# Oncocyte Reports Commercial Launch Progress; On Track to Sign 20 Transplant Centers by End of 2025

Nov 12, 2024

- Transplant centers representing about 9% of German transplant volumes and about 2% of U.S. transplant volumes have signed on to use GraftAssure kitted research test in early launch phase
- FDA pre-submission process for approval of kitted clinical test is underway

IRVINE, Calif., Nov. 12, 2024 (GLOBE NEWSWIRE) -- Oncocyte Corporation (Nasdaq: OCX) ("Oncocyte" or the "Company"), a diagnostics technology company, today published the following letter to shareholders in conjunction with its third quarter results:

Fellow Shareholders,

We are pleased to report that we are making considerable progress on two fronts that help de-risk our path to meaningful revenue. First, we are continuing to sign new research customers at well-respected hospitals and universities. In addition to the two customers mentioned in our August update, we have now signed agreements with two leading transplant university hospitals in the U.S. and Germany, as well as major research hospitals in Switzerland, Austria, and the U.K. Given the concentrated nature of the transplant market, we believe each new customer represents a key step toward capturing an estimated $1 billion global total addressable market for our transplant rejection testing technology.

Second, our clinical kitted test product development remains on track, and we have already had productive dialogue with the U.S. Food and Drug Administration (FDA), which we describe below.

The international response to GraftAssure™, which is our research-use-only assay that can detect early evidence of graft organ damage, is exceeding our expectations. We attribute this success to our robust research partnerships in Europe, and to our team's scientific leadership in researching the dd-cfDNA biomarker[1] for over a decade. Our customers in Germany now represent about 9% of the country's annual organ transplant volumes.[2]

Additionally, we are making inroads toward capturing share in the much larger U.S. market. In August, we reported that our U.S. sales funnel represents 25% of transplant volumes. Three months later, we are pleased to report that hospitals representing about 2% of overall organ transplant volumes[3] have now signed up to use GraftAssure.

We also received significant interest and engagement from the transplant lab community at the American Society for Histocompatibility & Immunogenetics (ASHI) conference in Anaheim in October. This

continuous positive reinforcement from the customer base gives us confidence that we are on the right track.

**Executive summary**

Oncocyte is at a pivotal stage in commercializing our IP in organ transplant, primarily by making a kitted test that quantifies an established biomarker, donor-derived cell-free DNA (dd-cfDNA), and uses a digital-PCR workflow that we believe offers distinct advantages over assays run on Next-Generation Sequencing (NGS) technology. Our scientists have played a pivotal role over the past decade in developing the science that established dd-cfDNA as a trusted biomarker[4], and we are now commercializing a product by pursuing a market disruptive approach. We aim to deliver proven, more affordable, faster tests that can be run at local labs.

While we don't expect meaningful revenue in transplant rejection testing until we have reached the clinical in-vitro diagnostic (IVD[5]) stage of our kitted product development, we believe that customers who are signing up for GraftAssure RUO are motivated by the eventual opportunity to use our IVD kits to measure this biomarker in their own labs, capturing the benefit of a rapid response time and the ability to generate revenue by running the test.

We also can run our clinical-use assay, VitaGraft, at our clinical lab in Nashville. We received Medicare reimbursement on that test in August 2023.

**Strategic progress**

We are on track to meet the commitment that we made to investors in August to have more than 20 transplant centers running GraftAssure tests through the end of 2025. We estimate that each center represents a potential annual high-margin revenue stream of several hundred thousand dollars to $2 million of clinical-use tests, depending on the size of the center.

By staying science-driven and putting customers first, we are building solid relationships. Deploying our GraftAssure assay is a key part of our land-and-expand strategy to drive commercial adoption of our tests.

We are especially pleased to report on how quickly we are moving to capture market share. GraftAssure began shipping in June and in less than five months, we are well into step two of our land-and-expand strategy. In fact, we have one customer in the U.S. and one prominent university hospital in Europe that are progressing to stage three. A simple breakdown:

**Land: Drive market penetration with GraftAssure to build customer install base**

1. **Convert sales funnel into signed customers:** Either our sales team or Bio-Rad's, or a combination of both, helps introduce our assay to potential academic research customers. Then, we work with institutions to sign agreements to run GraftAssure.

