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## The Offering

Issuer	Oncocyte Corporation
Ticker / Exchange	OCX / NASDAQ
Offering Size	\$15+ million (100% primary)
Offering Type	Private Placement in Public Securities (PIPE)
Use of Proceeds	Series A Preferred / General Corporate and Working Capital
Expected Announcement Date	Thursday, April 11
Lockup Period	60 days
Sole Placement Agent	Needham & Company



## **Oncocyte Investment Summary**



- Disruptive transplant monitoring technology
- Partnership with and strategic equity investment by industry leader Bio-Rad Laboratories, Inc. (NYSE:BIO)
  - Up-front equity investment
  - Potential milestone-based equity investment
- CMS reimbursement for VitaGraft Kidney received 8/25/23
- VitaGraft Kidney IVD assay launch expected 4Q 2025
- GraftAssure launch expected **2Q 2024**
- Differentiated, multi-channel commercial approach, with capital light business model
- Anticipated 2024 publications may lead to CMS claims expansion
- Pipeline of additional innovative diagnostic tests with opportunities for **reimbursement in 2024**



# **Oncocyte's Multi-Channel Approach**

Ensuring the broadest possible access to our technology







# **CONCOCYTE** (BIO-RAD) Partnership

### **Key Terms**

- Commercial mutual exclusivity in donor-derived cell-free DNA (dd-cfDNA) monitoring
- Commercialization of GraftAssure RUO product
  - □ Co-marketing in US and Germany, Oncocyte to act as commercial lead
  - □ Bio-Rad exclusive commercial and distribution rights in rest of world
- Coordinated effort on rapid development of IVD assay and platform

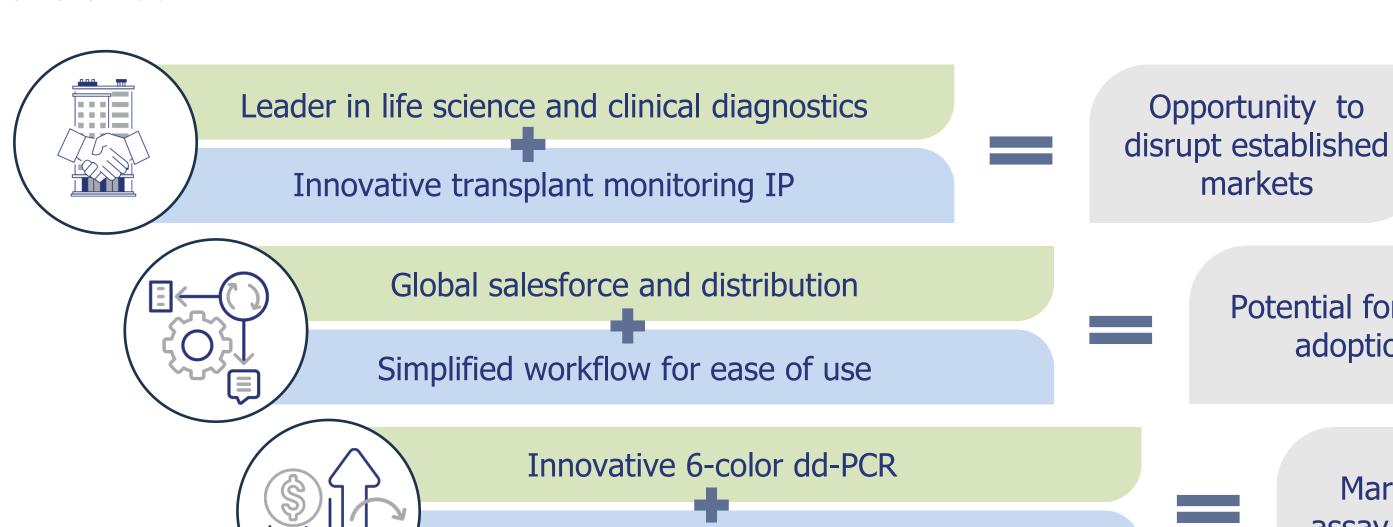
#### **Financial Terms**

- Upfront equity investment
- At FDA clearance, option period for Bio-Rad to acquire IVD commercial rights with additional equity investment



# **ONCOCYTE** / BIO-RAD Partnership

At a Glance...



