shares of common stock. See Note 14, “Subsequent Events – Private Placement Transaction” and “Subsequent Events – Registered Direct Offering” for additional information.

For the years ended December 31, 2024 and 2023, all common stock equivalents are antidilutive because Oncocyte reported a net loss. The following table presents the calculation of basic and diluted loss per share of common stock:

	Years Ended December 31,	
	2024	2023
	(In thousands, except per share data)	
Numerators:		
Loss from continuing operations	\$ (60,663)	\$ (24,855)
Accretion of Series A redeemable convertible preferred stock	(263)	(824)
Deemed dividend on Series A redeemable convertible preferred stock	—	(118)
Net loss from continuing operations - basic and diluted	<u>\$ (60,926)</u>	<u>\$ (25,797)</u>
Loss from discontinued operations	\$ —	\$ (2,926)
Net loss from discontinued operations - basic and diluted	<u>\$ —</u>	<u>\$ (2,926)</u>
Net loss	\$ (60,663)	\$ (27,781)
Accretion of Series A redeemable convertible preferred stock	(263)	(824)
Deemed dividend on Series A redeemable convertible preferred stock	—	(118)
Net loss attributable to common stockholders - basic and diluted	<u>\$ (60,926)</u>	<u>\$ (28,723)</u>
Denominator:		
Weighted average shares outstanding - basic and diluted	<u>13,071</u>	<u>7,651</u>
Net loss per share:		
Net loss from continuing operations per share - basic and diluted	<u>\$ (4.66)</u>	<u>\$ (3.37)</u>
Net loss from discontinued operations per share - basic and diluted	<u>\$ —</u>	<u>\$ (0.38)</u>
Net loss attributable to common stockholders per share - basic and diluted	<u>\$ (4.66)</u>	<u>\$ (3.75)</u>
Anti-dilutive potential common shares excluded from the computation of diluted net loss per common share:		
Stock options	1,091	532
RSUs	100	5
Warrants	761	820
Series A redeemable convertible preferred stock	<u>—</u>	<u>5</u>
Total	1,952	1,362

ONCOCYTE CORPORATION
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

Recent Accounting Pronouncements

Recently Adopted

In November 2023, the Financial Accounting Standards Board (“FASB”) issued Accounting Standards Update (“ASU”) No. 2023-07, *Segment Reporting (Topic 280): Improvements to Reportable Segment Disclosures*, to improve financial reporting by requiring disclosure of incremental segment information on an annual and interim basis for all public entities to enable investors to develop more decision-useful financial analyses. The amendments in this Update: (i) require enhanced disclosures about significant segment expenses, (ii) clarify that if the chief operating decision maker uses more than one measure of a segment’s profit or loss, a public entity may report one or more of those additional measures of segment profit or loss, (iii) require disclosure of the title and position of the chief operating decision maker and an explanation of how the chief operating decision maker uses the reported measure(s) of segment profit or loss in assessing segment performance and deciding how to allocate resources, and (iv) require that a public entity that has a single reportable segment provide all the disclosures required by the amendments in this Update and all existing segment disclosures in Topic 280. The amendments in this Update should be applied retrospectively. The Company adopted this ASU as of December 31, 2024 and has included the new requirements in Note 11, “Segment Reporting.” The adoption of this new standard did not have an impact on the Company’s consolidated balance sheets and consolidated statements of operations, comprehensive loss, shareholders’ (deficit) equity and cash flows.

Not Yet Adopted

In December 2023, the FASB issued ASU No. 2023-09, *Income Taxes (Topic 740): Improvements to Income Tax Disclosures*, to address investor requests for more transparency about income tax information by requiring improvements to income tax disclosures, including, (i) consistent categories and greater disaggregation of information in the rate reconciliation, and (ii) income taxes paid disaggregated by jurisdiction. Additional amendments in this Update improve the effectiveness and comparability of disclosures by, (i) adding disclosures of pretax income (or loss) and income tax expense (or benefit), and (ii) removing disclosures that no longer are considered cost beneficial or relevant. The amendments in this Update should be applied prospectively (retrospective application is permitted) and are effective for annual periods beginning after December 15, 2024, with early adoption permitted. Management is currently evaluating the impact that the amendments in this Update will have on the Company’s financial statement disclosures. The adoption of this new standard will not have an impact on the Company’s consolidated balance sheets and consolidated statements of operations, comprehensive loss, shareholders’ (deficit) equity and cash flows.

In November 2024, the FASB issued ASU No. 2024-03, *Income Statement—Reporting Comprehensive Income—Expense Disaggregation Disclosures (Subtopic 220-40): Disaggregation of Income Statement Expenses*, to address investor requests for more detailed information about certain types of reported costs and expenses. The amendments in this Update require disclosure, in the notes to financial statements, at each interim and annual reporting period an entity: 1) disclose the amounts of (a) purchases of inventory, (b) employee compensation, (c) depreciation, and (d) intangible asset amortization included in each expense caption presented on the face of the income statement within continuing operations; 2) include certain amounts that are already required to be disclosed under current GAAP in the same disclosure as the other disaggregation requirements; 3) disclose a qualitative description of the amounts remaining that are not separately disaggregated quantitatively; and 4) disclose the total amount of selling expenses and, in annual reporting periods, an entity’s definition of selling expenses. The amendments in this Update should be applied either prospectively or retrospectively, and are effective for annual periods beginning after December 15, 2026, and interim periods beginning after December 15, 2027, with early adoption permitted. Management is currently evaluating the impact that the amendments in this Update will have on the Company’s financial statement disclosures. The adoption of this new standard will not have an impact on the Company’s consolidated balance sheets and consolidated statements of operations, comprehensive loss, shareholders’ (deficit) equity and cash flows.

3. Business Combinations and Contingent Consideration Liabilities

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. 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.

ONCOCYTE CORPORATION
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

There were three milestones comprising the Milestone Contingent Consideration, in connection with the Insight Merger which Oncocyte valued and recorded as part of the contingent consideration as of the Insight Merger Date (see table below), which consisted of (i) a payment for clinical trial completion and related data publication (“Milestone 1”), (ii) a payment for an affirmative final LCD 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's common stock as determined by Oncocyte. There can be no assurance that any of the Milestones will be achieved.

The following table shows the Insight Merger Date contractual payment amounts, as applicable, and the corresponding fair value of each respective contingent consideration liability:

	Contractual Value	Fair Value on the Merger Date
	(In thousands)	
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	<u>\$ 6,000</u>	<u>\$ 11,130</u>

(a) Indicates the maximum amount 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 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. Since December 2023, Milestone 1 and Royalty 2 (Pharma Services) are not expected to be paid and are excluded from the current fair value. During 2024, based on Oncocyte's reassessment of significant assumptions, there was an increase of approximately \$553,000 to the fair value of the contingent consideration primarily attributable to revised estimates of the possible future payouts and, accordingly, this amount was recorded as a change in fair value of contingent consideration in the consolidated statement of operations for the year ended December 31, 2024.

Oncocyte uses a discounted cash flow valuation technique to determine the fair value of its Level 3 contingent consideration liabilities. The significant unobservable inputs used in Insight's contingent consideration valuation on December 31, 2024, included: (i) a discount period, based on the expected Milestone payment dates, ranging from 1.7 years to 7.8 years, (ii) a discount rate of 13.2% to 13.5%, and (iii) a management probability estimate of 25% to 50%. The significant unobservable inputs used in Insight's contingent consideration valuation on December 31, 2023, included: (i) a discount period, based on the expected Milestone payment dates, ranging from 1.3 years to 1.5 years, (ii) a discount rate of 13.9%, and (iii) a management probability estimate of 25% to 50%. Changes to significant unobservable inputs to different amounts could result in a significantly higher or lower fair value measurement at the reporting date.

The following tables reflect the activity for the Insight contingent consideration measured at fair value using Level 3 inputs:

	Fair Value (In thousands)
Balance at December 31, 2022	\$ 5,370
Change in estimated fair value	(3,330)
Balance at December 31, 2023	<u>\$ 2,040</u>
Balance at December 31, 2023	\$ 2,040
Change in estimated fair value	553
Balance at December 31, 2024	<u>\$ 2,593</u>

ONCOCYTE CORPORATION
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

Acquisition of Chronix Biomedical, Inc.

On April 15, 2021 (the “Chronix Merger Date”), Oncocyte completed its acquisition of Chronix pursuant to the Chronix Merger Agreement. As additional consideration for holders of certain classes and series of Chronix capital stock, the Chronix Merger Agreement required Oncocyte to pay certain contingent consideration. On February 8, 2023, the Company and the equity holder representative named in the Chronix Merger Agreement entered into Amendment No. 1 to the Chronix Merger Agreement, pursuant to which the parties agreed 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) all of the previous payment obligations were eliminated.

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. During 2024, based on Oncocyte’s reassessment of significant assumptions, there was a decrease of approximately \$4.8 million to the fair value of the contingent consideration primarily attributable to revised estimates of the possible future payouts and, accordingly, this amount was recorded as a change in fair value of contingent consideration in the consolidated statement of operations for the year ended December 31, 2024.

Oncocyte uses a discounted cash flow valuation technique to determine the fair value of its Level 3 contingent consideration liabilities. The significant unobservable inputs used in Chronix’s contingent consideration valuation on December 31, 2024, included: (i) a discount period, based on the related patent expiration dates, ranging from 9.8 years to 10.7 years, (ii) a discount rate of 13.1% to 13.6%, and (iii) a payout percentage of 10% based on the earnout provision. The significant unobservable inputs used in Chronix’s contingent consideration valuation on December 31, 2023, included: (i) a discount period, based on the related patent expiration dates, ranging from 9.9 years to 11.7 years, (ii) a discount rate of 14.7% to 15.8%, and (iii) a payout percentage of 10% based on the earnout provision. Changes to significant unobservable inputs to different amounts could result in a significantly higher or lower fair value measurement at the reporting date.

The following tables reflect the activity for the Chronix contingent consideration measured at fair value using Level 3 inputs:

	Fair Value (In thousands)
Balance at December 31, 2022	\$ 42,606
Change in estimated fair value	(2,432)
Balance at December 31, 2023	<u>\$ 40,174</u>
Balance at December 31, 2023	\$ 40,174
Change in estimated fair value	(4,828)
Balance at December 31, 2024	<u>\$ 35,346</u>

As of December 31, 2024 and 2023, the total Chronix contingent consideration fair values, as presented in the tables above, include \$2.3 million of severance obligations related to the Chronix acquisition. The accompanying consolidated balance sheets separately present the Insight and Chronix total contingent consideration liabilities as current and noncurrent based on our expectations of the timing of product commercialization and subsequent revenues that trigger the payouts. Contingent consideration is not deductible for tax purposes, even if paid; therefore, no deferred tax assets related to the contingent consideration were recorded.

ONCOCYTE CORPORATION
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

4. Property and Equipment, Net

Right-of-use and financing lease assets, net, machinery and equipment, net, and construction in progress were as follows:

	December 31,	
	2024	2023
	(In thousands)	
Right-of-use and financing lease assets	\$ 5,323	\$ 4,036
Machinery, equipment and leasehold improvements	8,366	6,909
Accumulated depreciation and amortization	(7,705)	(6,235)
Right-of-use and financing lease assets and machinery and equipment, net	5,984	4,710
Construction in progress	340	726
Total	\$ 6,324	\$ 5,436

Property and equipment depreciation and amortization expense amounted to \$1.5 million and \$1.6 million for the years ended December 31, 2024 and 2023, respectively.