2. **Empower labs to run our assay in-house:** Our team provides comprehensive training on the digital-PCR workflow used for GraftAssure, which we believe offers distinct advantages over assays run on Next-Generation Sequencing (NGS) technology.[6]

3. **Drive routine use of GraftAssure & reorders:** Customer labs begin to run GraftAssure to perform research. Once the lab uses up the initial GraftAssure marketing samples, they place orders

for additional kits. Initially, we expect kit orders will reflect nominal (low revenue) amounts and will increase significantly in the next phase of our strategy.

**Expand: Democratize testing through FDA-cleared VitaGraft+ kit**

4. **Obtain regulatory clearance for clinical use:** Oncocyte is pursuing IVD clearance from the FDA for VitaGraft+, which is based on the same underlying IP and is similar to GraftAssure. In Europe, we will be pursuing CE Marketing under In Vitro Diagnostic Regulation (IVD-R).[7]

5. **Obtain reimbursement from Medicare and other payors:** Shortly after FDA clearance, we expect MolDx to attach a coverage decision to VitaGraft+, making it a reimbursed test. (Note that the version of the test that we run at our Nashville lab received reimbursement in August 2023).

6. **Begin to generate meaningful revenue:** Oncocyte expects to sell about $1 million per year in VitaGraft+ kits to an average hospital lab customer, which would order the test to manage its patients in house. Our goal is to enable labs to serve patients more quickly, and to bill payors, thus generating revenue for the hospital and increasing the sustainability of local care for the community. To put it simply, we expect our kits would enable the lab to perform the test to generate revenue for the lab.

To recap, our strategy is to *land* major transplant centers and research universities with our research-use-only (RUO) product. Doing so establishes our technology and increases its potential utility by enabling researchers to explore and expand potential applications of dd-cfDNA.

Once we have achieved FDA clearance for our test kits to be used to make clinical decisions – that is, approved as an IVD – we believe that these institutions will begin using our VitaGraft+ tests to manage their patients, while continuing to use our GraftAssure test kit to perform research. Of note, our GraftAssure research product *may not be used* to support clinical treatment decisions.

We are pleased with our strategic progress and our ability to move quickly to establish a customer base to support future revenue growth. As a reminder of our journey to date: The first prototypes of GraftAssure were completed in December 2023, and by April 2024, we welcomed Bio-Rad Laboratories as an investor and strategic partner, supporting GraftAssure's global launch. Under this partnership, Bio-Rad and Oncocyte are co-marketing GraftAssure in the U.S. and Germany. Bio-Rad has exclusive distribution and commercial rights of the RUO product outside the U.S. and Germany, with the exception of several major potential international customers where both companies have mutually agreed to allow Oncocyte to take commercial lead.

The transplant market is highly concentrated with fewer than 100 academic and research centers in the U.S. that account for approximately 80% of transplant volumes[8]. Markets outside the U.S. are similarly concentrated within high-end academic institutions. Bio-Rad's global infrastructure puts those centers well within reach, allowing for high-touch sales and service in those regions.

**Regulatory update**

We are pleased to report that our FDA pre-submission remains on track. Since our last quarterly update, we have cleared the first stage gate in our clinical product development process and submitted a Q-Sub to the FDA.

Specifically, Oncocyte has submitted its plan for an IVD version of the dd-cfDNA kitted test to the FDA, beginning the Q-submission process. We already have begun to engage in productive dialogue with the FDA, and a meeting is scheduled for early December in connection with the submission. The Q-sub is a

formal pathway for companies to get written feedback on their development plan and is a critical step in gaining confidence in the validation process that we expect to begin in early 2025.

As a reminder, the IVD development process occurs in three phases, culminating in FDA submission. Since our August update, we have completed Phase 1: Planning and Inputs. We are currently in Phase 2: Design and Outputs and will proceed with Phase 3: Verification and Validation thereafter.

