

# Investor Presentation

**NASDAQ: OCX** 







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#### Disclaime

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#### **MISSION**

# Democratize access to novel molecular diagnostic testing to improve patient outcomes

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#### **Experienced leadership**

### **Pioneering Molecular Diagnostics & Disruptive Growth**



Josh Riggs

President & Chief Executive
Officer









Ekkehard Schütz, MD, PHD, FADLM

Chief Science Officer







Yuh-Min (Johnson) Chiang, PHD

Chief Technology Officer











**Andrea James** 

Chief Financial Officer





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# Innovative science meets simple business model

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# Oncocyte Investment Summary

- Disruptive approach to molecular diagnostic testing: Empower local labs with kits, versus central lab model
- · Proven credibility in first strategic market: Kidney transplant
- Go-to-market strategic partner and equity investment secured
- Science-driven team, experienced in molecular diagnostics and rapid growth
- Full R&D pipeline to fuel growth and portfolio expansion over the next decade
- IP portfolio attractive to partners and enables value protection





# Why invest in molecular diagnostics?

High value co	reation
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Empowers doctors to reduce uncertainty to **make better decisions** to save lives. Enables researchers to measure biomarkers to **inspire innovation**.

#### High value capture

Intellectual property protects our market position, commands high reimbursement rates, and therefore, can lead to **potential high margins and profitability**. Capitallight business model enjoys potential software-like gross margins.

# High-quality recurring revenue

Once a standard of care is proven or adopted, customer **life-time value** often exceeds 30 years.

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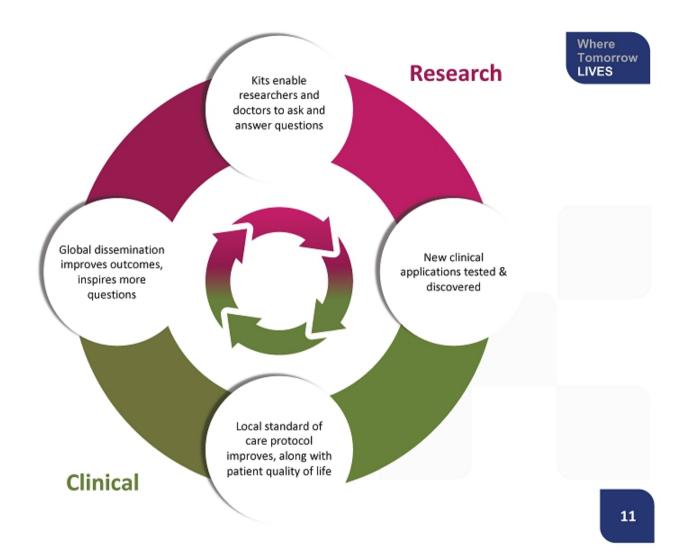
# Why kitted products?

Disruptive & superior business model	Empower our customers (the labs) to capture value. Counter-positioned to the central lab model, which is ripe for disruption with high cash burn.					
Compelling flywheel	Our decentralized approach puts testing in the hands of researchers to enable more studies. Innovation drives more testing, which drives more innovation, which drives more testing. Highly scalable.					
Social good	Democratizes access to testing to foster scientific innovation and treatment, and ultimately, reduces the cost of care while <b>improving outcomes</b> .					

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# Innovation flywheel







# Every clinical indication is a recurring revenue opportunity

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# Oncocyte's first strategic market Organ Transplant

#### ONCOCYTE



# **Transplant testing matters**

Kidney transplant patients face a 1 in 5 chance that their body will reject the donor kidney.

Oncocyte's test finds early evidence of organ damage in the blood.

Source on "1 in 5 chance:" Specifically, Antibody-mediated rejection (AMR) is a leading cause of kidney allograft failure. Up to 20.2% of kidney transplant patients will develop oncocyte.com AMR within 10 years of transplant and up to 70% of those patients will progress to graft failure. Reference: Mujtahedi, S.S., Yigitbilek, F., Ozdogan, E. et al. Antibody-Mediated Rejection: the Role of Plasma Cells and Memory B Cells. Curr Transpl Rep 8, 272-280 (2021). https://doi.org/10.1007/s40472-021-00342-1

Source on "Oncocyte's test finds early evidence of organ damage in the blood," Reference; https://investors.oncocyte.com/news-releases/2023/09-18-2023





# **US transplant market**

#### Ripe for disruption

In the U.S., donor-derived cell free DNA (dd-cfDNA) testing is delivered in **restrictive central lab service model**. Two companies command ~90% market share<sup>1</sup>.