During the third quarter of 2023, in connection with a new sublease arrangement (see Note 6), the Company identified circumstances that indicated a potential impairment of certain leasehold improvements and after a valuation was performed, management concluded that such leasehold improvements were impaired. Accordingly, the Company recorded an impairment of approximately \$1.8 million. The Company used a discounted cash flow valuation method to determine the Level 3 fair value of the leasehold improvements. The significant unobservable inputs used, effective as of September 30, 2023, included: (i) a discount period of 50 months based on the required sublease payments, and (ii) a discount rate of 7.25%. This valuation approach yielded a fair value of \$1.2 million as of September 30, 2023.

5. Intangible Assets, Net

As part of the Insight and Chronix acquisitions completed on January 31, 2020 and April 15, 2021, respectively, the Company has acquired IPR&D and customer relationships (see Note 3).

During the first quarter of 2023, due to changes in management and the economic condition of the Company, management shifted the Company's business strategy to direct efforts on fewer studies and to transition from tests that are LDTs to RUO. Due to the change in strategy, the Company's long range plan forecasts were updated, resulting in a change to anticipated future benefits derived from the Company's assets. The change in strategy represented a significant indicator for change in value of the Company's long-lived assets. The original IPR&D balances were reassessed based on the updated long range plan, using the multi-period excess earnings method ("MPEEM") approach. The results of the valuations noted that the carrying value of the DetermaIO related IPR&D intangible assets was greater than the fair market value, whereas the carrying value of the DetermaCNI related IPR&D intangible assets was lower than the fair market value. Accordingly, the Company recorded an impairment of approximately \$5.0 million related to DetermaIO as of March 31, 2023. During the fourth quarter of 2023, the IPR&D balances were reassessed using the MPEEM approach and the results of the valuations noted that the carrying values of the DetermaIO and DetermaCNI related IPR&D intangible assets were lower than the fair market values. During the fourth quarter of 2024, the IPR&D balances were reassessed using the MPEEM approach and the results of the valuations noted that the carrying values of the DetermaIO and DetermaCNI related IPR&D intangible assets were greater than the fair market values. Accordingly, the Company recorded impairments of \$6.8 million and \$35.1 million related to DetermaIO and DetermaCNI, respectively, as of December 31, 2024.

The MPEEM valuation approach is a discounted cash flow valuation technique and was used to determine the Level 3 fair value of the IPR&D discussed above. The significant unobservable inputs used related to DetermaIO as of March 31, 2023, included: (i) a discount period of 20.0 years, based on the expected life of patent, (ii) a royalty rate of 0.3%, and (iii) a weighted average cost of capital rate of 30.0%, as well as certain assumptions about future cash flows. This valuation approach yielded a fair value of \$9.7 million as of March 31, 2023.

ONCOCYTE CORPORATION
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

The significant unobservable inputs used related to DetermaIO as of December 31, 2024, included: (i) a discount period of 19.5 years, based on the expected life of patent, and (ii) a weighted average cost of capital rate of 29.0%, as well as certain assumptions about future cash flows. This valuation approach yielded a fair value of \$2.9 million as of December 31, 2024. The significant unobservable inputs used related to DetermaCNI as of December 31, 2024, included: (i) a discount period of 19.5 years, based on the expected life of patent, and (ii) a weighted average cost of capital rate of 19.5%, as well as certain assumptions about future cash flows. This valuation approach yielded a fair value of \$11.7 million as of December 31, 2024. As market conditions change, the Company will re-evaluate assumptions used in the determination of fair value for IPR&D and is uncertain to the extent of the volatility in the unobservable inputs in the foreseeable future. Refer to Note 2, “Intangible Assets” for additional IPR&D information.

Intangible assets, net, consisted of the following:

	December 31,	
	2024	2023
	(In thousands)	
Intangible assets:		
Acquired IPR&D - DetermaIO™ ⁽¹⁾	\$ 2,900	\$ 9,700
Acquired IPR&D - DetermaCNI™ ⁽²⁾	11,700	46,800
Intangible assets subject to amortization:		
Acquired intangible assets - customer relationship	440	440
Total intangible assets	15,040	56,940
Accumulated amortization - customer relationship ⁽³⁾	(433)	(345)
Intangible assets, net	<u>\$ 14,607</u>	<u>\$ 56,595</u>

⁽¹⁾ See Note 3 for information on the Insight Merger.

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

⁽³⁾ Amortization of intangible assets is included in “Cost of revenues – amortization of acquired intangibles” on the consolidated statements of operations because the intangible assets pertain directly to the revenues generated from the acquired intangibles.

Intangible asset amortization expense amounted to \$88,000 for the years ended December 31, 2024 and 2023. The remaining \$7,000 of intangible assets subject to amortization will be expensed during the first quarter of 2025.

6. Commitments and Contingencies

Office and Facilities Leases

Irvine Office Lease

On December 23, 2019, Oncocyte and Cushing Ventures, LLC (“Landlord”) 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 serves as Oncocyte’s principal executive and administrative offices. The Irvine Lease has a term of 89 calendar months (the “Term”), which commenced on June 1, 2020 (the “Commencement Date”) and will end on October 31, 2027. Oncocyte agreed to pay base monthly rent in the amount of \$61,640 during the first 12 months of the Term. Base monthly rent increases annually, over the base monthly rent then in effect, by 3.5%.

Effective as of January 2, 2025, Oncocyte, Landlord and Subtenant (as defined below under the caption "Irvine Office Sublease") entered into an amendment to the Irvine Lease, dated December 26, 2024 (the “Amendment”). Pursuant to the terms of the Amendment, among other things: (a) Oncocyte and Subtenant agreed that all rights to extend the Term of the Irvine Lease for a period of five years were terminated, and (b) Landlord and Oncocyte agreed that, provided the Company is not in default under any of the terms and conditions of the Irvine Lease that is continuing beyond any and all applicable notice and cure periods, then, commencing on July 1, 2025 and continuing on the first day of each calendar month thereafter, the provided letter of credit (as further discussed below) in the amount of \$1.7 million (the “Letter of Credit Amount”) shall be reduced by an amount equal to \$60,714.29 on each such date, until the Letter of Credit Amount is fully reduced, after which the letter of credit shall be deemed to have been terminated and Oncocyte shall have no further obligation to maintain or deliver the letter of credit under the Irvine Lease. The new Letter of Credit Amount corresponds to the Company’s restricted cash on the accompanying consolidated balance sheet as of December 31, 2024 and the reductions in the Letter of Credit Amount would correspondingly reduce the associated amount of such restricted cash.

ONCOCYTE CORPORATION
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

In addition to base monthly rent, Oncocyte agreed to 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 lessor 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 Irvine 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 provided 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 retained 1.5% of the Tenant Improvement Allowance as an administrative fee as provided in the Irvine Lease. As of June 2021, the lessor had provided \$1.3 million of the total Tenant Improvement Allowance, which is being amortized over the Term.

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 instances of insolvency or bankruptcy 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 Irvine 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. The Irvine Lease provides that Oncocyte has the right to cancel the letter of credit at any time if it meets certain market capitalization and balance sheets thresholds provided that Oncocyte is not then in default under the Irvine 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. The Letter of Credit Amount shall be reduced as described in the Amendment above.

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. Accordingly, Oncocyte has reflected \$1.7 million as restricted cash in the accompanying consolidated balance sheets as of December 31, 2024 and 2023.

Irvine Office Sublease

On August 8, 2023, Oncocyte and Induce Biologics USA, Inc. (“Subtenant”) entered into a Sublease Agreement (the “Sublease Agreement”), which subsequently became effective as of September 14, 2023, upon the execution and delivery by the Company, Subtenant, and Landlord, of that certain Landlord’s Consent to Sublease dated September 12, 2023 (the “Consent Agreement”), under which Landlord consented to the Sublease Agreement, on the terms and subject to the conditions set forth therein. The Sublease Agreement is subject and subordinate to the Irvine Lease.

Under the Sublease Agreement, the Company agreed to initially sublet to Subtenant a portion of the Premises consisting of approximately 13,400 square feet of rentable space for a term (the “Initial Period”) commencing on the date that is 120 days after the effective date of the Consent Agreement (the “Sublease Commencement Date”) and ending on the date that is 18 months following the Sublease Commencement Date or such earlier date as Subtenant may elect upon the exercise of its one-time option to accelerate such date upon 90 days prior written notice to the Company (the date on which the Initial Period ends, the “Expansion Date”). On the Expansion Date, the portion of the Premises that is subleased to Subtenant under the Sublease Agreement will automatically increase to include the remaining portion of the Premises, which consists of approximately 13,400 square feet of additional rentable space for a term (the “Expansion Period”) beginning on the Expansion Date through the expiration of the Irvine Lease on October 31, 2027, unless earlier terminated.

ONCOCYTE CORPORATION
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

The Sublease Agreement provides that, from and after the Sublease Commencement Date, Subtenant will pay to the Company monthly base rent in the following amounts: (i) \$36,850 for rental periods beginning on the Sublease Commencement Date and ending on or before December 31, 2024; (ii) \$37,955 for rental periods beginning on or after January 1, 2025 and ending on or before June 20, 2025 (subject to adjustment in the event that Subtenant exercises its option to accelerate the Expansion Date, such that the Expansion Period begins prior to June 20, 2025); (iii) \$75,844 for rental periods beginning on or after July 1, 2025 and ending on or before December 31, 2025; (iv) \$78,188 for rental periods beginning on or after January 1, 2026 and ending on or before December 31, 2026; and (v) \$80,534 for rental periods beginning on or after January 1, 2027 and ending on or before October 31, 2027.

Following the Sublease Commencement Date, Subtenant is responsible for the payment of Additional Rent, including Expenses and Taxes (as each such term is defined in the Irvine Lease), provided that, with respect to the Initial Period, Subtenant will be responsible for only 50% of the Expenses and Taxes due. In addition, Subtenant will pay the Company a security deposit in the amount of \$101,987 in connection with the transactions contemplated by the Sublease Agreement.

The Sublease Agreement contains customary provisions with respect to, among other things, Subtenant's obligation to comply with the Irvine Lease and applicable laws, the payment of utilities and similar services utilized by Subtenant with respect its use of the Premises, the indemnification of the Company by Subtenant, and the right of the Company to terminate the Sublease Agreement in its entirety and retake the Premises if Subtenant fails to remedy certain defaults of its obligations under the Sublease Agreement within specified time periods.

Nashville Leases

Insight operates a CLIA-certified laboratory and has additional office space located at 2 International Plaza, Nashville, Tennessee, under lease arrangements with MPC Holdings, LLC. As of December 31, 2023, the Company had Nashville office leases that comprised 8,362 square feet of rentable office space with a term ending April 2024. On January 1, 2024, the Company renewed its exiting leases with MPC Holdings, LLC and added a new lease agreement to further expand its Nashville office space. The new lease contains 2,319 square feet for an aggregate of 10,681 square feet of rentable space. Lab space is approximately 4,826 square feet of the total. The new lease agreements each have an initial term of 36 months, which commenced on January 1, 2024 and will end in January 2027. The Company has the option to renew the term of each lease for four additional one year periods.