Meanwhile, we also are thrilled to report that several hospitals have expressed interest in supporting the FDA submission process. Six hospitals or clinics, all of which are in major cities (given the highly concentrated nature of the transplant market) have expressed interest in participating in our clinical observational study. In addition, four institutions have expressed interest in participating in the reproducibility study. We believe these sites represent potential future VitaGraft+ customers.

The clinical director of one transplant center, who expressed interest in supporting our FDA submission, told us that his transplant center would benefit from having access to a kitted product. Because Oncocyte's kitted test is run on a digital PCR instrument[9], our FDA-cleared tests will be designed to provide actionable information when the time to treat is critical. "In a for-cause setting, send out testing doesn't do me any good," the clinical director said. "I cannot wait for two days."

**Scientific update**

We continue to advance the science of dd-cfDNA and demonstrate its clinical value.

On August 11, Transplant Internationalpublished a review that concluded that dd-cfDNA is a valuable, non-invasive biomarker that enhances graft surveillance and personalized therapy for patients with antibody-mediated rejection (AMR), potentially improving outcomes and reducing premature graft loss.

Also in August, we announced a case series that represented the second study showing VitaGraft Kidney as a measure of response to the benefit of therapy on AMR, which is a leading cause of allograft failure. The case series study, involving two patients, underscored the significant potential of using repeated VitaGraft Kidney measurements to monitor the efficacy of a targeted therapy drug, in this case, daratumumab.

The daratumumab study represented the second publication this year that showed Oncocyte's ability to monitor therapeutic efficacy. In the phase 2 randomized controlled trial published in The New England Journal of Medicine in May 2024, VitaGraft Kidney was also used to measure the response to the drug felzartamab for patients with AMR after kidney transplantation.

These papers' authors included Oncocyte's Chief Science Officer, Ekke Schuetz, and Senior R&D Director, Julia Beck.

We believe that the growing body of literature around the dd-cfDNA biomarker should support claims expansion, which we expect to translate to an increase in our total addressable market. Within the coming years, we expect to see claims expansion regarding using dd-cfDNA to monitor DSA+ patients, in the application of anti-CD38 drugs, as described above with daratumumab and felzartamab, and claims expansion to monitoring for minimal residual disease (MRD) in transplant rejection. Notably, in October, felzartamab received Breakthrough Therapy Designation (BTD) from FDA for the treatment of late AMR in kidney transplant patients.

Finally, our engagement in oncology also continues to make progress, even with limited additional investment, as we primarily focus on commercializing our transplant products. In October, we

announced the peer-reviewed publication of positive data related to our proprietary gene expression test, DetermaIO™.

Our DetermaIO immuno-oncology assay predicted response to the drug atezolizumab in a phase 2 clinical trial, the results of which were published in the peer-reviewed journal, Clinical Cancer Research[10]. In the study, only DetermaIO was both statistically significant and predictive of a pathologic complete response (pCR) among the various biomarkers assessed. This study validated DetermaIO's utility in identifying which breast cancer patients are most likely to benefit from neoadjuvant atezolizumab therapy and furthered our progress into the multi-billion-dollar addressable market in oncology diagnostics.

With this publication, DetermaIO continues to solidify its added value over standard-of care biomarkers and assays. The aforementioned study has been included in our CMS submission as we continue our efforts to secure reimbursement coverage to increase access to this valuable test.

While we don't expect to realize meaningful revenue related to our oncology IP within the near term, these studies support partnering discussions with larger companies, support our CMS submission, and validate our research and development pipeline, which is designed to drive sustained rapid growth over the next decade.

**Financing update**

We continue to prudently manage the inherent tradeoffs between investing for rapid growth and controlling expenses to limit dilutive capital raises ahead of a material potential valuation increase.

On October 2, we announced that we entered into a securities purchase agreement for a private placement that generated gross proceeds of $10.2 million, before deducting banking and legal fees and other capital raising expenses. We sold 3.46 million[11] shares of our common stock in the private placement, which priced *at the market* at $2.948 per share.