#### **Highly concentrated**

About 250 kidney transplant centers nationwide. Fewer than 100 generate ~80% of transplant volume<sup>2</sup>

#### **Established science**

More than 90% of U.S. transplant surgeons order dd-cfDNA tests. Physicians send more than 200,000 tests per year<sup>1</sup> to two California labs because they do not have a way to run tests in house

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<sup>1.</sup> Internal estimate based on publicly available data

<sup>2.</sup> UNOS data; As of 2021, https://unos.org/about/national-organ-transplant-system/





# Global transplant underserved

Market wants affordable, easy-to-use, rapid testing

- Central lab model is difficult to implement outside the US, leaving significant unmet demand
- More than \$1 billion global transplant testing opportunity\*
- Global transplants growing ~9% per year
- Concentrated customer base with fewer than 1,000 labs





# Oncocyte's product appeal

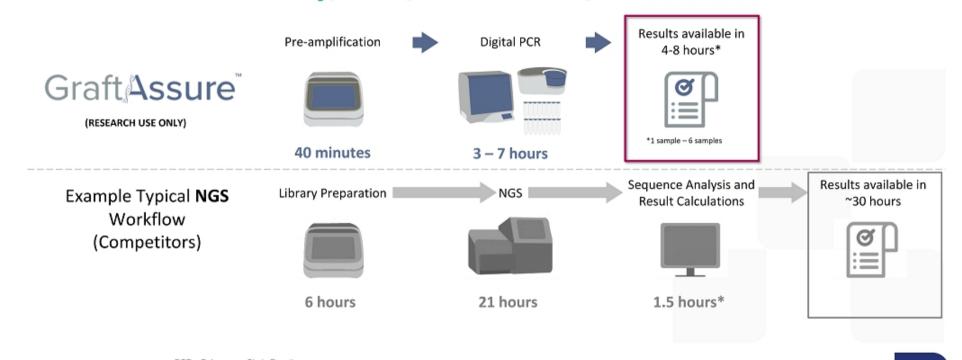
# Transplant centers want a test that is

- √ easy to use and
- ✓ returns a same day answer that is
- ✓ clinically actionable and
- ✓ cost effective





## PCR workflow: Easy, fast, actionable, affordable



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PCR = Polymerase Chain Reaction
NGS = Next Generation Sequencing
Users = Researchers, scientists, lab technicians
\* Based on management estimate

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## Oncocyte's proven credibility in transplant . . .

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 – Center for Medicaid Services LDT – Lab Developed Test RUO – Research Use Only FDA – US Food and Drug Administration IVD – In Vitro Diagnostic

Medicare (CMS) Reimbursement, 2023

major milestone

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

LDT and RUO Launched 2024

FDA IVD Clearance For Clinical Use Targeted Late 2025

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Transplant credibility, continued . . .

# New England Journal of Medicine study

- Favorable Oncocyte VitaGraft kidney study results published in NEJM, May 30, 2024
- Data show potential to monitor for therapeutic efficacy and recurrence
- Potential repeat testing opportunities with claims expansion

I™ NEW ENGLAND JOURNAL of MEDICINE

The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

#### A Randomized Phase 2 Trial of Felzartamab in Antibody-Mediated Rejection

K.A. Mayer, E. Schrezenmeier, M. Diebold, P.F. Halloran, M. Schatzl, S. Schranz, S. Haindl, S. Kasbohm, A. Kainz, F. Eskandary, K. Doberer, U.D. Patel, J.S. Dudani, H. Regele, N. Kozakowski, J. Kläger, R. Boxhammer, K. Amann, E. Puchhammer-Stockl, H. Vietzen, J. Bock, E. Schütz, A. Akifova, C. Firbas, H.N. Gilbert, B. Osmanodja, F. Halleck, B. Jilma, K. Budde, and G.A. Böhmig

#### ABSTRACT

#### BACKGROUND

Antibody-mediated rejection is a leading cause of kidney-transplant failure. The targeting of CD38 to inhibit graft injury caused by alloantibodies and natural killer (NK) cells may be a therapeutic option.