The office and facilities leases discussed above are operating leases under ASC 842 and are included in the tables below. The tables below provide the amounts recorded in connection with the application of ASC 842 for Oncocyte's operating and financing leases (see Note 2 for additional policy information).

Financing Leases

As of December 31, 2024, Oncocyte had various financing leases for certain laboratory equipment, as shown in the tables below. As of December 31, 2023, Oncocyte had no financing lease obligations. Oncocyte's lease obligations are collateralized by the equipment financed under the lease schedules. In January 2025, the Company entered into a new financing lease arrangement for laptop computers, over a 36 month term and aggregate payments of approximately \$98,000.

ONCOCYTE CORPORATION
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

Operating and Financing Leases

The following table presents supplemental balance sheet information related to operating and financing leases:

	December 31,	
	2024	2023
	(In thousands)	
Operating leases		
Right-of-use assets, net	\$ 1,789	\$ 1,637
Right-of-use lease liabilities, current	\$ 914	\$ 628
Right-of-use lease liabilities, noncurrent	1,713	2,102
Total operating lease liabilities	\$ 2,627	\$ 2,730
Financing leases		
Machinery and equipment	\$ 1,673	\$ 537
Accumulated depreciation	(705)	(537)
Machinery and equipment, net	\$ 968	\$ —
Current liabilities	\$ 381	\$ —
Noncurrent liabilities	554	—
Total financing lease liabilities	\$ 935	\$ —
Weighted average remaining lease term:		
Operating lease	2.6 years	3.7 years
Financing lease	2.4 years	n/a
Weighted average discount rate:		
Operating lease	10.44 %	11.31 %
Financing lease	10.23 %	n/a

Future minimum lease commitments are as follows:

	Operating Leases	Financing Leases
	(In thousands)	
Year Ending December 31,		
2025	\$ 1,144	\$ 455
2026	1,182	400
2027	695	191
Total minimum lease payments	3,021	1,046
Less amounts representing interest	(394)	(111)
Present value of net minimum lease payments	\$ 2,627	\$ 935

The following table presents supplemental cash flow information related to operating and financing leases:

	Years Ended December 31,	
	2024	2023
	(In thousands)	
Cash paid for amounts included in the measurement of lease liabilities:		
Operating cash flows from operating leases	\$ 1,106	\$ 1,048
Operating cash flows from financing leases	\$ 42	\$ 7
Financing cash flows from financing leases	\$ 201	\$ 117

ONCOCYTE CORPORATION
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

The Company incurred total lease cost, including short-term lease expense, of \$607,000 and \$842,000, which was net of sublease income of \$442,000 and \$64,000, for the years ended December 31, 2024 and 2023, respectively.

Litigation – General

Oncocyte may 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.

On March 3, 2025, the Company received a letter claiming that a recent study regarding the Company's DetermaIO immuno-oncology assay for breast cancer had triggered the Company's first milestone payment obligation under the January 10, 2020 Agreement and Plan of Merger between the Company, Insight Genetics, Inc., and certain other parties. The Company strongly disputes the position taken in the letter, believes the arguments to be ill-founded, and intends to vigorously defend its own position. More information regarding the milestone payments related to the Insight Genetics acquisition may be found in Note 3, "Business Combinations and Contingent Consideration Liabilities."

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. See Note 12, "Income Taxes" for additional information.

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 in the respective contracts, and certain terminations of executives. As of December 31, 2024 and 2023, Oncocyte accrued approximately \$2.3 million and \$2.5 million, respectively, in severance obligations for certain executive officers, in accordance with the severance benefit provisions of their respective employment and severance benefit agreements, primarily related to Oncocyte's acquisition of Chronix in 2021. For the periods presented, management has classified \$2.3 million of the accrued severance obligations related to the Chronix acquisition as current and noncurrent based on our expectations of the timing of product commercialization and subsequent revenues that trigger the payouts. Such balances are included in the consolidated balance sheets under contingent consideration liabilities, current and noncurrent. See Note 3, "Business Combinations and Contingent Consideration – Acquisition of Chronix Biomedical, Inc." for additional information.

ONCOCYTE CORPORATION
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

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 Razor Stock Purchase Agreement also contains provisions under which Oncocyte has agreed to indemnify Razor and Encore Clinical, Inc., a former stockholder of Razor, 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 Razor Stock Purchase Agreement. Oncocyte periodically enters into underwriting and securities sales agreements with broker-dealers in connection with the offer and sale of Oncocyte securities. The terms of those underwriting and securities sales agreements include indemnification provisions pursuant to which Oncocyte agrees to indemnify the broker-dealers from certain liabilities, including liabilities arising under the Securities Act of 1933, as amended (the "Securities Act"), in connection with the offer and sale of Oncocyte securities. 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, 2024 and 2023.

7. Series A Redeemable Convertible Preferred Stock and Shareholders' Equity

Series A Redeemable Convertible Preferred Stock

On April 13, 2022, the Company entered into a Securities Purchase Agreement with institutional accredited investors (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 384,477 shares of the Company's common stock, at a conversion price of \$30.60 per share. 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 provided that the closing of the Series A Preferred Stock offering will occur, subject to the satisfaction 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 did not occur due to certain closing conditions.

The Series A Preferred Stock was convertible into shares of the Company's common stock at any time at the holder's option. The conversion price would 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 was 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 Stock Market LLC ("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. ("Broadwood").

In the event of the Company's liquidation, dissolution, or winding up, holders of Series A Preferred Stock would have received 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.

ONCOCYTE CORPORATION
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

Shares of Series A Preferred Stock generally had 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 would be required to amend any provision of our certificate of incorporation that would have had 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 remained 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, were 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 prohibited, prevented, or otherwise limited 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 were 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 was 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) and (4) at the election and upon notice of 51% in interest of the holders, if the Company failed to meet the Cash Minimum Requirement. Additionally, the Company had 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.

On April 5, 2023, the Company redeemed 1,064 shares of the Series A Preferred Stock for approximately \$1.1 million (see “Common Stock – April 2023 Offering” below). In connection with the April 2023 redemption, the Company recorded a deemed dividend of \$118,000 based on the difference between the Series A Preferred Stock redemption value and carrying value. On April 15, 2024, Company redeemed the remaining 4,818 shares of the Series A Preferred Stock for approximately \$5.4 million (see “Common Stock – April 2024 Offering” below). As of April 15, 2024, the Company accreted dividends of \$570,000, net of the April 2023 redemption.

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 (“SEC”) 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.

As of December 31, 2024 and 2023, Oncocyte had zero and 4,818 shares of the Series A Preferred Stock issued and outstanding, respectively.

Preferred Stock

As of December 31, 2024 and 2023, Oncocyte had 5,000,000 shares of preferred stock, no-par value, authorized. As of December 31, 2024 and 2023, Oncocyte had no shares of preferred stock issued and outstanding.

Common Stock

As of December 31, 2024 and 2023, Oncocyte had 230,000,000 shares of common stock, no-par value, authorized. As of December 31, 2024 and 2023, Oncocyte had 17,452,824 and 8,261,073 shares of common stock issued and outstanding, respectively.

ONCOCYTE CORPORATION
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

April 2023 Offering

On April 3, 2023, the Company entered into an agreement (the “April 2023 Offering”) with several institutional and accredited investors, including Broadwood, 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 2,278,121 shares of the Company’s common stock at an offering price of \$7.08 per share to board members and \$6.03 per share to the other investors participating in the April 2023 Offering. The April 2023 Offering was intended to be priced at-the-market for purposes of complying with applicable Nasdaq Listing Rules. The Company issued an aggregate of 2,274,709 shares of common stock from this offering, as further discussed in Note 9, “Related Party Transactions.” 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 Preferred Stock.

April 2024 Offering

On April 15, 2024, the Company consummated a private placement of its securities to certain accredited investors for the issuance and sale of 5,076,900 shares of the Company’s common stock and Pre-Funded Warrants to purchase 342,888 shares of the Company’s common stock, with an exercise price of \$0.0001 per share. The purchase price for one common share was \$2.9164, and the purchase price for one Pre-Funded Warrant was \$2.9163. Certain insiders of the Company subscribed for 42,373 of the shares of common stock sold in the private placement, at a purchase price of \$2.95 per share (see Note 9). The related securities purchase agreement contains customary representations, warranties and agreements by the Company, indemnification obligations of the Company and the accredited investors, including for liabilities under the Securities Act, other obligations of the parties and termination provisions.

A holder of the Pre-Funded Warrants may not exercise any portion of such holder’s Pre-Funded Warrants to the extent that the holder, together with its affiliates, would beneficially own more than 4.99% (or, at the election of the holder, 9.99%) of the Company’s outstanding shares of common stock immediately after exercise, except that upon at least 61 days’ prior notice from the holder to the Company, the holder may increase the beneficial ownership limitation to up to 9.99% of the number of shares of common stock outstanding immediately after giving effect to the exercise. The Pre-Funded Warrants are exercisable immediately and will expire when exercised in full. As of December 31, 2024, none of such Pre-Funded Warrants have been exercised. See Note 9 “Related Party Transactions” for additional information.

The gross proceeds to the Company from the April 2024 Offering were approximately \$15.8 million, before deducting approximately \$538,000 in placement agent fees and expenses and offering expenses payable by the Company. The Company used the net proceeds received for general corporate purposes and working capital. In addition, approximately \$5.4 million of the net proceeds was used to redeem the outstanding shares of the Company’s Series A Redeemable Convertible Preferred Stock.

August 2024 Offering

On August 9, 2024, the Company entered into a sales agreement with a sales agent, pursuant to which the Company could offer and sell from time to time up to an aggregate of \$7.5 million of shares of the Company’s common stock (the “Placement Shares”), through the sales agent.

Sales of the Placement Shares were made in sales deemed to be “at-the-market offerings” as defined in Rule 415 promulgated under the Securities Act. The sales agent used commercially reasonable efforts to sell, on the Company’s behalf, all of the Placement Shares requested to be sold by the Company, consistent with its normal trading and sales practices, the terms of the sales agreement, and applicable law and regulations. The Company could also sell Placement Shares to the sales agent as principal in negotiated transactions. The Company had no obligation to sell any Placement Shares, and could at any time suspend offers under the sales agreement or terminate the sales agreement. The Company is using the net proceeds from this offering for working capital and other general corporate purposes. The sales agreement will terminate, and offer and sale of the Placement Shares pursuant to the sales agreement will cease, upon the earlier of (a) the issuance and sale of all of the Placement Shares subject to the sales agreement or (b) the termination of the sales agreement by the sales agent or the Company pursuant to the terms thereof. The sales agreement contained customary representations, warranties and agreements by the Company, as well as indemnification obligations of the Company for certain liabilities under the Securities Act. On February 8, 2025, the Company terminated the sales agreement. As a result, the Company may not make any further sales pursuant to such sales agreement. See Note 14, “Subsequent Events” for additional information.

ONCOCYTE CORPORATION
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

Under the terms of the sales agreement, the Company paid the sales agent a commission equal to 3.0% of the aggregate gross proceeds from each sale of Placement Shares. As of December 31, 2024, the Company had sold 610,622 Placement Shares for net proceeds of approximately \$1.7 million, at an average purchase price of \$3.05 per share. In addition, the Company agreed to pay certain expenses incurred by the sales agent in connection with the offering. Total offering expenses incurred in the amount of \$367,000 are being deferred and expensed ratably over a one year period. As of December 31, 2024, the remaining deferred financing costs of \$279,000 are included in deferred financing costs in the consolidated balance sheet.