We were pleased to welcome support from new and existing investors, including Bio-Rad Laboratories, and to be able to finance the company's continued operations by selling common stock priced at the market, meaning without any discount to the closing price.

We feel confident in our ability to continue to execute on critical milestones and access capital to fund operations and growth.

**Q3 2024 Financial Overview**

- Relative to our strategic objective of commercializing our transplant tests, we consider ourselves to be "pre-revenue." Our reported revenue of $115,000 in the third quarter was derived from pharma services performed at our clinical laboratory in Nashville.
- A gross profit of $50,000 reflected the relatively fixed costs of operating our Nashville laboratory. These costs include labor as well as infrastructure expenses such as the depreciation of laboratory equipment, allocated rent costs, leasehold improvements, and allocated information technology costs.
- Operating expenses of $13.6 million included $448,000 in non-cash stock-based compensation expenses, $318,000 in non-cash depreciation and amortization expenses and a $7.1 million non-cash expense from the change in fair value of contingent consideration. Excluding these non-cash items in the current and prior periods, our Q3 operating expenses increased approximately 13% sequentially and decreased 8% year over year.

- Research and development expenses of $2.8 million reflected the incremental investments we are making in our IVD product launch. Specifically, we increased investment in IVD software development and regulatory consulting expenses in the third quarter compared with the second quarter.
- Sales and marketing expenses of $1.0 million reflected added costs as we commercialize our transplant tests. Specifically, we recorded growth in commissions, lease expenses associated with the cost of digital PCR instruments at our customer pilot sites, and incremental travel to newly signed European customers and potential customers.
- General and administrative expenses of $2.6 million were roughly flat, reflecting cost discipline as we focus on investing in research and development on IVD product development, and sales and marketing of GraftAssure.
- The $7.1 million non-cash expense associated with the increase in the fair value of the contingent consideration liability was tied primarily to a decrease in the discount rate percentage used in valuing our transplant intellectual property, due to both macro and micro factors, including the lowered interest rate targets from the Federal Reserve and Oncocyte's progress toward achieving revenue.

- Loss from continuing operations was $13.5 million, or $0.98 share.
- Non-GAAP loss from operations was $5.6 million and excludes certain non-cash items. Please refer to the table below, "Reconciliation of Non-GAAP Financial Measure," for additional information.
- Our Q3 2024 per share results reflect 13.7 million weighted average shares outstanding. Including the shares issued as part of our October private placement, we currently have 16.8 million shares outstanding.
- Oncocyte's cash, cash equivalents, and restricted cash balance at the end of the third quarter was approximately $5.1 million, down $5.9 million sequentially. As mentioned, on October 2, 2024, we entered into a securities purchase agreement for a private placement. After deducting banking and legal fees and other transaction-related expenses, net proceeds were approximately $9.4 million from the private placement.

We are pleased that our third quarter outgoing cash flow from operations (net cash used in operating activities) of $5.55 million came in favorable to our budget of $6 million, which was partially a result of operational efficiency and partly a result of inventory manufacturing timing.

**Webcast and Conference Call Information**

**Conference Call and Webcast on Tuesday, November 12, 2024, at 2:00 p.m. PT / 5:00 p.m. ET**

Interested parties may access the live call via telephone by dialing toll free 800-715-9871 for domestic callers. Once dialed in, ask to be joined to the Oncocyte Corporation call.

The live webcast of the call may be accessed by visiting the "Events & Presentations" section of the Company's website at https://investors.oncocyte.com/. A replay of the webcast will be available on the Company's website shortly after the conclusion of the call.