#### METHOD

In this phase 2, double-blind, randomized, placebo-controlled trial, we assigned patients with antibody-mediated rejection that had occurred at least 180 days after transplantation to receive nine infusions of the CD38 monoclonal antibody feltzartamab (at a dose of 16 mg per kilogram of body weight) or placebo for 6 months, followed by a 6-month observation period. The primary outcome was the safety and sideeffect profile of feltzartamab. Key secondary outcomes were renal-biopsy results at 24 and 52 weeks, donor-specific antibody levels, peripheral NK-cell counts, and donor-derived cell-free DNA levels.

#### RESULTS

A total of 22 patients underwent randomization (11 to receive felzartamab and 11 to receive placebo). The median time from transplantation until trial inclusion was 9 years. Mild or moderate infusion reactions occurred in 8 patients in the felzartamab group. Serious adverse events occurred in 1 patient in the felzartamab group and in 4 patients in the placebo around a serious description of the placebo around a serious description.





#### **Transplant: Leading the science**



Our centralized assay, VitaGraft, has been validated in clinical studies with an aggregate of ~800 patients and >3,000 samples.

#### 215 Liver Recipients

PLoS Med (2017)1, Liver Transpl (2022)2

#### **631 Kidney Recipients**

Am J Transplant (2019)<sup>3</sup>, Clin Chem (2020)<sup>4</sup>, Transplant Direct (2021)<sup>5</sup>, Kidney International Reports (2023)<sup>6</sup>, J Clin Med (2023),<sup>7</sup> New England Journal of Medicine (2024)<sup>8</sup>

#### **87 Heart Recipients**

Transplantation (2022)9

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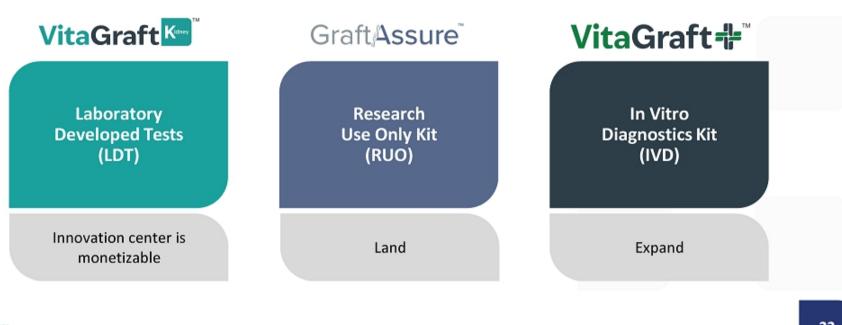
1. Schür E, Fischer A, Beck J, et al. (2017) Graft-derived cell-Free DNA, a nonimacine early rejection and graft damage marker in liver transplantation: A prospective, observational, multicenter colons touty. PLoS Med 14(4)xs1002286. 2, Baumann AK, Beck J, Kirchner T, et al. (2022) Elevated fractional domo-derived cell-Free DNA during subdiminizing graft injury after liver transplantation. No. 5, Shenor T, et al. (2023) A second T





Transplant, continued . . .

# One IP drives land & expand strategy



## Transplant commercialization strategy (1 - 3 years)



		Proof points	Targeted initial revenue
Innovation center	Perform testing at our clinical lab.	Medicare reimbursement achieved August 2023	Actively pursuing a partner
Land	Transplant centers and major research universities adopt research-only product	US funnel of confirmed interest represents 25% of transplant volumes <sup>1</sup> . As of September, we have signed several leading transplant centers, including a top-five transplant center in the U.S. and another top-five center in Germany.	2025
Expand	Achieve FDA clearance for the tests to make clinical decisions. Favorable to margins and testing volumes.	FDA review of clinical validation plan expected complete by December 2024. Final data submission mid-2025. FDA decision targeted late 2025.	2026
Expand II	EU approval for clinical use	Pursuing dual-pathway regulatory submission.	Late 2026
Expand III	Claims expansion. Clinical application use cases expand, such as from "for cause" to "monitoring"	NEJM article published May 2024 Phase II clinical trial began June 2024 with European pharma co. Case series study published August 2024	Ongoing TAM expansion

<sup>1.</sup> Based on management's estimates





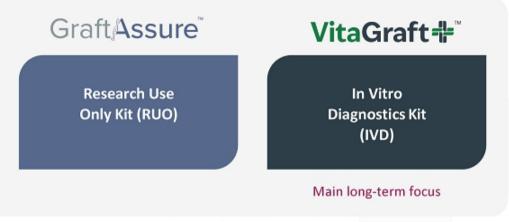
#### Transplant total addressable market

# **Annual recurring revenue potential**



Laboratory Developed Tests (LDT)