Market leading assay performance Novel assay design

Complementary product portfolio

Repeat testing opportunities

Strong recurring revenue

Potential for rapid

adoption



# Large Global Transplant Market Opportunity



(RESEARCH USE ONLY)

800,000 est.\*
testing opportunities US market

2 million est.\*
testing opportunities ex-US

By providing a cost-efficient test for dd-cfDNA, we enable researchers to explore new indications

Strong ex-US demand for access to technology that has largely been trapped in central lab model



<sup>\*</sup> Clinical Rationale for a Routine Testing Schedule Using Donor-Derived Cell-Free DNA After Kidney Transplantation - PMC (nih.gov)







# **US Clinical Market for Transplant**



## \$500M est.\*

US revenue currently generated by competitors

## VitaGraft Kidney LDT

US Reimbursement -**\$2,222** first contact\*\*, **\$1,030** repeat Mature clinical market, with strong reimbursement

Growing demand for decentralized testing at local lab

Single-site de novo pathway to establish predicate device at FDA



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### Without better testing, most high-risk patients require invasive biopsy



#### **Potential Problems with Biopsy**

- Expensive compared to blood test
- Increases risk of complications including hospitalization
- Invasive procedure





### But with VitaGraft, many biopsies are unnecessary



**Up to 86%** (lower CI: 59%) **of biopsies in patients with elevated Creatinine may possibly be avoided by using VitaGraft**<sup>1</sup>



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# Significant Progress on Path to Commercialization



Transplant Product Design, 2012



Initial Peer-Reviewed Publication, 2013<sup>1</sup>



Definitive Clinical Publication, 2019<sup>2</sup>



US Patent Issued, 2021<sup>3</sup>



US LDT Validation, 2022



CMS Reimbursement, 2023



LDT Launching and RUO Expected 2024



**FDA Clearance & IVD Launch Expected 2025** 

CMS – Center for Medicaid Services LDT – Lab Developed Test RUO – Research Use Only FDA – US Food and Drug Administration

- 1. Beck et al. ddPCR for Tx Injury, Clinical Chemistry 59:12 1732–1741 (2013)
  - Oellerich et al. Kidney Validation Cohort 2019 AJT
- 3. U.S. Patent No. 11,155,872



IVD - In Vitro Diagnostic

## **Global Revenue Opportunity**

Strong pre-launch interest in RUO assay from leading transplant centers in multiple global markets:







# **Untapped Demand at US Transplant Institutions**

dd-cfDNA testing delivered in restrictive central lab service model

## **Highly Concentrated Market**

- <100 transplant centers in U.S. market generate approximately 80% of the transplant volume<sup>1</sup>
- Recent market research shows >90% of U.S. transplant surgeons order dd-cfDNA tests
  - Physicians send over 200,000 tests/yr.<sup>2</sup> to two
- California labs because they do not have a way to run tests in house





# **Growing Untapped Global Market**

Central lab model is difficult to export, leaving significant unmet demand



- >\$1B global transplant testing opportunity\*
- Number of transplants globally growing 9.1% per year
- Fewer than **1,000** call points globally
- Up to 90% of the potential market is unserved
- Market is looking for affordable, easy-to-use, rapid testing