The Placement Shares were registered under the Securities Act pursuant to the registration statement on Form S-3 (File No. 333-281159) filed with the SEC on August 1, 2024 and declared effective by the SEC on August 7, 2024, the base prospectus contained within the registration statement, and a prospectus supplement dated August 9, 2024.

October 2024 Offering

On October 4, 2024, the Company consummated a private placement of its securities to certain accredited investors for the issuance and sale of 3,461,138 shares of the Company's common stock. The purchase price for one common share was \$2.948. Certain insiders of the Company subscribed for 37,037 of the shares of common stock sold in the private placement, at a purchase price of \$2.97 per share. The related securities purchase agreement contains customary representations, warranties and agreements by the Company, indemnification obligations of the Company and the investors, including for liabilities under the Securities Act, other obligations of the parties and termination provisions.

The gross proceeds to the Company from the October 2024 Offering were approximately \$10.2 million, before deducting approximately \$836,000 in placement agent fees and expenses and offering expenses payable by the Company. The Company is using the net proceeds received of approximately \$9.4 million for general corporate purposes and working capital.

February 2025 Offering

On February 10, 2025, the Company consummated the February 2025 Offering. The aggregate gross proceeds from the February 2025 Offering were approximately \$29.1 million. After deducting offering expenses payable by the Company of \$480,000, the resulting net proceeds were approximately \$28.7 million. See Note 14, "Subsequent Events – Private Placement Transaction" and "Subsequent Events – Registered Direct Offering" for additional information.

Unregistered Restricted Stock Issuance

During the year ended December 31, 2024, the Company issued 26,664 shares of restricted common stock in connection with an ongoing investor relations consulting service arrangement for a total fair value of \$72,000. During the year ended December 31, 2023, the Company issued 9,091 shares of restricted common stock to this consulting firm for a total fair value of \$36,000. The Company has issued additional RSUs to this consulting firm under the Company's Amended and Restated 2018 Incentive Plan, refer to Note 8, "Stock-Based Compensation" for additional information.

Common Stock Purchase Warrants

As of December 31, 2024 and 2023, Oncocyte had common stock purchase warrants issued and outstanding of 760,866 and 819,767, respectively. During the year ended December 31, 2024, 58,901 warrants expired. As of December 31, 2024, the outstanding warrants had exercise prices ranging from \$30.60 to \$109.20 per share, are set to expire on various dates ranging from February 2027 to October 2029 and have a weighted average remaining life of 2.31 years. 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 Bank Warrants discussed below 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. All of the outstanding warrants meet the equity classification criteria and have been classified as equity, refer to Note 2, "Accounting for Warrants" for additional information.

ONCOCYTE CORPORATION
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

In connection with the April 2024 Offering, discussed above, the Company issued Pre-Funded Warrants to purchase 342,888 shares of common stock. For accounting purposes, the Pre-Funded Warrants are equity-classified, contain no contingencies to exercise and are therefore considered outstanding for purposes of calculating basic earnings per share. As of December 31, 2024, none of such Pre-Funded Warrants have been exercised. In connection with the February 2025 Offering, the Company issued additional pre-funded warrants to purchase 3,069,925 shares of common stock (see Note 14, “Subsequent Events – Private Placement Transaction” for additional information).

Bank Warrants

In connection with a loan that matured in September 2022 from Silicon Valley Bank (the “Bank”), in February 2017, Oncocyte issued common stock purchase warrants to the Bank (the “2017 Bank Warrants”). The Bank was issued warrants to purchase 412 shares of Oncocyte common stock at an exercise price of \$97.00 per share, through February 21, 2027. In March 2017, the Bank was issued warrants to purchase an additional 366 shares at an exercise price of \$109.20 per share, through March 23, 2027. In October 2019, Oncocyte issued a common stock purchase warrant to the Bank (the “2019 Bank Warrant”) entitling the Bank to purchase 4,928 shares of Oncocyte common stock at an exercise price of \$33.80 per share, through October 17, 2029. The Bank may elect to exercise the 2017 Bank Warrants and 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 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. These warrants meet the equity classification criteria and have been classified as equity. As of December 31, 2024, no Bank Warrants have been exercised.

8. Stock-Based Compensation

Equity Incentive Plan

In August 2018, Oncocyte shareholders approved a new Equity Incentive Plan to replace the 2010 Stock Option Plan (the “2010 Plan”) and on October 11, 2024, Oncocyte shareholders approved an amendment and restatement of such new Equity Incentive Plan (as amended and restated, the “2018 Incentive Plan”). The 2018 Incentive Plan will expire on July 2, 2028. In initially adopting the 2018 Incentive Plan, Oncocyte terminated the 2010 Plan and ceased to 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 continue in effect in accordance with their terms and the terms of the 2010 Plan until the exercise or expiration of the individual options. Total remaining stock options outstanding under the 2010 Plan as of December 31, 2024 and 2023 were 16,217.

As of December 31, 2024, 2,560,000 aggregate shares of common stock have been reserved for issuance under the equity incentive plans for the grant of stock options or the sale of restricted stock or for the settlement of RSUs. Oncocyte may also grant stock appreciation rights under the 2018 Incentive Plan. Upon the exercise of stock options, the issuance of RSAs, or the delivery of shares pursuant to vested RSUs or performance-based restricted stock units (“PSUs”), it is Oncocyte’s policy to issue new shares of common stock. The Board may amend or modify the 2018 Incentive Plan at any time, subject to any required stockholder approval. As of December 31, 2024, 1,026,314 shares were available for grant under the 2018 Incentive Plan.

ONCOCYTE CORPORATION
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

Plan Activity

A summary of Oncocyte's 2010 Plan and 2018 Incentive Plan activity and related information follows:

	Options				Nonvested RSUs	
	Number Outstanding	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life	Aggregate Intrinsic Value	Number Outstanding	Weighted Average Grant Date Fair Value
	(In thousands, except weighted average amounts)					
Balance at December 31, 2023	532	\$ 24.56	8.30 years	\$ —	5	\$ 4.00
Options granted	604	\$ 2.83			n/a	n/a
RSUs and PSUs granted	n/a	n/a			113	\$ 1.85
Options exercised	—	\$ —		\$ —	n/a	n/a
RSUs and PSUs vested	n/a	n/a			(17)	\$ 3.10
Options forfeited/expired	(45)	\$ 26.74			n/a	n/a
RSUs forfeited	n/a	n/a			(1)	\$ 4.00
Balance at December 31, 2024	1,091	\$ 12.42	8.56 years	\$ —	100	\$ 1.73
Options vested and expected to vest at December 31, 2024	1,091	\$ 12.42	8.56 years	\$ —		
Options exercisable at December 31, 2024	246	\$ 40.77	6.27 years	\$ —		
Stock-based compensation expense for the period	\$ 1,731				\$ 22	
Unrecognized stock-based compensation expense	\$ 2,029				\$ 156	
Weighted average remaining recognition period	2.31 years				2.00 years	

Option Awards

During the year ended December 31, 2024, the Company granted 604,000 total stock options with a weighted average grant date fair value of \$2.13. During the year ended December 31, 2023, the Company granted 354,790 total stock options with a weighted average grant date fair value of \$4.13.

During the years ended December 31, 2024 and 2023, the assumptions used to calculate the grant date fair value for the time-based awards of 604,000 and 234,790, respectively, were as follows:

	Years Ended December 31,	
	2024	2023
Expected life	7.37 years	6.24 years
Risk-free interest rates	4.31 %	3.99 %
Volatility	106.32 %	107.05 %
Dividend yield	0 %	0 %

In October 2024, the Company awarded a 200,000 stock option grant with standard time-based vesting conditions, a grant date market price of \$3.05 and an exercise price of \$2.87 to a Company executive. The fair value of such award was estimated using the Monte Carlo simulation model and the following assumptions: estimated risk-free interest rate of 4.10 percent; term of 9.7 years; expected volatility of 105.0 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 term is based on the contractual life. The expected stock price volatility was determined using historical volatility. The expected dividend yield was based on expectations regarding dividend payments. The grant date fair value of the award was \$1.65, amounting to a total fair value of \$330,000.

ONCOCYTE CORPORATION
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

In August 2023, the Company awarded 120,000 stock option grants with market-based and time-based vesting conditions to certain executives. The fair value of such awards 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 executives through December 31, 2025. These awards vest only to the extent that the market-based conditions are satisfied as specified in the vesting conditions. 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-based conditions. Assumptions utilized in connection with the Monte Carlo valuation technique included: estimated risk-free interest rate of 4.81 percent; term of 6.19 years; expected volatility of 91.0 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. Based on the market-based conditions, the grant date fair values of these awards ranged from \$1.09 to \$1.74, amounting to a total fair value of approximately \$156,000. As of December 31, 2024, no awards have vested as none of the market-based conditions have been satisfied.

RSU Awards

The aggregate fair value of RSUs vested during the years ended December 31, 2024 and 2023, was \$47,000 and \$88,000, respectively. The weighted average grant date fair value of RSUs granted during the years ended December 31, 2024 and 2023, was \$1.85 and \$4.00, respectively.

In October 2024, the Company awarded 100,000 PSUs with market-based and service-based vesting conditions to a Company executive. Vesting is subject to continuous service as an employee of the Company or a subsidiary thereof from hire date through the applicable vesting date, and shall performance vest as follows: (i) 50% will vest upon the Company's achievement of an aggregate market value of voting and non-voting common equity held by non-affiliates of the Company of \$75.0 million or more, such that the Company is no longer subject to the "Baby Shelf Rules" of Form S-3, and (ii) 50% will vest upon the Company's achievement of a market capitalization of \$200.0 million, which shall be determined based on the 30-day volume weighted average price of the common stock measured as of the end of each full calendar month following the date of grant. No units will vest prior to June 20, 2025, and any units that are not performance vested on December 31, 2026 shall automatically be forfeited. The fair value of such award 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 expected period to achievement of the market conditions. The grant date fair value and associated compensation cost of the market-based award 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-based conditions. Assumptions utilized in connection with the Monte Carlo valuation technique included: estimated risk-free interest rate of 3.93 percent; term of 2.2 years; expected volatility of 90.0 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. Based on the two described performance vesting conditions, the grant date fair values were \$2.03 and \$1.43, respectively, amounting to a total fair value of \$173,000.

In November 2024, the Company issued 12,677 shares of common stock under an immediate vest RSU award in connection with an ongoing investor relations consulting service arrangement for a total fair value of \$36,000. The Company has issued additional restricted shares to this consulting firm under unregistered restricted stock arrangements, refer to Note 7, "Common Stock – Unregistered Restricted Stock Issuance" for additional information. Total shares issued during the years ended December 31, 2024 and 2023, were 39,341 and 9,091, respectively. The total related expense, included in general and administrative expenses, for this consulting firm was \$108,000 and \$36,000 for the years ended December 31, 2024 and 2023, respectively.

ONCOCYTE CORPORATION
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

Stock-Based Compensation Expense

Oncocyte recorded stock-based compensation expense in the following categories on the accompanying consolidated statements of operations:

	Years Ended December 31,	
	2024	2023
	(In thousands)	
Cost of revenues	\$ —	\$ 14
Research and development	810	1,238
Sales and marketing	174	241
General and administrative	769	1,249
Expense included in discontinued operations	—	18
Total	<u>\$ 1,753</u>	<u>\$ 2,760</u>

Total unrecognized stock-based compensation expense as of December 31, 2024 was \$2.2 million, which will be amortized over a weighted average remaining recognition period of 2.29 years.