US market supports \$500 million annual revenue, which is currently generated by competitors<sup>1</sup>

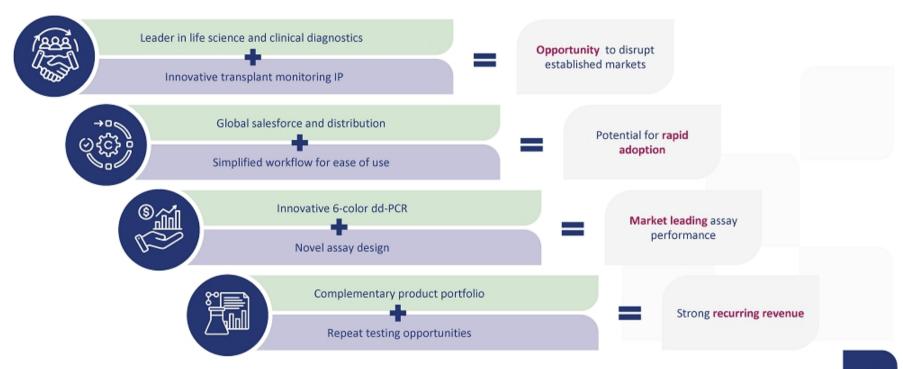


\$1 billion global TAM today<sup>1</sup>
Can expand to approximately \$2 billion with claims expansion<sup>1</sup>

#### Transplant: Key go-to-market strategic partner signed Q2 2024



# **■ONCOCYTE** / **BIO-RAD** Partnership



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#### Transplant strategic partner: Key terms



# **♣ONCOCYTE** / **BIO-RAD** Partnership

- BioRad (NYSE: BIO) became second largest shareholder
   April 2024 with upfront equity investment
- Commercial mutual exclusivity in dd-cfDNA monitoring
- Coordinated rapid development of IVD platform
- At FDA clearance, option for Bio-Rad to acquire commercial rights with additional investment

# Bio-Rad to help commercialize GraftAssure

- Co-marketing in US and Germany,
   Oncocyte to act as commercial lead
- Bio-Rad exclusive commercial and distribution rights in rest of world

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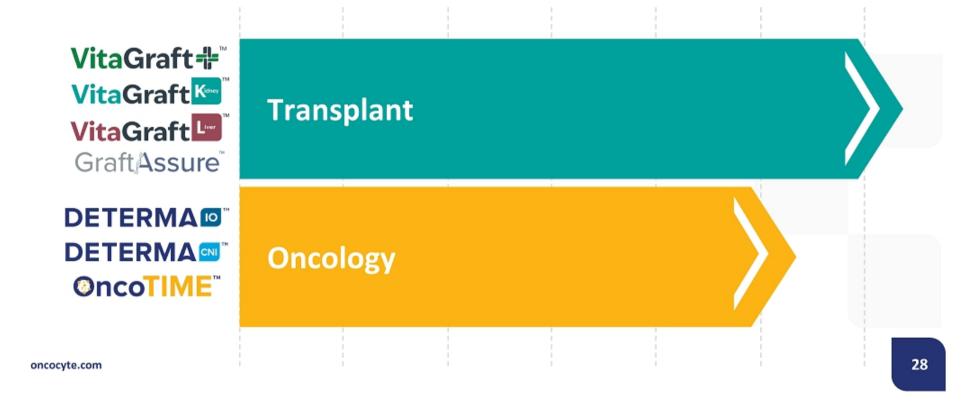


# What comes after transplant?





## Full R&D pipeline, to fuel a decade of growth





# Oncocyte's second strategic market Oncology



#### **Oncology Pipeline**

# DETERMA

## \$2 billion estimated TAM (US only)

2.6 million estimated annual global testing opportunities

Sources: 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 2.0 million 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>). (2.0 million x 43.6% = 872,000 US testing opportunities annually.)

Management estimates global addressable market to be 3x US market. (872,000 testing opportunities x 3 = 2.6 million global opportunities).

US TAM based on US testing apportunities of 872,000/year and estimated reimbursement ASP of \$2,400/test, 872k \* \$2,400 = \$2 billion

#### -ONCOCYTE\*



## **Oncology Pipeline**

#### Tumor Immune Micro-Environment

# **DETERMA**

Will patient benefit from immuno-therapy?



What is immune status at tumor site?