**CONFERENCE CALL DETAILS:**
Participant Toll-Free Dial-In Number: (800) 715-9871
Participant Toll Dial-In Number: +1 (646) 307-1963
Conference ID: 4153469

**WEBCAST DETAILS: https://events.q4inc.com/attendee/686764682**

**About Oncocyte**

Oncocyte is a diagnostics technology company. The Company's tests are designed to help provide clarity and confidence to physicians and their patients. VitaGraft™ is a clinical blood-based solid organ transplantation monitoring test. GraftAssure™ is a research use only (RUO) blood-based solid organ transplantation monitoring test. DetermaIO™ is a gene expression test that assesses the tumor microenvironment to predict response to immunotherapies. DetermaCNI™ is a blood-based monitoring tool for monitoring therapeutic efficacy in cancer patients. For more information about Oncocyte, please visit https://oncocyte.com/. For more information about our products, please visit the following web pages:

**VitaGraft Kidney™ - https://oncocyte.com/vitagraft-kidney/VitaGraft Liver™ - https://oncocyte.com/vitagraft-liver/**
**GraftAssure™ - https://oncocyte.com/graftassure/DetermaIO™ - https://oncocyte.com/determa-io/**
**DetermaCNI™ - https://oncocyte.com/determa-cni/**

VitaGraft™, GraftAssure™, DetermaIO™, and DetermaCNI™ are trademarks of Oncocyte Corporation.

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**Forward-Looking Statements**

Any statements that are not historical fact (including, but not limited to statements that contain words such as "will," "believes," "plans," "anticipates," "expects," "estimates," "may," and similar expressions) are forward-looking statements. These statements include those pertaining to, among other things, future expansion and growth, the Company's land-and-expand strategy to drive commercial adoption of its tests and capture market share, plans to have transplant centers running GraftAssure tests through the end of 2025, projected revenue path, IVD strategy, assumptions regarding regulatory approvals and clearances, timing and planned regulatory submissions, the ongoing global launch of GraftAssure with the support of Bio-Rad Laboratories, our ability to continue to access capital, and other statements about the future expectations, beliefs, goals, plans, or prospects expressed by management. Forward-looking statements involve risks and uncertainties, including, without limitation, risks inherent in the development and/or commercialization of diagnostic tests or products, uncertainty in the results of clinical trials or regulatory approvals, the capacity of Oncocyte's third-party supplied blood sample analytic system to provide consistent and precise analytic results on a commercial scale, potential interruptions to supply chains, the need and ability to obtain future capital, maintenance of intellectual property rights in all applicable jurisdictions, obligations to third parties with respect to licensed or acquired technology and products, the need to obtain third party reimbursement for patients' use of any diagnostic tests Oncocyte or its subsidiaries commercialize in applicable jurisdictions, and risks inherent in strategic transactions such as the potential failure to realize anticipated benefits, legal, regulatory or political changes in the applicable jurisdictions, accounting and quality controls, potential greater than estimated allocations of resources to develop and commercialize technologies, or potential failure to maintain any laboratory accreditation or certification. Actual results may differ materially from the results anticipated in these forward-looking statements and accordingly such statements should be evaluated together with the many uncertainties that affect the business of Oncocyte, particularly those mentioned in the "Risk Factors" and other cautionary statements found in Oncocyte's Securities and Exchange Commission (SEC) filings, which are available from the SEC's website. You are cautioned not to place undue reliance on forward-looking

statements, which speak only as of the date on which they were made. Oncocyte undertakes no obligation to update such statements to reflect events that occur or circumstances that exist after the date on which they were made, except as required by law.

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

| | September 30, 2024 | December 31, 2023 |
|---|---|---|
| | (Unaudited) | |
| **ASSETS** | | |
| CURRENT ASSETS | | |
| Cash and cash equivalents | $ 3,363 | $ 9,432 |
| Accounts receivable, net of allowance for credit losses of $2 and $5, respectively | 209 | 484 |
| Inventories | 232 | — |
| Deferred financing costs | 330 | — |
| Prepaid expenses and other current assets | 627 | 643 |
| Assets held for sale | 32 | 139 |
| Total current assets | 4,793 | 10,698 |
| NONCURRENT ASSETS | | |
| Right-of-use and financing lease assets, net | 3,001 | 1,637 |
| Machinery and equipment, net, and construction in progress | 3,494 | 3,799 |
| Intangible assets, net | 56,529 | 56,595 |
| Restricted cash | 1,700 | 1,700 |
| Other noncurrent assets | 699 | 463 |