Other Information

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 periods presented may have been significantly different. Refer to Note 2, “Stock-Based Compensation” for additional information.

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.

9. Related Party Transactions

Financing Transactions

On April 13, 2022, Oncocyte entered into the Securities Purchase Agreement with the Investors, including Broadwood, for the Series A Preferred Stock offering. Broadwood had a direct material interest in the Series A Preferred Stock offering and agreed to purchase 5,882 in the Series A Preferred Stock offering and on the same terms as other investors. In April 2024, Company redeemed the remaining shares of the Series A Preferred Stock, see Note 7 for additional information.

Further, on April 13, 2022, Oncocyte entered into an underwriting agreement pursuant to which the Company agreed to issue and sell certain shares of common stock and warrants to purchase common stock (“April 2022 Warrants”). The April 2022 Warrants have an exercise price of \$30.60 per share and will expire on April 19, 2027. Pursuant to the underwritten offering, Broadwood acquired from us (i) 261,032 shares of common stock, and (ii) 300,187 April 2022 Warrants to purchase up to 150,093 shares of common stock. However, the total number of shares of common stock that Broadwood purchased in the underwritten offering was 300,187, of which 39,154 existing shares were acquired by the underwriters in the open market and re-sold to Broadwood. Pura Vida acquired from us (i) 249,204 shares of common stock, and (ii) 286,585 April 2022 Warrants to purchase up to 143,292 shares of common stock. However, the total number of shares of common stock that Pura Vida purchased in the underwritten offering was 286,585, of which 37,380 existing shares were acquired by the underwriters in the open market and re-sold to Pura Vida.

ONCOCYTE CORPORATION
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

On April 3, 2023, Oncocyte entered into a securities purchase agreement with certain investors, including Broadwood, Pura Vida and entities affiliated with AWM, and certain individuals, including Oncocyte's Chairman, Andrew Arno, and certain of their affiliated parties, which provided for the sale and issuance by the Company of an aggregate of 2,274,709 shares of common stock at an offering price of: (i) \$6.03 to investors who are not considered to be "insiders" of the Company pursuant to Nasdaq Listing Rules ("Insiders"), which amount reflected the average closing price of our common stock on Nasdaq during the five trading day period immediately prior to pricing, and (ii) \$7.08 to Insiders, which amount reflected the final closing price of our common stock on Nasdaq on the last trading day immediately prior to pricing. Broadwood purchased 1,341,381 shares of common stock for \$8,093,362, Pura Vida purchased 33,150 shares of common stock for \$200,014 and entities affiliated with AWM purchased 472,354 shares of common stock for \$2,850,000. Mr. Arno and his affiliated parties purchased 21,162 shares of common stock for \$150,001. See Note 7, "Common Stock – April 2023 Offering" for additional information.

On April 15, 2024, Oncocyte consummated a private placement of its securities to certain investors, including Broadwood, entities affiliated with AWM, Bio-Rad, and certain individuals, including Oncocyte's Chairman, Andrew Arno, for the issuance and sale of 5,076,900 shares of its common stock and Pre-Funded Warrants to purchase 342,888 shares of its common stock. The purchase price for one share of common stock was \$2.9164, and the purchase price for one Pre-Funded Warrant was \$2.9163. Insiders subscribed for 42,373 of the shares of common stock sold in the private placement, at a purchase price of \$2.95 per share of common stock, which amount reflected the final closing price of the common stock on Nasdaq on the last trading day immediately prior to pricing. Broadwood purchased 2,420,000 shares of common stock for \$7,057,688, entities affiliated with AWM purchased 342,889 shares of common stock and 342,889 Pre-Funded Warrants for \$2,000,000, and Bio-Rad purchased 1,200,109 shares of common stock for \$3,499,998. Mr. Arno purchased 33,898 shares of common stock for \$100,000. One of Oncocyte's directors, Andrew Last, served as the Executive Vice President and Chief Operating Officer of Bio-Rad before retiring on September 6, 2024. See Note 7, "Common Stock – April 2024 Offering" for additional information.

On October 4, 2024, Oncocyte consummated the October 2024 Offering involving certain investors, including Broadwood, Bio-Rad, and certain individuals, including Oncocyte's Chief Financial Officer, Andrea James. The gross proceeds from the October 2024 Offering were approximately \$10.2 million. Officers of the Company subscribed for 37,037 of the shares of common stock in the aggregate sold in the October 2024 Offering, at a purchase price of \$2.97 per share of common stock. Broadwood purchased 1,315,339 shares of common stock for approximately \$3,878,000, and Bio-Rad purchased 310,835 shares of common stock for approximately \$916,000. Ms. James purchased 33,670 shares of common stock for \$100,000. See Note 7, "Common Stock – October 2024 Offering" for additional information.

On February 10, 2025, Oncocyte consummated the February 2025 Offering involving certain investors, including Broadwood, Bio-Rad, AWM, Patrick W. Smith, and certain other individuals, including Oncocyte's Chief Financial Officer, Andrea James, and Chief Science Officer, Ekkehard Schütz. The gross proceeds from the February 2025 Offering were approximately \$29.1 million. Officers of the Company subscribed for 109,756 of the shares of common stock in the aggregate sold in the February 2025 Offering, at a purchase price of \$2.05 per share of common stock. Broadwood purchased 5,165,695 shares of common stock for approximately \$10,590,000, Bio-Rad purchased 1,253,134 shares of common stock for approximately \$2,569,000, AWM purchased 2,052,026 shares of common stock and pre-funded warrants to purchase up to 3,069,925 shares of common stock for approximately \$10,500,000, and Patrick W. Smith purchased 1,463,414 shares of common stock for \$3,000,000. Ms. James purchased 97,561 shares of common stock for \$200,000 and Mr. Schütz purchased 12,195 shares of common stock for \$25,000. See Note 14, "Subsequent Events – Private Placement Transaction" and "Subsequent Events – Registered Direct Offering" for additional information.

Bio-Rad Transactions

During 2024, the Company purchased \$538,000 in laboratory equipment and incurred \$413,000 in laboratory related costs from Bio-Rad. During 2024, the Company also made finance lease payments of \$217,000 under four laboratory equipment leases from Bio-Rad with a remaining financing lease liability of \$796,000 as of December 31, 2024. During 2023, the Company purchased \$581,000 in laboratory equipment and incurred \$375,000 in laboratory related costs from Bio-Rad. As of December 31, 2024 and 2023, the Company had accounts payable due to Bio-Rad of \$638,000 and \$206,000, respectively. One of Oncocyte's directors, Andrew Last, served as the Executive Vice President and Chief Operating Officer of Bio-Rad before retiring on September 6, 2024.

ONCOCYTE CORPORATION
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

On April 5, 2024, the Company entered into an agreement with Bio-Rad to collaborate in the development and the commercialization of RUO and IVD kitted transplant products (the “Collaboration Agreement”). Under the Collaboration Agreement, Bio-Rad agreed to purchase shares of our common stock equal to 9.99% of the total number of shares of common stock issued and outstanding immediately after the closing of such investment, provided that the total purchase price would not exceed \$3,500,000 unless Bio-Rad chooses to exceed such limit (the “Bio-Rad Investment”) (see “Financing Transactions” above). The Bio-Rad Investment was completed in connection with a private placement (See Note 7, “Common Stock – April 2024 Offering”). In addition, we will pay Bio-Rad a single digit royalty payment based on certain net sales under the Collaboration Agreement, and Bio-Rad has an option for the exclusive right to promote, market and sell certain kits worldwide subject to certain conditions. If and when such option is exercised, Bio-Rad will purchase additional shares of our common stock, at the then-current market price per share, up to a specified maximum aggregate purchase price. On November 8, 2024, the Company and Bio-Rad entered into a memorandum of understanding with respect to the Collaboration Agreement to establish additional activities to be performed by each party pursuant to the Collaboration Agreement. One of Oncocyte's directors, Dr. Last, recused himself from all Board discussions related to transactions with Bio-Rad. See Note 10, “Collaborative Arrangements” for additional information.

10. Collaborative Arrangements

Bio-Rad

On April 5, 2024, the Company entered into the Collaboration Agreement with Bio-Rad to collaborate in the development and the commercialization of RUO and IVD kitted transplant products using Bio-Rad’s ddPCR instruments and reagents. The Collaboration Agreement has a term of 10 years unless earlier terminated pursuant to customary termination provisions.

The Collaboration Agreement provides that through the oversight of a joint steering committee comprised of representatives from both parties, the parties will collaborate on the development of (i) the Company’s series of GraftAssureIQ™ Transplant Monitoring Assays to measure and test the concentration of donor-derived cell free DNA for RUO (the “RUO Assays”); and (ii) the Company’s GraftAssureDx™ Transplant Monitoring Assays that have received regulatory approval as an in vitro diagnostic device (the “IVD Kits”) for use on one or more Bio-Rad ddPCR instruments. Pursuant to the Collaboration Agreement, and toward the development of the RUO Assays and the IVD Kits, the Company will collect and screen samples, conduct feasibility testing and stability studies, and perform analytical validation, among other things; and Bio-Rad will supply its ddPCR instruments and platforms as well as manufacture and supply all consumables.

Prior to the commercial launch of the RUO Assays, under the Collaboration Agreement, the parties will develop a plan to market and sell the RUO Assays. The Company will be responsible for the manufacture and supply of all RUO Assays, and Bio-Rad will supply to the Company Bio-Rad’s ddPCR instruments and reagents for use in commercializing the RUO Assays, which products will be purchased by the Company exclusively from Bio-Rad. The Company and Bio-Rad will be jointly responsible for co-promoting and co-marketing the RUO Assays within the United States and Germany (the “Territory”). The Company has the exclusive right to sell the RUO Assays in the Territory exclusively with the use of Bio-Rad ddPCR instruments and reagents. Bio-Rad will be responsible for promoting and marketing, and has the exclusive right to sell, the RUO Assays outside the Territory. For the sales of the RUO Assays in the Territory, the Company will pay to Bio-Rad a single digit royalty payment based on net sales. The Company will manufacture and supply the RUO Assays to Bio-Rad for resale outside the Territory.

Additionally, the Collaboration Agreement provides Bio-Rad a 90-day exclusive negotiating period, post regulatory clearance, for the right to exclusively promote, market and sell IVD Kits worldwide subject to certain conditions. If and when such option is exercised, Bio-Rad will purchase additional shares of the Company’s common stock, no par value per share, at the then-current market price per share, up to a specified maximum aggregate purchase price, and the Company will manufacture and supply IVD Kits exclusively for Bio-Rad. See Note 9, “Related Party Transactions” for additional information.

On November 8, 2024, Oncocyte and Bio-Rad entered into a binding Memorandum of Understanding (the “Memorandum”) in connection with the Collaboration Agreement. The Memorandum establishes additional activities (described below) to be performed by Oncocyte and Bio-Rad prior to the commercial launch of the RUO Assays specifically related to pilot study sites outside the Territory (the “Pilot Sites”).

