



Investor Presentation

NASDAQ: OCX



oncoocyte.com

Forward looking statements

Safe-Harbor Statement

This presentation and the accompanying oral presentation contain “forward-looking” statements that are based on Oncocyte’s management’s beliefs and assumptions and on information currently available to management. 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, among others, those pertaining to the Oncocyte’s development and commercial model (including margin and cost, reimbursement, revenue and profitability, strategic partnerships, market positioning and competitive advantage, global scalability, capital efficiency, accelerated adoption and clinical development), anticipated timing of regulatory clearances, product development and launch and milestone opportunities, along with 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.

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MISSION

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

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



Innovative science **meets** simple business model

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** enables value protection while decentralizing

Why invest in molecular diagnostics?

High value creation

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, **high margins and profitability**. Capital-light business model enjoys 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.

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.

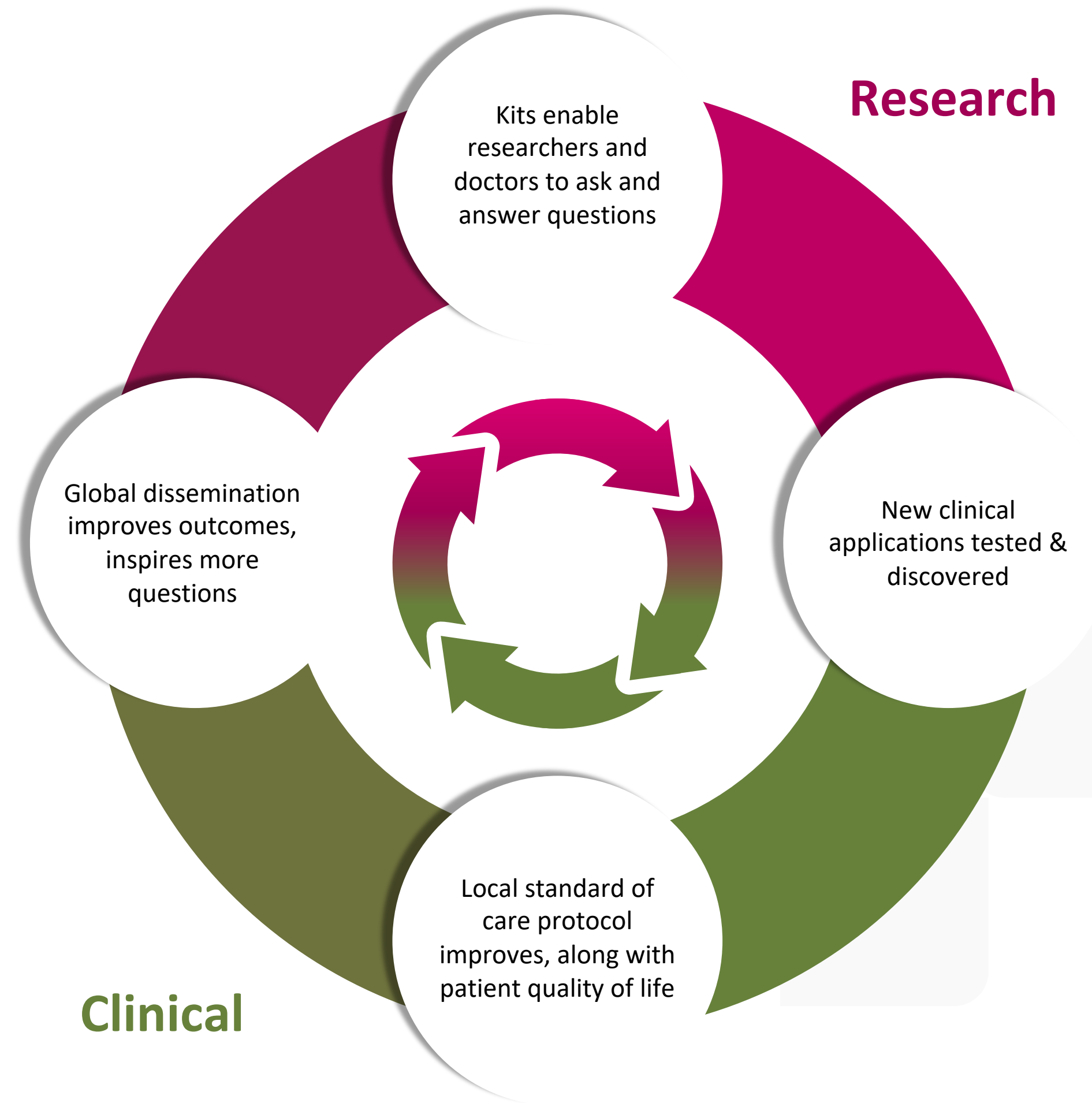
Compelling flywheel

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 **improving outcomes**.