| | | |
|---|---|---|
| TOTAL ASSETS | $ 70,216 | $ 74,892 |
| | | |
| **LIABILITIES AND SHAREHOLDERS' EQUITY** | | |
| CURRENT LIABILITIES | | |
| Accounts payable | $ 872 | $ 953 |
| Accrued compensation | 1,906 | 1,649 |
| Accrued royalties | 1,116 | 1,116 |
| Accrued expenses and other current liabilities | 985 | 452 |
| Accrued severance from acquisition | 2,314 | 2,314 |
| Right-of-use and financing lease liabilities, current | 1,283 | 665 |
| Current liabilities of discontinued operations | — | 45 |
| Contingent consideration liabilities, current | 614 | 393 |
| Total current liabilities | 9,090 | 7,587 |
| NONCURRENT LIABILITIES | | |
| Right-of-use and financing lease liabilities, noncurrent | 2,708 | 2,204 |
| Contingent consideration liabilities, noncurrent | 48,707 | 39,507 |
| TOTAL LIABILITIES | 60,505 | 49,298 |
| | | |
| Commitments and contingencies | | |
| | | |
| 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' EQUITY | | |
| Preferred stock, no par value, 5,000 shares authorized; no | — | — |

| | | |
|---|---|---|
| shares issued and outstanding | | |
| Common stock, no par value, 230,000 shares authorized; 13,374 and 8,261 shares issued and outstanding at September 30, 2024 and December 31, 2023, respectively | 326,682 | 310,295 |
| Accumulated other comprehensive income | 57 | 49 |
| Accumulated deficit | (317,028) | (289,876) |
| Total shareholders' equity | 9,711 | 20,468 |
| TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY | $ 70,216 | $ 74,892 |

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

| | Three Months Ended September 30, | | Nine Months Ended September 30, | |
|---|---|---|---|---|
| | **2024** | **2023** | **2024** | **2023** |
| **Net revenue** | $ 115 | $ 429 | $ 395 | $ 1,189 |
| Cost of revenues | 43 | 159 | 184 | 593 |
| Cost of revenues – amortization of acquired intangibles | 22 | 22 | 66 | 66 |
| Gross profit | 50 | 248 | 145 | 530 |
| **Operating expenses:** | | | | |
| Research and development | 2,817 | 2,185 | 7,582 | 6,747 |

| | | | | |
|---|---|---|---|---|
| Sales and marketing | 1,043 | 713 | 2,742 | 2,213 |
| General and administrative | 2,565 | 2,487 | 7,645 | 9,430 |
| Change in fair value of contingent consideration | 7,140 | (435) | 9,421 | (16,947) |
| Impairment losses | — | 1,811 | — | 6,761 |
| Impairment loss on held for sale assets | — | — | 169 | 1,283 |
| Total operating expenses | 13,565 | 6,761 | 27,559 | 9,487 |
| Loss from operations | (13,515) | (6,513) | (27,414) | (8,957) |
| **Other (expenses) income:** | | | | |
| Interest expense | (31) | (14) | (54) | (39) |
| Unrealized (loss) gain on marketable equity securities | — | (89) | — | 8 |
| Other income, net | 53 | 127 | 316 | 125 |
| Total other income, net | 22 | 24 | 262 | 94 |
| **Loss from continuing operations** | (13,493) | (6,489) | (27,152) | (8,863) |
| Loss from discontinued operations | — | — | — | (2,926) |
| **Net loss** | $ (13,493) | $ (6,489) | $ (27,152) | $ (11,789) |
| **Net loss per share:** | | | | |
| Net loss from continuing | $ (13,493) | $ (6,687) | $ (27,415) | $ (9,602) |