ONCOCYTE CORPORATION
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

Pursuant to the Memorandum, Oncocyte (i) will setup commercialization of Pilot Sites to use the RUO Assays, (ii) may sell RUO Assays to Pilot Sites, (iii) will train and support the Pilot Sites on the use of the RUO Assays, and (iv) if Oncocyte receives any net sales from the sale of the RUO Assays to the Pilot Sites, then Oncocyte shall pay to Bio-Rad a royalty payment based on a percentage of such net sales under the terms and conditions of the Collaboration Agreement. In addition, pursuant to the Memorandum, Bio-Rad will evaluate commercialization efforts for the RUO Assays, which will include (i) supporting installation and training for Pilot Sites, and (ii) evaluating distribution of the RUO Assays to Pilot Sites.

For the year ended December 31, 2024, the income statement amounts attributable to Bio-Rad transactions arising from the Collaboration Agreement, included in research and development expenses, sales and marketing expenses, general and administrative expenses, and interest expense, in the aggregate have not been significant. Beginning in September 2024, the Company has capitalized certain inventory costs (see Note 2 “Inventories” for additional information).

Life Technologies Corporation

In January 2022, Oncocyte entered into a collaboration agreement (the “LTC Agreement”) with Life Technologies Corporation, a Delaware corporation and subsidiary of Thermo Fisher Scientific (“LTC”), in order to partner in the development and collaborate in the commercialization of Thermo Fisher Scientific’s existing Oncomine Comprehensive Assay Plus and Oncocyte’s DetermaIO assay for use with LTC’s Ion Torrent™ Genexus™ Integrated Sequencer and LTC’s Ion Torrent™ Genexus™ Purification System in order to obtain IVD regulatory approval. In February 2023, Oncocyte entered into a Termination Agreement with LTC, pursuant to which the parties terminated the LTC Agreement. As of the termination date, Oncocyte was responsible for reimbursing LTC for \$749,000 of certain development costs under the terms of the LTC Agreement, which were fully paid in 2023.

11. Segment Reporting

As of December 31, 2024, the Company operates and reports its results in one reportable segment, on a consolidated basis. The Company reports segment information based on the management approach and organizes its business based on products and services. The management approach designates the internal reporting information regularly reviewed by the chief operating decision maker (the “CODM”) to make decisions about resources to be allocated to the segment and assess its performance as the basis for determining a company’s reportable segments. The Company’s CODM is the senior executive management team that includes the Chief Executive Officer and Chief Financial Officer. Oncocyte is an early-stage diagnostics technology company with core operations that include the research, development and commercialization of diagnostic tests. Currently, the Company’s revenues include Pharma Services from its pharmaceutical customers, including testing for biomarker discovery, assay design and development, clinical trial support, and a broad spectrum of biomarker tests, and to a lesser extent from performing Laboratory Developed Test Services (see Note 2, “Revenue Recognition” for additional information). Additionally, the Company is primarily focused on developing and commercializing new diagnostic tests for medical use related to organ transplant and in the field of oncology, accordingly, extensive resources, time and expense will be required to complete the development and commercialization of those tests.

Adjusted income or loss from operations is the measure of segment profit or loss that the CODM uses in assessing segment performance and deciding how to allocate resources. Adjusted income or loss from operations is used to monitor budget versus actual results and for long range planning. Segment loss from operations in the table below includes revenues, cost of revenues, research and development, and other significant operating expenses directly attributable to our reportable segment. Such operating expenses exclude depreciation and amortization expenses, stock-based compensation, the change in fair value of contingent consideration, and impairments. As an early-stage company with limited revenue, management believes this measure of profit or loss is helpful in assessing our ongoing performance, providing insight into the Company’s core operating costs and performance by excluding certain noncash items that may obscure the underlying trends in the business. The reconciling items and significant segment expense categories and amounts, as included in the table below, are based on the Company’s internal general ledger reporting system that is used in preparing our consolidated financial statements and are included in determining the measure of segment profit or loss that is used by the CODM.

The measure of segment assets is reported on the consolidated balance sheets as total assets. Total segment expenditures for additions to long-lived assets is reported on the consolidated statements of cash flows as a component of cash used in investing activities.

ONCOCYTE CORPORATION
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

The Company's single reportable segment profit or loss information is as follows:

	Years Ended December 31,	
	2024	2023
	(In thousands)	
Pharma Services	\$ 1,859	\$ 1,467
Laboratory Developed Test Services	22	36
Total net revenues	1,881	1,503
Less:		
Cost of revenues	983	925
Personnel-related expenses and board fees	11,000	8,927
Professional fees, legal, and outside services	3,994	3,795
Facilities and insurance	3,085	3,377
Laboratory supplies and expenses	1,826	1,676
Marketing and advertising	257	187
Other segment items ⁽¹⁾	666	1,052
Segment loss from operations	(19,930)	(18,436)
Reconciliation of segment profit and loss:		
Depreciation and amortization expenses	(1,564)	(1,680)
Stock-based compensation	(1,753)	(2,742)
Change in fair value of contingent consideration	4,275	5,762
Impairment losses	(41,900)	(6,757)
Impairment loss on held for sale assets	(169)	(1,283)
Loss from operations	(61,041)	(25,136)
Interest expense	(84)	(52)
Other income, net	462	333
Loss from discontinued operations	—	(2,926)
Net loss	\$ (60,663)	\$ (27,781)

⁽¹⁾ Other segment items primarily includes travel and entertainment related expenses, delivery expenses, other business taxes, clinical trial expenses and severance costs.

The Company's revenues and long-lived tangible assets by geographic area are presented below. Revenues are based on the customer country of domicile. Assets are based on the location of held assets.

	Years Ended December 31,	
	2024	2023
	(In thousands)	
Revenues by geographic area:		
United States	\$ 1,673	\$ 923
Germany	18	—
Spain	—	11
United Kingdom	45	409
Asia-Pacific	145	160
Total net revenues	\$ 1,881	\$ 1,503

ONCOCYTE CORPORATION
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

	December 31,	
	2024	2023
	(In thousands)	
Long-lived tangible assets by geographic area:		
United States	\$ 5,543	\$ 5,370
Germany	340	66
Switzerland	271	—
Asia-Pacific	170	—
Total	\$ 6,324	\$ 5,436

12. Income Taxes

In 2024, the Company incurred \$60.7 million of pretax book losses in the United States and \$37,000 of net operating income internationally from continuing operations. In 2023, the Company incurred \$24.9 million of pretax book losses in the United States and \$12,000 of net operating income internationally from continuing operations.

The Company did not record any provision or benefit for income taxes for the years ended December 31, 2024 and 2023, as the Company had a full valuation allowance for the periods presented. Oncocyte will file a consolidated return with its subsidiaries for the year ended December 31, 2024.

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 were as follows:

	December 31,	
	2024	2023
	(In thousands)	
Deferred tax assets:		
Net operating loss carryforwards	\$ 49,953	\$ 61,760
Research and development credit carryforwards	1,951	4,054
Stock-based and other compensation	1,997	2,368
Right-of-use liability	828	756
Razor investment	2,303	2,303
Capitalized R&D ⁽¹⁾	6,711	6,026
Capital loss carryforward	5,372	5,372
Other	1	8
Total deferred tax assets	69,116	82,647
Valuation allowance	(64,436)	(67,314)
Deferred tax assets, net of valuation allowance	4,680	15,333
Deferred tax liabilities:		
Right-of-use asset	(564)	(453)
Intangibles and fixed assets	(4,116)	(14,880)
Total deferred tax liabilities	(4,680)	(15,333)
Net deferred taxes	\$ —	\$ —

⁽¹⁾ Relates to research and development expenditures required to be capitalized as of December 31, 2024 and 2023.

ONCOCYTE CORPORATION
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

Income taxes differed from the amounts computed by applying the applicable U.S. federal income tax rates indicated to pretax losses. A reconciliation of the difference between the federal statutory tax rates and the Company's effective tax rates from continuing operations is as follows:

	Years Ended December 31,	
	2024	2023
Computed tax benefit at federal statutory rate	21 %	21 %
State tax benefit	(4)%	13 %
Research and development credits	0 %	1 %
Change in fair value of contingent consideration	2 %	5 %
Change in valuation allowance	5 %	(48)%
Stock-based compensation	(1)%	(11)%
Officers compensation	0 %	2 %
Razor investment	0 %	19 %
Expiring tax attributes	0 %	(2)%
Section 382 limitation	(23)%	0 %
Total	<u>0 %</u>	<u>(0)%</u>

As of December 31, 2024, Oncocyte had net operating loss ("NOL") carryforwards of approximately \$208.6 million for U.S. federal income tax purposes and \$78.5 million for state income tax purposes. The federal net operating losses generated on or prior to December 31, 2017 expire in varying amounts, while the federal net operating losses generated after December 31, 2017 carryforward indefinitely. The state net operating losses expire in varying amounts between 2029 and 2044. Oncocyte also has capital loss carryforwards of approximately \$25.7 million, for both federal and state income tax purposes, which expire in 2028.

As of December 31, 2024, Oncocyte has research and development credit carryforwards for federal and state purposes of \$151,000 and \$2.9 million, respectively. The federal credits will expire in 2044, 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. Oncocyte has 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 a \$2.9 million decrease and a \$12.9 million increase for the years ended December 31, 2024 and 2023, respectively.

Oncocyte has unrecognized tax benefits ("UTBs") totaling \$1.1 million and \$2.3 million as of December 31, 2024 and 2023, respectively, which were netted against deferred tax assets subject to a valuation allowance. 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, 2024 and 2023. Oncocyte's management does not expect its UTBs to change significantly over the next twelve months.

A reconciliation of the annual beginning and ending UTBs is as follows:

	Years Ended December 31,	
	2024	2023
	(In thousands)	
Balance at the beginning of the year	\$ 2,296	\$ 1,921
Additions based on tax positions related to current year	189	375
Adjustments based on tax positions related to prior years	(1,398)	—
Settlements	—	—
Balance at end of year	<u>\$ 1,087</u>	<u>\$ 2,296</u>

ONCOCYTE CORPORATION
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

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. Oncocyte has performed a 382 analysis as of December 31, 2024 and determined an ownership change as of October 2024. The federal and state NOL and tax credit carryforwards are stated net of any such anticipated limitations.

In general, Oncocyte is no longer subject to tax examination by the Internal Revenue Service or state taxing authorities for years before 2020. 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.

13. Discontinued Operations of Razor

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 was approximately 70% of the issued and outstanding equity interests of Razor on a fully-diluted basis. On February 16, 2023, Oncocyte completed the Razor Sale Transaction. In connection with the Razor Closing, Oncocyte transferred to Razor all of the assets and liabilities related to DetermaRx. Refer to additional Razor information in Note 1.

In addition to the transfer of 70% of the equity interests of Razor, the Razor Stock Purchase Agreement provided that Dragon would purchase furniture, fixtures and equipment from the Company for a cash consideration of approximately \$116,000. Upon the Razor Closing, the Company deconsolidated the assets and liabilities of Razor as control of Razor had transferred to Dragon.

The Company recorded the final adjustment related to the disposal, including final working capital adjustments, and recognized an impairment loss of \$1.3 million during the first quarter of 2023. Including the impairment losses we recognized as of December 31, 2022 related to this transaction, we recorded an overall impairment loss of \$27.2 million.

The operating results for Razor have been recorded in discontinued operations of the accompanying 2023 consolidated statement of operations and we have reclassified the remaining liabilities as discontinued operations in the accompanying balance sheet. The 2023 discontinued operations reflect operating results of Razor up to the closing of the sale.