(RESEARCH USE ONLY)

- ✓ Published/Presented data: ~1,400 patients across 6 tumor types
- ✓ Medicare (CMS) coverage submission in Q4 2022
- ✓ Ongoing 800+ patient NIH funded study
- **✓ Favorable study in Clinical Cancer Research, September 2024**

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### **Oncology Pipeline**

# DETERMACNI

## \$4 billion estimated TAM (US Market)

7.8 million estimated annual global testing opportunities

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 10 therapy monitoring. American Cancer Society estimates 2.0 million new cancer cases in United States in 2024 (<a href="https://acsiournals.onlinelibrary.wiley.com/doi/10.3322/caac,21820">https://acsiournals.onlinelibrary.wiley.com/doi/10.3322/caac,21820</a>). Assumes 3 CNI monitoring tests per patient. (2.0 million x 43.6% x 3 = 2.6 million US testing opportunities annually.) Management estimates global addressable market to be 3x US Market. (2.6 million x 3 = 7.8 million global testing opportunities.)

US TAM based on 2.6 million testing opportunities/year) and estimated reimbursement ASP of \$1,600-\$1,900/test. (2.6 million x \$1,600 = "\$4 billion)

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## **Oncology Pipeline**

# Copy Number Instability (CNI)

## **DETERMA CNI**

Is the cancer therapeutic drug working?

MoIDX: Minimal Residual Disease Testing for Cancer, Local Coverage Determination: https://www.cms.gov/medicare-coverage-database/vlew/lcd.aspx?lcdId=38779&ver=4

US Patents: US10047397; US10214775; US9909186; US10378064; US10378064; EU Patents: EP2576837; EP2558854; EP2768985; EP2931922; EP3201361

- ✓ Published data: 1,300+ samples across
  9 tumor types
- ✓ CMS submission expected Q4 2024
- Patents issued in US and EU
- ✓ Pre-existing Medicare coverage (established LCD) for Therapy Efficacy

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# IP attractive to industry partners



Multiple strategic partnership opportunities

IP Category	Products	Product Partner	Service Lab Partner
Organ Transplant	VitaGraft ** VitaGraft ** VitaGraft ** Graft Assure*	✓ Bio-Rad signed Q2 2024	Actively pursuing
Oncology Therapy Selection	DETERMA©* OncoTIME*	Actively pursuing	
Oncology Therapy Monitoring	<b>DETERMA</b> ••		34





## **Oncocyte Investment Summary Recap**

- Disruptive approach to molecular diagnostic testing
  - Empower local labs with kits
  - · Better business model
  - Proven, more affordable, faster tests
- Science-driven team, experienced in molecular diagnostics and rapid growth

- Proven credibility in first strategic market: Kidney transplant
  - U.S. Medicare (CMS) reimbursement for VitaGraft Kidney received 8/25/23
  - New England Journal of Medicine (NEJM) study published May 2024
- ✓ Full R&D pipeline to fuel growth and portfolio expansion over the next decade

- Go-to-market strategic partner and equity investment secured
  - Industry leader Bio-Rad Laboratories, Inc. (NYSE:BIO) signed and invested in Q2 2024
  - Opportunities for future milestone-based investments
- IP portfolio protects market position and is attractive to potential partners



Thank You

MONCOCYTE"



# **Appendix**



**Molecular diagnostic testing** combines laboratory testing with the precision of molecular biology and has revolutionized the way clinical and public health laboratories investigate the human, viral, and microbial genomes, their genes, and the products they encode.

Molecular diagnostic tests are increasingly being used, and have supplanted numerous conventional tests, in many areas of laboratory medicine including oncology, infectious diseases, clinical chemistry, and clinical genetics.

Advancements in molecular diagnostic testing will continue to improve the accuracy and speed by which we can detect microbial pathogens or analyze a patient's genes, and is becoming an essential aspect of patient-tailored interventions and therapeutics.

-- U.S. Department of Health and Human Services

Molecular – relating to or consisting of molecules, which are groups of atoms bonded together, representing the smallest fundamental unit of a chemical compound that can take part in a chemical reaction

Molecular biology – the branch of biology that studies the molecular basis of biological activity

**DNA** – a molecule that stores the genetic information of living beings, and the substance on which molecular biology focuses its research.

