Oncocyte Reports Q1 2025 Results and Business Progress

- Q1 2025 pharma services revenue of $2.1 million, at 62% gross margin
- Three of the top 10 U.S. transplant centers expected to participate in clinical trial
- Ten globally leading transplant hospitals are now using our GraftAssure research-use-only kits
- To reflect our larger market opportunity, we plan to rename the company in Q2

IRVINE, Calif., May 12, 2025 (GLOBE NEWSWIRE) -- Oncocyte Corp. (Nasdaq: OCX), a diagnostics technology company, today published the following letter to shareholders in conjunction with its first quarter results:

Fellow Shareholders,
We're off to a fast and intensely focused start in 2025. Just two months ago, we shared our strategic outlook — and since then, we've remained heads down, executing. Our top priority is unchanged: bringing our first clinical molecular diagnostic test kit to market so that we may begin capturing value in the estimated $1 billion total addressable market for transplant rejection testing. The first quarter was defined by disciplined progress, as our team performed the essential work required to advance from development to commercialization.

In parallel, our Nashville lab generated $2.1 million in pharma services revenue in Q1 2025, exceeding expectations. We supported a major corporate customer by processing samples on their behalf. This revenue helps to offset costs as we continue to make progress with our core transplant and oncology product opportunities. That benefit was larger this quarter because of process improvements that raised our gross margins from 40% in Q4 to 62% in Q1.

In the sections that follow, we provide updates on our clinical trial, general business momentum, renaming and rebranding plans, and our first-quarter 2025 financial results.

Clinical trial progress:

Oncocyte has completed the clinical trial design for its clinical molecular diagnostic testing kit and has received approval from a large central institutional review board (IRB). Central IRBs are committees that review and oversee the safety and ethics of clinical trials across multiple hospital sites. Obtaining IRB approvals is a key step in setting up a clinical trial.

In the coming weeks, Oncocyte expects to welcome at least three of the top 10 transplant centers in the United States as clinical trial participants. These three institutions are the largest of several transplant hospitals that are actively engaged in supporting Oncocyte's clinical trial, and collectively represent nearly 10% of U.S. transplanted organ volume. We value the clinical expertise and diverse patient populations that these leading transplant centers will contribute to the trial.

We look forward to announcing the first patient being enrolled as well as introducing the study's National Principal Investigator (NPI) and key opinion leaders to the medical and investor communities.

We expect that the strong support we see from leading transplant centers will serve us well once our lead transplant test receives FDA authorization and reaches the commercialization stage. Our research shows that transplant centers prefer in-house testing rather than send-out, central lab testing and that physicians are likely to continue managing the treatment of patients using the transplant centers' preferred testing platform. As a result, we believe that becoming the in-house testing technology of choice at transplant centers should support a sustainable, long-term, high-margin recurring revenue business model.

Importantly, we expect the upcoming clinical trial to satisfy clinical evidence requirements for our planned FDA submission. In 2026, we expect clearance of that submission, which will support U.S. marketing authorization of our first clinical use transplant test kit. For clarity, we are pursuing a Class II *de novo* pathway – a regulatory route for lower-risk medical devices. Class II medical devices carry lower risk than Class III devices, which are typically life-supporting technologies. We already have achieved CLIA (Clinical Laboratory Improvement Amendments) validation and reimbursement of the lab-developed version of our test with Centers for Medicare & Medicaid Services (CMS). But for commercialization of the *kitted version* of our assay to begin, it must be cleared by regulatory bodies in the U.S., Europe and elsewhere as an *in-vitro* diagnostic (IVD) test to be used in clinical decision making.

We remain pleased with the quality of the engagement we've had with the FDA and are looking forward to our final pre-submission (Q-Sub) meeting in the coming weeks.