The Company’s 2023 consolidated balance sheet and consolidated statement of operations report discontinued operations separate from continuing operations. Our 2023 consolidated statement of comprehensive loss, statement of shareholders’ equity and statement of cash flows combined continuing and discontinued operations. A summary of financial information related to the Company’s discontinued operations is as follows.

As of December 31, 2023, the Company’s consolidated balance sheet included \$45,000 in accounts payable related to discontinued operations, which was paid during the first quarter of 2024.

ONCOCYTE CORPORATION
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

The following table represents the results of the discontinued operations of Razor:

	Year Ended December 31, 2023 (In thousands)
Net revenue	\$ 421
Cost of revenues	507
Research and development	702
Sales and marketing	498
General and administrative	329
Loss from impairment of held for sale assets	1,311
Net loss from discontinued operations	<u>\$ (2,926)</u>

The following table summarizes cash used related to the discontinued operations of Razor:

	Year Ended December 31, 2023 (In thousands)
CASH FLOWS FROM OPERATING ACTIVITIES:	
Net cash used in operating activities	<u>\$ (2,985)</u>
CASH FLOWS FROM INVESTING ACTIVITIES:	
Net cash used in investing activities	<u>\$ (1,372)</u>

14. Subsequent Events

Private Placement Transaction

On February 7, 2025, the Company entered into a securities purchase agreement (the “PIPE Purchase Agreement”) with certain accredited investors for the issuance and sale in a private placement of an aggregate of 7,536,708 shares of common stock of the Company, no par value per share, and pre-funded warrants to purchase up to 3,069,925 shares of common stock, with an exercise price of \$0.0001 per share. The purchase price for one common share was \$2.05, and the purchase price for one pre-funded warrant was \$2.05. Certain officers of the Company subscribed for 109,756 of the shares of common stock sold in the private placement, at a purchase price of \$2.05 per share. The closing of the private placement occurred on February 10, 2025. The PIPE Purchase Agreement contains customary representations, warranties and agreements by the Company, indemnification obligations of the Company and the investors, including for liabilities under the Securities Act, other obligations of the parties and termination provisions.

A holder of the pre-funded warrants may not exercise any portion of such holder’s pre-funded warrants to the extent that the holder, together with its affiliates, would beneficially own more than 4.99% (or, at the election of the holder, 9.99%) of the Company’s outstanding shares of common stock immediately after exercise, except that upon at least 61 days’ prior notice from the holder to the Company, the holder may increase the beneficial ownership limitation to up to 9.99% of the number of shares of common stock outstanding immediately after giving effect to the exercise.

The gross proceeds to the Company from the private placement were approximately \$21.7 million, before deducting offering expenses payable by the Company. The Company is using the net proceeds received for general corporate purposes and working capital.

ONCOCYTE CORPORATION
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

Registered Direct Offering

Concurrently with the execution and delivery of the PIPE Purchase Agreement, on February 7, 2025, the Company entered into a securities purchase agreement (the “RD Purchase Agreement”) with certain investors, pursuant to which the Company agreed to issue and sell, in a registered direct offering priced at-the-market under the rules of The Nasdaq Stock Market (the “Registered Offering”), an aggregate of 3,609,755 shares of common stock. The purchase price for one common share was \$2.05. The closing of the Registered Offering occurred on February 10, 2025. The RD Purchase Agreement contains customary representations, warranties and agreements by the Company, indemnification obligations of the Company and the investors, including for liabilities under the Securities Act, other obligations of the parties and termination provisions.

The gross proceeds to the Company from the Registered Offering were approximately \$7.4 million, before deducting offering expenses payable by the Company. The Company is using the net proceeds received for general corporate purposes and working capital.

The shares of common stock were offered by the Company pursuant to its shelf registration statement on Form S-3 (File No. 333-281159), which was filed with the SEC on August 1, 2024, and declared effective by the SEC on August 7, 2024, including the base prospectus contained therein, and a related prospectus supplement, dated February 7, 2025, filed with the SEC on February 10, 2025.

The aggregate gross proceeds from the private placement and Registered Offering were approximately \$29.1 million. After deducting offering expenses payable by the Company of \$480,000, the resulting net proceeds were approximately \$28.7 million.

Termination of At-the-Market Offering

On February 6, 2025, the Company provided notice of its intention to terminate that certain sales agreement dated as of August 9, 2024 (see Note 7, “August 2024 Offering”), pursuant to which, the Company could offer and sell from time to time up to an aggregate of \$7.5 million of common stock through a sales agent in transactions deemed to be “at-the-market” offerings as defined in Rule 415(a)(4) of the Securities Act, effective immediately. As a result, on February 8, 2025, the sales agreement terminated in accordance with its terms. Prior to the termination of the sales agreement, the Company sold an aggregate of \$1.8 million of its common stock under the sales agreement.

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 preferred stock, no par value. The Preferred Stock may be issued in one or more series as the Oncocyte Board of Directors may by resolution designate. The Oncocyte Board of 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 of 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.

Series A Convertible Preferred Stock

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 ranked 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 had 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 were 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 remained 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, was 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 was 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 the Company or its assets, (3) a Change of Control Transaction (as defined) and (4) at the election and upon notice of 51% in interest of the holders, if the Company failed to meet the Cash Minimum Requirement. Additionally, the Company had 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 Investors will have the right to participate in such financing.

On April 5, 2023, Oncocyte redeemed 1,064 shares of the Series A Convertible Preferred Stock for approximately \$1.1 million. On April 15, 2024, Oncocyte redeemed the remaining 4,818 shares of the Series A Convertible Preferred Stock for approximately \$5.4 million.

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 December 31, 2024, the Company has outstanding warrants to purchase 760,866 shares of the Company's common stock. The warrants are exercisable at prices ranging from \$30.60 to \$109.20 per share and expire on dates ranging from February 2027 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.

In April 2024, the Company issued pre-funded warrants to purchase 342,888 shares of common stock to a certain investor. In February 2025, the Company issued additional pre-funded warrants to purchase 3,069,925 shares of common stock to funds associated with the same investor. For accounting purposes, the pre-funded warrants are equity-classified, contain no contingencies to exercise and are therefore considered outstanding for purposes of calculating basic earnings per share. As of December 31, 2024, none of such pre-funded warrants have been exercised.

ONCOCYTE CORPORATION**INSIDER TRADING POLICY****February 2025**

Federal and state securities laws prohibit the purchase or sale of a company's securities by persons who are aware of material information about that company that is not generally known or available to the public. These laws also prohibit persons who are aware of such material nonpublic information from disclosing this information to others who may trade. Companies and their controlling persons are also subject to liability if they fail to take reasonable steps to prevent insider trading by company personnel.

It is important that you understand the breadth of activities that constitute illegal insider trading and their potentially severe consequences. Both the Securities and Exchange Commission and the Financial Industry Regulatory Authority investigate and are very effective at detecting insider trading. The Securities and Exchange Commission, together with the US Attorneys, pursue insider-trading violations vigorously. Cases have been successfully prosecuted against trading by employees through foreign accounts, trading by family members and friends, and trading involving only a small number of shares.

This Policy provides guidelines with respect to transactions in the securities of Oncocyte Corporation (the "Company").

APPLICABILITY OF POLICY***Who is covered by this Policy?***

This Policy applies to you if you are an "Insider" to the Company, which is defined as:

- an officer or employee of the Company or its subsidiaries;
- a member of the Board of Directors or similar governing body of the Company or its subsidiaries; or
- a consultant or contractor of the Company who receives or has access to Material Nonpublic Information (as defined below) regarding the Company.

Insiders are also responsible for making sure that the purchase or sale of any security covered by this Policy by any of the following persons or entities also complies with this Policy:

- any family member or other person who lives in the same household as the Insider;
 - any family member of the Insider who does not share the same household as the Insider but whose transactions in Company securities are directed by the Insider or are subject to their influence or control (such as parents, siblings or children who consult with the Insider before they trade in Company securities);
-

- any entity whose transactions in securities the Insider influences, directs or controls (including, e.g., a company or a venture or other investment fund if the Insider influences, directs or controls transactions by the fund); and
- any person who, directly or indirectly receives Material Nonpublic Information from the Insider.

This Policy continues to apply to your transactions in Company securities even after you have terminated your status as an Insider if you are aware of Material Nonpublic Information at the time your employment or other relationship terminates until that information has become public or is no longer material.

What transactions are covered by this Policy?

Transactions in Company Securities. This Policy generally applies to all transactions in securities of the Company, including common stock, options for common stock and any other securities the Company may issue from time to time, such as preferred stock, warrants and convertible debentures, as well as to derivative securities relating to the Company's stock, whether or not issued by the Company, such as exchange-traded put and call options.

Exception for Exercise of Stock Options, Warrants, and Certain Other Securities. This Policy's trading restrictions generally do not apply to the exercise of a stock option or warrant or the conversion of a convertible security. The trading restrictions do apply, however, to any sale of the underlying stock or to a cashless exercise of the option or warrant through a broker, as this entails selling a portion of the underlying stock to cover the costs of exercise.

Transactions in Other Companies' Securities. This Policy and the guidelines described herein also apply to Material Nonpublic Information relating to other companies, including the Company's customers, vendors or suppliers ("business partners"), when that information is obtained in the course of employment with, or other services performed on behalf of, the Company. Civil and criminal penalties, and termination of employment, may result from trading on inside information regarding the Company's business partners. All employees should treat Material Nonpublic Information about the Company's business partners with the same care required with respect to information related directly to the Company. You should keep in mind that information that is not material to the Company may nevertheless be material to one of the Company's business partners.

STATEMENT OF POLICY

What is the Company's general policy on insider trading and disclosure of nonpublic information?

It is the policy of the Company to oppose the unauthorized disclosure of any nonpublic information acquired in the workplace and the misuse of Material Nonpublic Information in securities trading.

What policies am I required to adhere to before trading in securities?

Trading on Material Nonpublic Information is Prohibited. You may not engage in any transaction involving a purchase or sale of the Company's securities, including any offer to purchase or offer to sell, directly or through family members or other persons or entities, if you are aware of Material Nonpublic Information relating to the Company. Similarly, you may not trade in the securities of any other company if you are aware of Material Nonpublic Information about that company which you obtained in the course of your employment with, or provision of services to, the Company. Such prohibition against trading shall remain in effect until the close of business on the first Trading Day following the date of public disclosure of that information, or at such time as such nonpublic information is no longer material. As used herein, the term "Trading Day," means a day on which national stock exchanges are open for trading.

Mandatory Trading Window Provisions Preclearance of Trades. All Insiders must refrain from trading in the Company's securities other than during the Trading Window. As used herein, the term "Trading Window" means the period in any fiscal quarter:

- beginning at the opening of business on the second (2nd) Trading Day following the date of public disclosure of the financial results for the prior fiscal quarter or year; and
- ending at the close of business on the 14th calendar day before the end of each fiscal quarter.

Even during the Trading Window, Insiders must first comply with the Company's "preclearance" process. Each Insider should contact the General Counsel, or in the absence of the General Counsel, the Chief Operating Officer, prior to commencing any trade in the Company's securities.