| | | | | |
|---|---|---|---|---|
| operations - basic and diluted | | | | |
| Net loss from discontinued operations - basic and diluted | $ — | $ — | $ — | $ (2,926) |
| Net loss attributable to common stockholders - basic and diluted | $ (13,493) | $ (6,687) | $ (27,415) | $ (12,528) |
| | | | | |
| Net loss from continuing operations per share - basic and diluted | $ (0.98) | $ (0.81) | $ (2.36) | $ (1.29) |
| Net loss from discontinued operations per share - basic and diluted | $ — | $ — | $ — | $ (0.39) |
| Net loss attributable to common stockholders per share - basic and diluted | $ (0.98) | $ (0.81) | $ (2.36) | $ (1.68) |
| | | | | |
| Weighted average shares outstanding - basic and diluted | 13,714 | 8,256 | 11,624 | 7,446 |

**ONCOCYTE CORPORATION**
**UNAUDITED CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS**
**(In thousands)**

| | Three Months Ended September 30, | | Nine Months Ended September 30, | |
|---|---|---|---|---|
| | **2024** | **2023** | **2024** | **2023** |
| **CASH FLOWS FROM OPERATING ACTIVITIES:** | | | | |
| Net loss | $ (13,493) | $ (6,489) | $ (27,152) | $ (11,789) |

| | | | | |
|---|---|---|---|---|
| Adjustments to reconcile net loss to net cash used in operating activities: | | | | |
| Depreciation and amortization expense | 318 | 404 | 935 | 1,289 |
| Amortization of intangible assets | 22 | 22 | 66 | 66 |
| Stock-based compensation | 450 | 608 | 1,254 | 2,276 |
| Equity compensation for bonus awards and consulting services | 14 | 108 | 110 | 108 |
| Unrealized gain on marketable equity securities | — | 89 | — | (8) |
| Change in fair value of contingent consideration | 7,140 | (435) | 9,421 | (16,947) |
| Impairment losses | — | 1,811 | — | 6,761 |
| 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 | (124) | (166) | 275 | 130 |
| Inventories | (232) | — | (232) | — |
| Prepaid expenses and other assets | (295) | 78 | (345) | 645 |
| Accounts payable and accrued liabilities | 649 | 126 | 263 | (4,193) |
| Lease assets and liabilities | — | 75 | (123) | (43) |
| Net cash used in operating activities | (5,551) | (3,769) | (15,359) | (18,901) |

| | | | | |
|---|---|---|---|---|
| **CASH FLOWS FROM INVESTING ACTIVITIES:** | | | | |
| Proceeds from sale of equipment | — | 231 | — | 354 |
| Construction in progress and purchases of furniture and equipment | (87) | (17) | (302) | (17) |
| Cash sold in discontinued operations | — | — | — | (1,372) |
| Net cash used in investing activities | (87) | 214 | (302) | (1,035) |
| **CASH FLOWS FROM FINANCING ACTIVITIES:** | | | | |
| Proceeds from sale of common shares | — | — | 15,807 | 13,848 |
| Financing costs to issue common shares | — | — | (538) | (427) |
| Proceeds from sale of common shares under at-the-market transactions | 18 | — | 18 | — |
| Financing costs for at-the-market sales | (187) | — | (187) | — |
| Redemption of Series A redeemable convertible preferred shares | — | — | (5,389) | (1,118) |
| Repayment of financing lease obligations | (86) | (30) | (119) | (87) |
| Net provided by financing activities | (255) | (30) | 9,592 | 12,216 |
| **NET CHANGE IN CASH, CASH EQUIVALENTS (INCLUDES DISCONTINUED** | (5,893) | (3,585) | (6,069) | (7,720) |

| | | | | |
|---|---|---|---|---|
| **OPERATIONS) AND RESTRICTED CASH** | | | | |
| **CASH, CASH EQUIVALENTS (INCLUDES DISCONTINUED OPERATIONS) AND RESTRICTED CASH, BEGINNING** | 10,956 | 19,068 | 11,132 | 23,203 |
| **CASH, CASH EQUIVALENTS AND RESTRICTED CASH, ENDING** | $ 5,063 | $ 15,483 | $ 5,063 | $ 15,483 |