Innovation flywheel



Every clinical indication is
a recurring revenue
opportunity



Oncocyte's first strategic market

Organ Transplant

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.

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.

Highly concentrated

About 250 kidney transplant centers nationwide. Fewer than 100 generate ~80% of transplant volume¹

Established science

More than **90% of U.S. transplant surgeons** order dd-cfDNA tests. Physicians send more than 200,000 tests per year² to other centralized labs **because they do not have a way to run tests in house**

1. UNOS data, <https://unos.org/about/national-organ-transplant-system/>
2. Internal estimate based on publicly available data

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

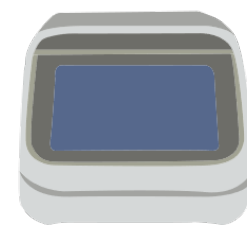
**Transplant centers
want a test that is**

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

PCR workflow: Easy, fast, actionable, affordable

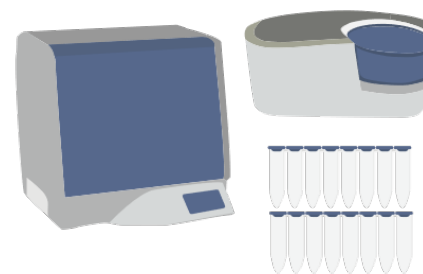
GraftAssure™
(RESEARCH USE ONLY)

Pre-amplification



40 minutes

Digital PCR



3 – 7 hours

Results available in
4-8 hours*



*1 sample – 6 samples

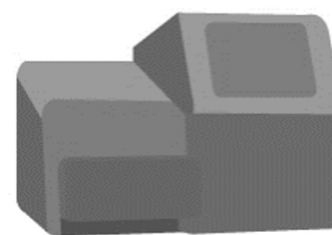
Example Typical **NGS**
Workflow
(Competitors)

Library Preparation



6 hours

NGS



21 hours

Sequence Analysis and
Result Calculations



1.5 hours*

Results available in
~30 hours



Oncocyte's proven credibility in transplant . . .

- ✓ Transplant Product Design, 2012
- ✓ Initial Peer-Reviewed Publication, 2013¹
- ✓ Definitive Clinical Publication, 2019²
- ✓ US Patent Issued, 2021³
- ✓ 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

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

➡ LDT and RUO Launched 2024

□ FDA IVD Clearance For Clinical Use Targeted Late 2025

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**



The 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-Stöckl, H. Vietzen, J. Beck, 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.

METHODS

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 felzartamab (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 side-effect profile of felzartamab. 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 group: graft loss occurred in 1 patient in the placebo