Business update:

Ten leading transplant centers are now using our GraftAssure research-use-only (RUO) kits: We remain on track to meet our August 2024 commitment to have at least 20 transplant centers adopting our GraftAssure RUO kits by the end of 2025. As a reminder, the first part of our strategy is to *land* major transplant centers and research universities with our research-use-only product. Doing so establishes our technology and increases its potential utility by enabling researchers to explore potential applications of donor derived cell free DNA (dd-cfDNA.) Then, once we have achieved FDA clearance for our test kits to be used to make clinical decisions – that is, cleared for commercialization as an IVD – we believe that these institutions will *expand* their use of our tests to manage their patient populations. (Importantly, research-use-only products may not be used to support clinical treatment decisions.) Once our test receives IVD authorization for clinical use from the FDA, we estimate that each transplant center that uses our test kit will have the potential to generate high-margin annual revenue in the range of several hundred thousand dollars up to $2 million, depending on that center's testing volume.

Since launching the RUO version of GraftAssure in summer 2024, interest from transplant centers has exceeded our expectations. Based on feedback from early pilot sites, we've now finalized key ease-of-use improvements to the research kit. The test now features minimal hands-on time, requiring only a few simple pipetting steps. First commercial orders are expected later this year.

The 10 centers currently using GraftAssure RUO kits include three in the U.S., six in Europe, and one in Southeast Asia—all leading, high-quality research hospitals.

GraftAssure discoveries point to pipeline expansion: Hospital labs are using GraftAssure to advance their research — and, in the process, are uncovering valuable new applications. For example, researchers are using GraftAssure to detect microchimerism (the presence of a small number of cells in an individual that originate from a genetically different individual). Microchimerism has become increasingly important in transplant biology, where its detection can provide insights into graft health, early signs of rejection, and long-term immune tolerance.

GraftAssure's use of digital PCR is a key differentiator and supports evolving research: Our assay appears to be demonstrating the utility of digital PCR (polymerase chain reaction) in the field – and we are receiving positive feedback that suggests our PCR-based workflow may be a strategic differentiator. Researchers are exploring our assay's potential to improve post-transplant monitoring and potentially identify complications earlier than traditional methods. These emerging use cases for our test underscore GraftAssure's versatility and precision, leveraging digital PCR to support broader innovation in the field.

To recap the significance of our test's use of digital PCR: We utilize a digital PCR workflow that we believe offers distinct advantages over assays run on Next-Generation Sequencing (NGS) technology. Digital PCR is fast, simple to use, quantitative, and has better sample economics at low volumes. Our transplant rejection assay runs on a Bio-Rad digital PCR instrument, which allows us to create a simple workflow for the lab technician. In addition, our PCR-based workflow delivers a result in four to eight hours, compared with an estimated ≥30 hours using NGS technology. Furthermore, testing a single sample is an affordable option given that the batch size – in contrast to NGS – does not meaningfully alter the cost per result. We look forward to continuing to demonstrate digital PCR's advantages in sample economics, with the flexibility to scale up *or down* at local labs.

Continuing to advance transplant science: A study recently published in Transplantation Direct that used our assay to identify graft rejection in patients up to 13 years post-transplant has been received positively in the field, as well as in strategic discussions with new potential corporate partners. This study delivered a robust data set involving 131 patients with 151 kidney biopsies enrolled over four years at Charité University in Berlin. We believe that the results of this study support market expansion for testing of the high-risk patient population and deliver new insights that advance our understanding of the biology of organ rejection.

Advancing our oncology pipeline: In addition to our solid momentum in transplant, we also are making selective investments in our longer-term product pipeline. For example, our NeoTRIP study has accelerated both the strategic and scientific direction of our DetermaIO assay, bringing pharmaceutical partners and clinical collaborators to the table to explore how the biomarker can be used to advance patient care and therapeutic development.

To recap the significance of the NeoTRIP study, which we announced in 2021 and published in 2024, our 27-gene expression assay, DetermaIO, was used to help identify which patients might benefit from adding atezolizumab—a monoclonal antibody immunotherapy—to a standard chemotherapy regimen for Stage II/III triple negative breast cancer in the neoadjuvant (pre-surgery) setting. The results showed that DetermaIO was able to statistically predict which patients would benefit from the addition of immunotherapy. In terms of pathologic complete response (meaning the tumor had completely disappeared as a result of neoadjuvant therapy prior to surgical resection) only DetermaIO-positive patients showed a benefit by adding atezolizumab to the

chemotherapy, compared with patients who were treated with chemotherapy alone. Remarkably, no such benefit was reported for DetermaIO-negative patients.