**Oncocyte Corporation**
**Reconciliation of Non-GAAP Financial Measure**
**Consolidated Adjusted Loss from Operations**

Note: In addition to financial results determined in accordance with U.S. generally accepted accounting principles ("GAAP"), this press release also includes a non-GAAP financial measure (as defined under SEC Regulation G). We believe that disclosing the adjusted amounts is helpful in assessing our ongoing performance, providing insight into the Company's core operating performance by excluding certain non-recurring, non-cash, and / or intangible items that may obscure the underlying trends in the business. The following is a reconciliation of the non-GAAP measure to the most directly comparable GAAP measure:

| | **Three Months Ended** | | |
|---|---|---|---|
| | **September 30, 2024** | **June 30, 2024** | **September 30, 2023** |
| | **(unaudited)** | **(unaudited)** | **(unaudited)** |
| **Consolidated GAAP loss from operations** | **$ (13,515)** | **$ (4,632)** | **$ (6,513)** |
| Stock-based compensation | 450 | 386 | 608 |
| Depreciation and amortization expenses | 340 | 326 | 426 |
| Change in fair value of contingent consideration | 7,140 | (1,031) | (435) |

| | | | |
|---|---|---|---|
| Impairment losses | — | — | 1,811 |
| **Consolidated Non-GAAP loss from operations, as adjusted** | **$ (5,585)** | **$ (4,951)** | **$ (4,103)** |

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[1] Donor-derived cell-free DNA (dd-cfDNA). The proprietary intellectual property we acquired in 2021 was developed in Germany.
[2] According to Deutsche Stiftung Organtransplantation (DSO) data, 2023 German organ transplant volumes were 3,586 and German hospitals using GraftAssure performed 323 transplants that year, representing about 9% of 2023 German transplant volumes.
[3] According to Organ Procurement and Transplantation Network data, 2023 U.S. kidney, liver, heart and lung transplant volumes were 45,562 and U.S. hospitals using GraftAssure performed about 930 transplants that year, representing about 2% of 2023 U.S. transplant volumes.
[4] MolDX, a program that identifies and establishes coverage and U.S. government reimbursement for molecular diagnostic tests, cited our publications twice when it established the LCD (Local Coverage Determination) for Medicare and Medicaid reimbursement coverage for cell free DNA testing. Source: https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?lcdId=38671&ver=4[5] The kitted version of our assay must be cleared by regulatory bodies in the U.S., Europe and elsewhere as an in-vitro diagnostic (IVD) to be used in clinical decision making.
[6] Our assay runs on a digital PCR (polymerase chain reaction) instrument, which allows us to create a simple workflow for the lab technician, delivering a result in four to eight hours, compared with ≥30 hours in estimated time using NGS technology. Further, testing a single sample is an affordable option, given that the batch size – in contrast to NGS – does not alter the cost per result.
[7] CE Marketing refers to Conformité Européenne (French for "European Conformity"), under the European Union's IVD-R.
[8] Company estimates based on UNOS data (https://unos.org/about/national-organ-transplant-system/)[9] Digital PCR provides ultrasensitive nucleic acid detection and absolute quantification.
[10] The NeoTRIP Phase 2 clinical trial (NCT002620280) randomized patients with triple-negative breast cancer (TNBC) to receive neoadjuvant carboplatin and nab-paclitaxel (chemotherapies to shrink tumors), with or without the immunotherapy, atezolizumab. Oncocyte's DetermaIO test was among several established biomarkers and gene signatures assessed for its ability to predict which patients with early stage TNBC are most likely to benefit from the immunotherapy. The study was performed in collaboration with the Michelangelo Foundation for Cancer Research, a well-regarded independent scientific organization based in Milan.
[11] For accuracy, this share amount includes insider purchases of 37,037 shares at $2.97 per share, a higher amount paid than non-insiders due to specific exchange rules regarding insider transactions.

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Source: OncoCyte Corporation

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