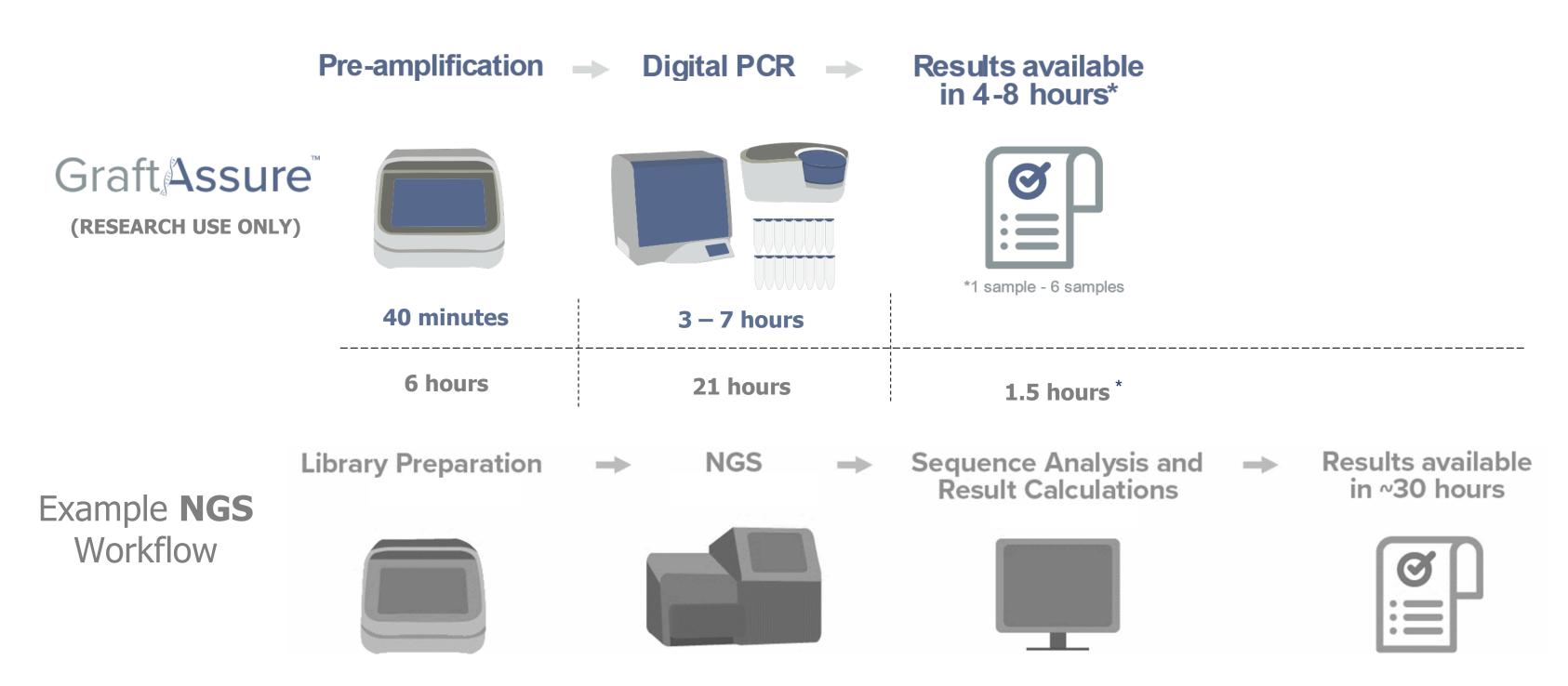
<sup>1.</sup> Home - GODT (transplant-observatory.org)

<sup>2. 2022</sup> organ transplants again set annual records (unos.org)

<sup>\*</sup> Assumes 2,800,000 testing opportunities annually and a management estimate of \$600 per test for a regulated product

# **Improving Transplant Monitoring with PCR**

Easy to use, easy to adopt, rapid turn-around time



PCR = Polymerase Chain Reaction
NGS = Next Generation Sequencing

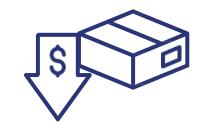
<sup>\*</sup> Based on management estimate

# **Capital Light Business Model**

Scalable with high margins and profitability



Low PCR variable costs



Freeze-dried reagent kit for easy global shipping



Commitment to partnering across product lines to maintain low operational overhead



Globally scalable business model, without the need for a large and expensive sales force



# **Oncology IP Pipeline**

#### **Tumor Immune Micro-Environment**

2.6M est. annual global testing opportunities\*

\$2B est. US Market\*\*

Will patient benefit from immuno-therapy?



What is immune status at tumor site?



Published/Presented data: ~1400 patients across 6 tumor types

CMS submission in Q4 2022

**Ongoing 800+ patient NIH funded study** 



<sup>\*</sup> Haslam, et al. <a href="https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7063495/">https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7063495/</a> Study estimates 43.6% of all cancer cases are eligible for immunotherapy. American Cancer Society estimates 2.0M new cancer cases in United States in 2024 (<a href="https://acsjournals.onlinelibrary.wiley.com/doi/10.3322/caac.21820">https://acsjournals.onlinelibrary.wiley.com/doi/10.3322/caac.21820</a>). 2.0M x 43.6% = 872k US testing opportunities annually. Management estimates global addressable market to be 3x US Market. 872k x 3 = 2.6M

<sup>\*\*</sup> Management estimates based on US testing opportunities (above: 872k/year) and estimated reimbursement ASP of \$2400/test. 872k \* \$2400 = \$2B

# Oncology IP Pipeline

#### **Copy Number Instability (CNI)**

7.8M est. annual global testing opportunities\* **\$4B est. US Market**\*\*

Is the cancer therapeutic drug working?



How much copy number variation is present in the blood?