No Exception for Hardship. Every Insider has individual responsibility to comply with this Policy against insider trading, regardless of whether the Company has recommended a trading window to that Insider or any other Insiders of the Company. The guidelines set forth in this Policy are guidelines only, and appropriate judgment should be exercised in connection with any trade in the Company's securities. An Insider may, from time to time, have to forego a proposed transaction in the Company's securities even if he or she planned to make the transaction before learning of the Material Nonpublic Information and even though the Insider believes he or she may suffer an economic loss or forego anticipated profit by waiting. The existence of a personal financial emergency does not excuse you from compliance with this policy.

If I receive Material Nonpublic Information about the Company or any of its business partners, may I disclose that information to others?

Maintaining the Confidentiality of Nonpublic Information. Nonpublic information relating to the Company or its business partners is the property of the Company, and the unauthorized disclosure of such information is forbidden.

Maintaining the confidentiality of Company information is essential for competitive, security and other business reasons, as well as to comply with applicable securities laws. You should treat all information you learn about the Company or its business plans in connection with your employment as confidential and proprietary to the Company. Inadvertent disclosure of

confidential or inside information may expose the Company and you to significant risk of investigation and litigation.

The timing and nature of the Company's disclosure of material information to outsiders is subject to legal rules, the breach of which could result in substantial liability to you, the Company and its management. Accordingly, it is important that responses to inquiries about the Company by the press, investment analysts or others in the financial community be made on the Company's behalf only through authorized individuals.

If you receive inquiries about the Company from securities analysts, reporters, or others, decline comment and direct them to the Chief Financial Officer or the Director, Marketing and Communications.

As a precaution, keep all memoranda, correspondence and other documents that reflect nonpublic information in a secure place, such as a locked office or a locked file cabinet, so that they cannot be seen by third persons.

Prohibition Against Disclosing Material Nonpublic Information to Others that Might Trade on the Basis of that Information. You must not disclose ("tip") Material Nonpublic Information to any other person (including family members) where such information may be used by such person to his or her profit by trading in the securities of companies to which such information relates, nor are you permitted to make recommendations or express opinions on the basis of Material Nonpublic Information as to trading in the Company's securities. Even if you are not in possession of Material Nonpublic Information, do not recommend to any other person that they buy or sell securities of the Company. (Remember that "tipping" Material Nonpublic Information is always prohibited, and that your recommendation could be imputed to the Company and may be misleading if you do not have all relevant information).

Do not discuss Material Nonpublic Information where it may be overheard, such as in restaurants, elevators, restrooms, and other public places. Remember that cellular phone conversations are often overheard and that persons other than their intended recipients may retrieve voice mail and e-mail messages.

May I trade in Company derivative securities or short sell Company securities?

The Company considers it improper and inappropriate for Insiders to engage in short-term or speculative transactions in the Company's securities or in other transactions in the Company's securities because those transactions may not be in alignment with the interests of the Company's shareholders and may lead to inadvertent violations of the insider trading laws. Accordingly, your trading in Company securities is subject to the following restrictions:

Short Sales and Hedging Transactions. You may not engage in short sales of the Company's securities (sales of securities that are not then owned), including a "sale against the box" (a sale with delayed delivery) or other hedging or monetization transactions with respect to the Company's securities, including, but not limited to, through the use of financial instruments such as exchange funds, prepaid variable forwards, equity swaps, puts, calls, collars, forwards and other derivative instruments.

Publicly Traded Options. You may not engage in transactions in publicly traded options, such as puts, calls and other derivative securities, on an exchange or in any other organized market on Company securities.

Standing Orders. Standing orders should be used only for a very brief period of time and only during an open Trading Window. A standing order placed with a broker to sell or purchase securities at a specified price leaves you with no control over the timing of the transaction. A standing order transaction executed by the broker when you are aware of Material Nonpublic Information may result in unlawful insider trading. Should you have an open standing order, you must cancel the order prior to the start of a closed trading period or as soon as you become aware of Material Nonpublic Information.

Margin Accounts and Pledges. Securities held in a margin account or pledged as collateral for a loan may be sold without your consent by the broker if you fail to meet a margin call or by the lender in foreclosure if you default on the loan. Because a margin or foreclosure sale may occur at a time when you are aware of Material Nonpublic Information or otherwise are not permitted to trade in Company securities, you are prohibited from holding Company securities in a margin account or pledging Company securities as collateral for a loan.

May I pre-establish a time for the purchase or sale of Company securities at a time that I am not aware of Material Nonpublic Information?

Pursuant to U.S. Securities and Exchange Rule 10b5-1, directors, officers and employees of the Company may establish written programs which permit (i) automatic trading of the Company's securities through a third-party broker or (ii) trading of the Company's securities by an independent person (e.g., an investment banker) who is not aware of Material Nonpublic Information at the time of a trade. All programs shall be pre-approved by the Company and the programs shall be updated from time to time to conform with any changes to Rule 10b5-1 or the practices thereunder. Once a program is implemented in accordance with Rule 10b5-1, trades pursuant to such program shall not be subject to the limitations and restrictions set forth in other sections of this Insider Trading Policy. Trading pursuant to a program may occur even at a time outside of the Company's Trading Window or when the person on whose behalf such trade is made is aware of Material Nonpublic Information. Each program (or the form of program established by an investment bank or other third party) must be reviewed by the General Counsel or, in the absence of the General Counsel, the Chief Operating Officer prior to establishment, to confirm compliance with this policy and the applicable securities laws.

POTENTIAL CRIMINAL AND CIVIL LIABILITY AND/OR DISCIPLINARY ACTION

What legal liability may I be subject to if I engage in securities transactions on the basis of Material Nonpublic Information?

Insiders that engage in securities transactions at a time when they have knowledge of Material Nonpublic Information may be subject to penalties that include:

- imprisonment for up to 20 years;
- criminal fines of up to \$5 million; and

- civil fines of up to three times the profit gained or loss avoided.

What legal liability may I be subject to if I disclose Material Nonpublic Information to others who engage in securities transactions?

Insiders may be liable for improper transactions by any person (commonly referred to as a “tippee”) to whom they have disclosed Material Nonpublic Information regarding the Company or to whom they have made recommendations or expressed opinions on the basis of such information as to trading in the Company’s securities. The U.S. Securities and Exchange Commission has imposed large penalties even when the disclosing person did not profit from the trading. The U.S. Securities and Exchange Commission, the stock exchanges and the Financial Industry Regulatory Authority use sophisticated electronic surveillance techniques to uncover insider trading.

Could the Company incur liability for my actions if I engage in securities transactions at a time that I have Material Nonpublic Information?

If the Company fails to take appropriate steps to prevent illegal insider trading, the Company may have “controlling person” liability for a trading violation, with civil penalties of up to the greater of \$1 million and three times the profit gained or loss avoided, as well as a criminal penalty of up to \$25 million. The civil penalties can extend personal liability to the Company’s directors, officers and other supervisory personnel if they fail to take appropriate steps to prevent insider trading.

What disciplinary actions may the Company take for violations of this Policy?

Insiders who violate this Policy will be subject to disciplinary action by the Company. This disciplinary action may include ineligibility for future participation in the Company’s equity incentive plans, other Company imposed sanctions, suspension or termination of employment.

DEFINITION OF MATERIAL NONPUBLIC INFORMATION

Note that inside information has two important elements - materiality and public availability.

What information is material?

It is not possible to define all categories of material information. However, information should be regarded as material if there is a reasonable likelihood that it would be considered important to an investor in making an investment decision (i.e., a decision to buy, hold or sell a security), or if it would significantly alter the total mix of information available to investors. While it may be difficult under this standard to determine whether particular information is material, there are various categories of information that are particularly sensitive and, as a general rule, should always be considered material. Examples of such information include:

- Financial results;
- Projections of future earnings or losses;

- News of a pending or proposed merger;
- News of the disposition of a subsidiary or significant assets;
- Impending bankruptcy or financial liquidity problems;
- Gain or loss of a substantial customer or supplier;
- Changes in a dividend policy;
- New project developments or announcements of a significant nature;
- Stock splits;
- New equity or debt offerings;
- Mergers or acquisitions;
- Significant litigation exposure due to actual or threatened litigation or developments in existing litigation;
- Major changes in senior management; and
- Information as to the success, failure or even the unchanging status of particular aspects of the Company's business.

Both positive and negative information may be material. Because trading that receives scrutiny will be evaluated after the fact with the benefit of hindsight, questions concerning the materiality of particular information should be resolved in favor of materiality, and trading should be avoided.

What constitutes non-public information?

Nonpublic information is information that has not been previously disclosed to the general public and is otherwise not available to the general public. One common misconception is that material information loses its "nonpublic" status as soon as a press release is issued disclosing the information. In fact, information is considered to be available to the public only when it has been released broadly to the marketplace (such as by a press release or an SEC filing) and the investing public has had time to absorb the information fully. As a general rule, information is considered nonpublic until after the first full trading day following the date when the information is released. For example, if the Company announces financial earnings before trading begins on a Tuesday, the first time you can buy or sell Company securities is the opening of the market on Thursday (assuming you are not aware of other Material Nonpublic Information at that time). However, if the Company announces earnings after trading begins on that Tuesday, the first time you can buy or sell Company securities is the opening of the market on Friday.

ADDITIONAL INFORMATION - DIRECTORS AND OFFICERS

Directors and officers of the Company must also comply with the reporting obligations and limitations on short-swing transactions set forth in Section 16 of the Securities Exchange Act of 1934, as amended. The practical effect of these provisions is that officers and directors who purchase and sell the Company's securities within a six-month period must disgorge all profits to the Company whether or not they had knowledge of any Material Nonpublic Information. Under these provisions, and so long as certain other criteria are met, neither the receipt of an option under the Company's option plans, nor the exercise of that option nor the receipt of stock under the Company's employee stock purchase plan is deemed a purchase under Section 16; however, the sale of any such shares is a sale under Section 16. Moreover, no officer or director may ever make a short sale of the Company's securities.

INQUIRIES ABOUT THIS POLICY

Please direct your questions as to any of the matters discussed in this Policy to the General Counsel, or in the absence of the General Counsel, the Chief Operating Officer of the Company.

ACKNOWLEDGMENT

This is to acknowledge that I have received, read and understand the Company's Amended and Restated Insider Trading Policy. I agree to comply fully with all of its terms.

Signature

Print Name

Date

PLEASE SIGN, DATE, AND RETURN THIS ACKNOWLEDGEMENT TO:

15 Cushing
Irvine, CA 92618

INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM'S CONSENT

We consent to the incorporation by reference in the Registration Statements of Oncocyte Corporation on Form S-1 (File No. 333-213810), Form S-3 (File Nos. 333-281159, 333-282683, 333-279350, 333-240207, and 333-257905) and Form S-8 (File Nos. 333-219109, 333-208935, 333-227118, 333-232773 and 333-257740) of our report dated March 24, 2025, with respect to our audits of the consolidated financial statements of Oncocyte Corporation as of December 31, 2024 and 2023 and for the years ended December 31, 2024 and 2023, which report is included in this Annual Report on Form 10-K of Oncocyte Corporation for the year ended December 31, 2024.

/s/ Marcum LLP

Marcum LLP
Costa Mesa, CA
March 24, 2025

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: March 24, 2025

/s/ Josh Riggs

Josh Riggs

President and Chief Executive Officer
(Principal Executive Officer)

CERTIFICATION

I, Andrea James, 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: March 24, 2025

/s/ Andrea James

Andrea James
Chief Financial Officer
(Principal Financial Officer)

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.

Andrea James
Chief Financial Officer
(Principal Financial Officer)