These developments point to a growing opportunity for our assay to support drug rescue -- reviving therapies that failed to meet their primary endpoint. Our biomarker can be used to enrich for likely patient responders increasing the chance of success for the drug in future studies.

Corporate and product renaming:

This year, we'll be unveiling a new company name that better reflects our strategic direction. While *Oncocyte* spoke to our origins, it no longer captures the full scope of our product pipeline. Our focus now includes both organ transplant and oncology. So, the "onco" prefix—derived from the Greek word for tumor—has become too narrow for a company with a broader mission to democratize access to molecular diagnostic testing. Though we remain committed to advancing oncology diagnostics, both our near-term focus and our long-term reach have considerably broadened.

Our new name is designed to reflect the depth of our pipeline and the insights we aim to bring to advancing molecular diagnostics. We are excited to unveil our new name to investors, who should be pleased to note that we expect this to be an efficient and relatively low-cost endeavor. As we keep our cash burn low, we plan to let the quality of our science speak for itself.

We also are rebranding our transplant diagnostic product portfolio. Going forward, we will set aside the *VitaGraft* name and *GraftAssure* will serve as the umbrella brand for our dd-cfDNA test portfolio.

- GraftAssureCore will refer to our lab-developed test (LDT), which currently is reimbursed by CMS and run at our CLIA-certified Nashville lab.
- GraftAssureIQ will be our RUO test kit, clearly labeled and positioned as such with customers.
- GraftAssureDx will be the name of our IVD test kit intended for use in clinical decision-making. This is the kitted product that we are currently working on to gain FDA authorization.

To summarize:

- VitaGraft Kidney (LDT) → GraftAssureCore
- GraftAssure (RUO) Kit → GraftAssureIQ
- VitaGraft + (IVD) Kit → GraftAssureDx

As we move deeper into 2025, our focus remains sharp: advancing our transplant test kit through clinical trial execution and toward FDA authorization, in preparation for commercialization. The early enthusiasm we're seeing from leading transplant centers to support in-house testing reinforces our confidence in our strategy.

We're encouraged by the operational discipline shown by our team—from improving gross margins in our Nashville lab, to demonstrating early utility of our assay in research settings.

We're managing capital carefully, investing where we believe we can drive the greatest returns, and staying true to our mission: to democratize access to high-impact molecular diagnostics that improve patient care.

- The Oncocyte Management Team

Q1 2025 Financial Overview

- Our reported revenues of $2.14 million in Q1 2025 were derived from pharma services performed at our clinical laboratory in Nashville. We see this revenue as a testament to our team's ability to achieve the on-time delivery of clear, scientifically sound, and accurate data sets to our clients. However, our reported revenue does not yet include sales of commercial transplant test kits, which is our primary business focus.

- We reported gross profit of $1.33 million in Q1 2025, representing a 62% gross margin—up from 40% in Q4 2024. This margin expansion was primarily driven by operational efficiencies achieved in our Nashville lab. Key contributors included automation and enhancements to our workflow, enabling a higher number of samples to be processed per batch and reducing labor cost per sample. By contrast, Q4 margins were impacted by the launch of a new workflow and deliberate trade-offs in sequencing efficiency made to meet an accelerated customer deadline.

- In Q1 2025, operating expenses of $8.1 million included $879,000 in a non-cash change in the fair value of our contingent consideration, as well as $473,000 in non-cash stock-based compensation expenses and $464,000 in non-cash depreciation and amortization expenses.
    - Research and development expenses of $2.9 million in the first quarter reflected increased expenses tied to our kitted product development – including FDA-compliant software development expenses, laboratory supplies and personnel.
    - Sales and marketing expenses were flat sequentially at $1.2 million, driven by cost discipline.
    - General and administrative expenses of $3.1 million in the quarter included a one-time charge of $279,000 tied to realizing previously deferred expenses in connection with the termination of our Sales Agreement with Needham & Company, LLC, pursuant to which we could sell shares of our common stock through Needham in "at-the-market" offerings as defined in Rule 415(a)(4) of the Securities Act.