### **Molecular diagnostics 101**



#### **ONCOCYTE**



## Transplant: US research market share potential

# Graft Assure<sup>™</sup>

(RESEARCH USE ONLY)

~800,000

estimated testing opportunities US market

~2 million

estimated testing opportunities rest-of-world



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



Strong international demand for access to technology that has largely been trapped in central lab model

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

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





### **Transplant: US clinical market share potential**



#### ~\$500 million

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

<sup>\*</sup> Management estimate based on public disclosures from competitors. Calculation includes competitor tests for heart, lung, and other organs in addition to kidney

<sup>\*\*</sup> https://app.dexzcodes.com/





For-cause testing example

# 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





For cause testing example

# But with VitaGraft, many biopsies are unnecessary





(lower CI: 59%)

of biopsies in patients with elevated Creatinine may possibly be avoided by using VitaGraft<sup>1</sup>

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Gellerich M, Shipkova M, Asendorf T, et al. (2019) Absolute quantification of donor-derived cell-free DNA as a marker of rejection and graft injury in kidney transplantation: Results from a prospective observational study. Am J Transplant 19(11):3087.

# MONCOCYTE® Q2 2024 GAAP P&L



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

\$'s in thousands

Results demonstrate prudent capital management and financial discipline ahead of revenue ramp.

	Three Months Ended June 30,			Six Months Ended June 30,				
		2024		2023		2024		2023
Net revenue	\$	104	S	463	\$	280	S	760
Cost of revenues		32		169		141		434
Cost of revenues - amortization of acquired intangibles		22		22		44		44
Gross profit		50		272		95		282
Operating expenses:								
Research and development		2,453		2,435		4,765		4,562
Sales and marketing		853		805		1,699		1,500
General and administrative		2,407		3,531		5,080		6,943
Change in fair value of contingent consideration		(1,031)		1,795		2,281		(16,512)
Impairment loss						-		4,950
Impairment loss on held for sale assets						169		1,283
Total operating expenses		4,682		8,566		13,994		2,726
Loss from operations	_	(4,632)	_	(8,294)	_	(13,899)		(2,444)
Other (expenses) income:								
Interest expense		(8)		(14)		(23)		(25)
Unrealized (loss) gain on marketable equity securities				(24)				97
Other income (expenses), net		110		(1)		263		(2)
Total other income (expenses)		102		(39)		240		70
Loss from continuing operations		(4,530)		(8,333)		(13,659)		(2,374)
Loss from discontinued operations (Note 11)	_	<u> </u>						(2,926)
Net loss	s	(4,530)	s	(8,333)	s	(13,659)	s	(5,300)

#### ONCOCYTE CORPORATION CONDENSED CONSOLIDATED BALANCE SHEETS

(In thousands, except per share data)

-ONCOCYTE® **Condensed Consolidated Balance Sheets** 

\$'s in thousands

		June 30, 2024		December 31, 2023	
	(1	Inaudited)			
ASSETS					
CURRENT ASSETS					
Cash and cash equivalents	\$	9,256	S	9,43	
Accounts receivable, net of allowance for credit losses of \$1 and \$5, respectively		85		48	
Prepaid expenses and other current assets		595		64	
Assets held for sale		32		13	
Total current assets		9,968		10,69	
NONCURRENT ASSETS					
Right-of-use and financing lease assets, net		2,591		1,63	
Machinery and equipment, net, and construction in progress		3,347		3,79	
Intangible assets, net		56,551		56,59	
Restricted cash		1,700		1,70	
Other noncurrent assets		563		46	
TOTAL ASSETS	\$	74,720	S	74,89	
LIABILITIES AND SHAREHOLDERS' EQUITY					
CURRENT LIABILITIES					
Accounts payable	\$	1,051	S	95	
Accrued compensation		1,309		1,64	
Accrued royalties		1,116		1,11	
Accrued expenses and other current liabilities		379		45	
Accrued severance from acquisition		2,314		2,31	
Right-of-use and financing lease liabilities, current		1,029		66	
Current liabilities of discontinued operations (Note 11)		-		4	
Total current liabilities		7,198		7,19	
NONCURRENT LIABILITIES					
Right-of-use and financing lease liabilities, noncurrent		2,638		2,20	
Contingent consideration liabilities		42,181	_	39,90	
TOTAL LIABILITIES		52.017		49.29	
				47,27	
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				5,12	
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; 13,368 and 8,261 shares issued and					
outstanding at June 30, 2024 and December 31, 2023, respectively		326,201		310,29	
Accumulated other comprehensive income		37		4	
Accumulated deficit		(303,535)	_	(289,87	
Total shareholders' equity	_	22,703		20,46	
TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY	\$	74,720	S	74,89	

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