<sup>\*</sup> Haslam, et al. <a href="https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7063495/">https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7063495/</a> Study estimates 43.6% of all cancer cases are eligible for immunotherapy and CNI IO therapy monitoring. American Cancer Society estimates 2.0M new cancer cases in United States in 2024 (<a href="https://acsjournals.onlinelibrary.wiley.com/doi/10.3322/caac.21820">https://acsjournals.onlinelibrary.wiley.com/doi/10.3322/caac.21820</a>). Three CNI monitoring tests per patient are assumed.  $2.0M \times 43.6\% \times 3 = 2.6M \times 3 = 7.8M = 2.6M \times 3 = 2$ 

Published data: 1,300+ samples across 9 tumor types

CMS submission expected Q4 2024

**Established LCD for Therapy Efficacy**#

Patents issued in US<sup>†</sup> and EU<sup>††</sup>

# https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?lcdId=38779&ver=4



<sup>\*\*</sup> Management estimates based on US testing opportunities (above: 2.6M/year) and estimated reimbursement ASP of \$1600-\$1900/test.  $2.6M \times $1600 > $4B$ 

<sup>†</sup> US Patents: US10047397; US10214775; US9909186; US10378064; US10378064;

<sup>&</sup>lt;sup>††</sup> EU Patents: EP2576837; EP2558854; EP2768985; EP2931922; EP3201361

# Non-GAAP Condensed Consolidated Income

Statements

**\$'s in thousands** 

	Three Months Ended December 31,				Years Ended December 31,			
	2023		2022		2023		2022	
NET REVENUE	\$	314	\$	1,123	\$	1,924	\$	5,631
Cost of revenues		431		2,377		1,597		8,906
Gross profit (loss)		(117)		(1,254)		327		(3,275)
OPERATING EXPENSES  Research and development Sales and marketing General and administrative Other operating expenses, net  Total operating expenses		2,547 582 2,028 9,811 14,968	<b>-</b>	4,314 2,830 5,523 30,688 43,355		9,996 3,293 11,787 2,219 27,295		19,437 13,594 22,450 13,531 69,012
Loss from operations		(15,085)		(44,609)		(26,968)		(72,287)
Total other income (expense), net		186		(369)		280		(615)
NET LOSS	\$	(14,899)	\$	(44,978)	\$	(26,688)	\$	(72,902)

Significant decreases in operating spend can be seen year over year as the Company shifts strategy in 2023.

#### **Recent Cash Burn -**

Q3 2023: **\$3.6MM**Q4 2023: **\$4.4MM**Q1 2024: **\$3.8MM** est.

## Non-GAAP Condensed Consolidated Balance Sheets

		December 31,			
	2023			2022	
CURRENT ASSETS					
Cash and cash equivalents	\$	9,432	\$	21,503	
Accounts receivable, net	•	1,625		2,012	
Other current assets		643		1,756	
Assets held for sale		139		-	
TOTAL CURRENT ASSETS		11,839		25,271	
NONCURRENT ASSETS					
Fixed assets and leases, net		5,436		11,062	
Intangible assets, net		56,595		87,553	
Other noncurrent assets		2,164		2,071	
Impairment of held for sale assets		-		(25,866)	
TOTAL ASSETS	\$	76,034	\$	100,091	
CURRENT LIABILITIES					
Accounts payable	\$	998	\$	1,745	
Accrued liabilities from acquisition	-	2,314		2,423	
Other current liabilities		3,882		7,938	
TOTAL CURRENT LIABILITIES		7,194		12,106	
ROU and Financing lease liabilities, noncurrent		2,204		2,729	
Contingent consideration liabilities, noncurrent		38,530		45,662	
TOTAL LIABILITIES		47,928		60,497	
Series A Redeemable Convertible Preferred Stock		5,126		5,302	
SHAREHOLDERS' EQUITY					
Common Stock		310,295		294,929	
Accumulated other comprehensive income		49		39	
Accumulated deficit		(287,364)		(260,676)	
TOTAL SHAREHOLDERS' EQUITY		22,980		34,292	
TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY	\$	76,034	\$	100,091	

**\$'s in thousands** 



# **Anticipated Major Milestone Opportunities**

- 1H24 Launch GraftAssure RUO assay
- 2H24 Publication of DSA+ data in kidney transplant
- 2H24 Submit VitaGraft Kidney for claim expansion
- 2H24 Publication of pancreatic data for DetermaCNI
- 2H24 Submit DetermaCNI for reimbursement
- 2H25 VitaGraft Kidney IVD FDA clearance and launch



### **Experienced Leadership Team**

## **Pioneering Molecular Diagnostics**



JOSH RIGGS
President & Chief
Executive Officer



**EKKEHARD SCHÜTZ, MD, PHD, FAACC**Chief Science Officer



YUH-MIN (JOHNSON) CHIANG, PHD Chief Technology Officer

















# Thank You!



## **Josh Riggs**

President and CEO
Oncocyte Corporation
NASDAQ: OCX