- Our Q1 2025 net loss was $6.7 million, or ($0.26) per share.

- Our Q1 2025 non-GAAP loss from operations was $5.0 million excluding certain non-cash items. Please refer to the table below, "Reconciliation of Non-GAAP Financial Measure," for additional information.
    - Our Q1 2025 per share results reflect 25.7 million weighted average shares outstanding. Including the shares issued as part of our February 2025 offering and private placement, as of May 12, we had 28.6 million shares outstanding.

- Oncocyte's cash, cash equivalents, and restricted cash balance at the end of the first quarter was $32.7 million. This number includes the $28.7 million in net financing cash flow from our registered direct offering and private placement in February 2025.
    - We are pleased that our first quarter outgoing cash flow from operations (net cash used in operating activities) of $5.9 million, combined with capital expenditures of $307,000, were in line with our targeted quarterly average spend of $6 million, which was partially a result of operational efficiency and partly a result of working capital management. Please note that at the end of the first quarter, we had $3.5 million in accounts receivable, and received $1.4 million in payments against those receivables in the first week of April.

Webcast and Conference Call Information

Live Zoom Call and Webcast on Monday, March 12, 2025, at 2:00 p.m. PT / 5:00 p.m. ET.

Those interested may access the live Zoom call by registering here:
Oncocyte Q1 2025 Earnings Webinar.

Once registered, a confirmation email will be sent with instructions.

A replay of the Zoom call will be available on the company's website shortly after the call.

About Oncocyte

Oncocyte is a pioneering diagnostics technology company whose mission is to democratize access to novel molecular diagnostic testing to improve patient outcomes. Investors may visit https://investors.oncocyte.com/ for more information.

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, the expectation that Oncocyte will welcome new transplant centers as clinical trial participants in the coming weeks, commercialization plans and the opportunity for a sustainable, long-term, high-margin recurring revenue business model, plans for future announcements, upcoming clinical trial(s), planned FDA submission, anticipated final pre-submission (Q-Sub) meeting with the FDA in the coming weeks, Oncocyte's commitment to have at least 20 transplant centers adopting its GraftAssure RUO kits by the end of 2025, expected regulatory clearance(s) and authorization(s) and the timing of such clearance(s) and authorization(s), the belief that major transplant centers and research universities will ultimately expand their use of the company's tests to manage their patient populations, estimates of revenue opportunities for transplant centers, expected timing of first commercial orders, the company's plans for a name change and product rebranding, 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.

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ONCOCYTE CORPORATION
CONDENSED CONSOLIDATED BALANCE SHEETS
(In thousands)

	March 31, 2025	December 31, 2024
	(Unaudited)	
ASSETS		
CURRENT ASSETS		
Cash and cash equivalents	$ 31,029	$ 8,636
Accounts receivable, net of allowance for credit losses of $36 and $16, respectively	3,540	1,613
Inventories	459	410
Deferred financing costs	—	279
Prepaid expenses and other current assets	1,235	821
Total current assets	36,263	11,759
NONCURRENT ASSETS		
Right-of-use and financing lease assets, net	2,589	2,757
Machinery and equipment, net, and construction in progress	4,566	3,567
Intangible assets, net	14,600	14,607
Restricted cash	1,700	1,700
Other noncurrent assets	642	691
TOTAL ASSETS	$ 60,360	$ 35,081
LIABILITIES AND SHAREHOLDERS' EQUITY (DEFICIT)		
CURRENT LIABILITIES		
Accounts payable	$ 2,279	$ 2,279
Accrued compensation	2,524	1,939
Accrued royalties	1,116	1,116
Accrued expenses and other current liabilities	1,927	418
Right-of-use and financing lease liabilities, current	1,404	1,295
Contingent consideration liabilities, current	433	228
Total current liabilities	9,683	7,275
NONCURRENT LIABILITIES		
Right-of-use and financing lease liabilities, noncurrent	2,074	2,369
Contingent consideration liabilities, noncurrent	38,385	37,711
TOTAL LIABILITIES	50,142	47,355
Commitments and contingencies		
SHAREHOLDERS' EQUITY (DEFICIT)		
Preferred stock, no par value, 5,000 shares authorized; no shares issued and outstanding	—	—
Common stock, no par value, 230,000 shares authorized; 28,599 and 17,453 shares issued and outstanding at March 31, 2025 and December 31, 2024, respectively	367,387	338,244
Accumulated other comprehensive income	41	21
Accumulated deficit	(357,210)	(350,539)
Total shareholders' equity (deficit)	10,218	(12,274)
TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY (DEFICIT)	$ 60,360	$ 35,081

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

	Three Months Ended March 31,	
	2025	2024
Net revenue	$ 2,138	$ 176
Cost of revenues	806	109
Cost of revenues – amortization of acquired intangibles	7	22
Gross profit	1,325	45
Operating expenses:		
Research and development	2,924	2,312
Sales and marketing	1,206	846
General and administrative	3,115	2,673
Change in fair value of contingent consideration	879	3,312
Impairment loss on held for sale assets	—	169
Total operating expenses	8,124	9,312
Loss from operations	(6,799)	(9,267)
Other (expenses) income:		
Interest expense	(29)	(15)
Other income, net	157	153
Total other income, net	128	138
Loss before income taxes	(6,671)	(9,129)
Income taxes	—	—
Net loss	$ (6,671)	$ (9,129)
Net loss per share:		
Net loss attributable to common stockholders - basic and diluted	$ (6,671)	$ (9,335)
Net loss attributable to common stockholders per share - basic and diluted	$ (0.26)	$ (1.13)
Weighted average shares outstanding - basic and diluted	25,694	8,264

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

	Three Months Ended March 31,	
	2025	2024
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	$ (6,671)	$ (9,129)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization expense	484	313
Amortization of intangible assets	7	22
Stock-based compensation	473	418
Equity compensation for bonus awards and consulting services	14	46
Change in fair value of contingent consideration	879	3,312
Impairment loss on held for sale assets	—	169
Changes in operating assets and liabilities:		
Accounts receivable	(1,927)	323
Inventories	(49)	—
Prepaid expenses and other assets	(65)	(62)
Accounts payable and accrued liabilities	1,027	854
Lease assets and liabilities	(30)	(96)
Net cash used in operating activities	(5,858)	(3,830)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Construction in progress and purchases of furniture and equipment	(307)	(24)
Net cash used in investing activities	(307)	(24)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from sale of common shares	29,143	—
Financing costs to issue common shares	(487)	—
Repayment of financing lease obligations	(98)	—
Net provided by financing activities	28,558	—
NET CHANGE IN CASH, CASH EQUIVALENTS AND RESTRICTED CASH	22,393	(3,854)
CASH, CASH EQUIVALENTS AND RESTRICTED CASH, BEGINNING	10,336	11,132
CASH, CASH EQUIVALENTS AND RESTRICTED CASH, ENDING	$ 32,729	$ 7,278

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-cash, and / or intangible items that may obscure the underlying trends in the business. These non-GAAP financial measures, when viewed in a reconciliation to respective GAAP measures, provide an additional way of viewing the Company's results of operations and factors and trends affecting the Company's business. These non-GAAP financial measures should be considered as a supplement to, and not as a substitute for, or superior to, the respective financial results presented in accordance with GAAP.

The following is a reconciliation of the non-GAAP measure to the most directly comparable GAAP measure

	Three Months Ended		
	March 31, 2025 (unaudited)	December 31, 2024 (unaudited)	March 31, 2024 (unaudited)
	(In thousands)		
Consolidated GAAP loss from operations	**$ (6,799)**	**$ (33,627)**	**$ (9,267)**
Stock-based compensation	473	499	418
Depreciation and amortization expenses	491	563	335
Change in fair value of contingent consideration	879	(13,696)	3,312
Impairment losses	—	41,900	—
Impairment loss on held for sale assets	—	—	169
Consolidated Non-GAAP loss from operations, as adjusted	**$ (4,956)**	**$ (4,361)**	**$ (5,033)**