Transplant: Leading the science

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

226 Liver Recipients

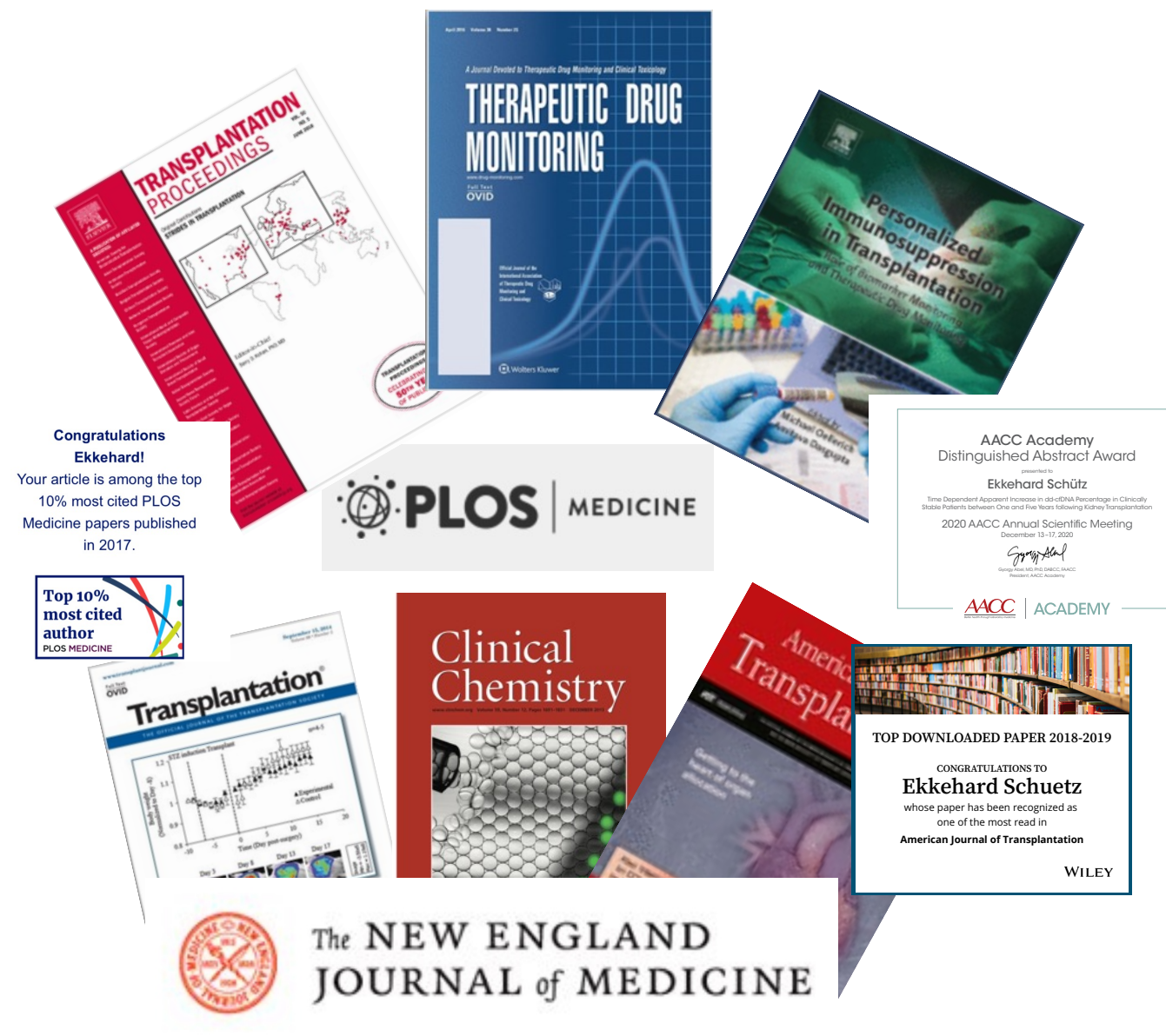
PLoS Med (2017)¹, Liver Transpl (2022)²

481 Kidney Recipients

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

87 Heart Recipients

Transplantation (2022)⁸



Transplant, continued . . .

One IP drives land & expand strategy

VitaGraft[™]
Kidney

Laboratory
Developed Tests
(LDT)

Innovation center is
monetizable

GraftAssure[™]

Research
Use Only Kit
(RUO)

Land

VitaGraft[™]
Kidney IVD

In Vitro
Diagnostics Kit
(IVD)

Expand

Transplant commercialization strategy (1 – 3 years)

		Proof points	Targeted initial revenue
Innovation center	Perform testing at our clinical lab on behalf of customers (doctors, hospitals, partners).	Medicare reimbursement achieved August 2023	Partner driven
Land	Transplant centers and major research universities adopt research-only product	Strong global pipeline & rapidly expanding funnel.	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 Separate Phase II clinical trial began June 2024	Ongoing TAM expansion

Transplant total addressable market

Annual recurring revenue potential

VitaGraftTM
Kidney

Laboratory
Developed Tests
(LDT)

US market supports
\$500 million annual revenue

GraftAssureTM

Research Use
Only Kit (RUO)

VitaGraftTM
Kidney IVD

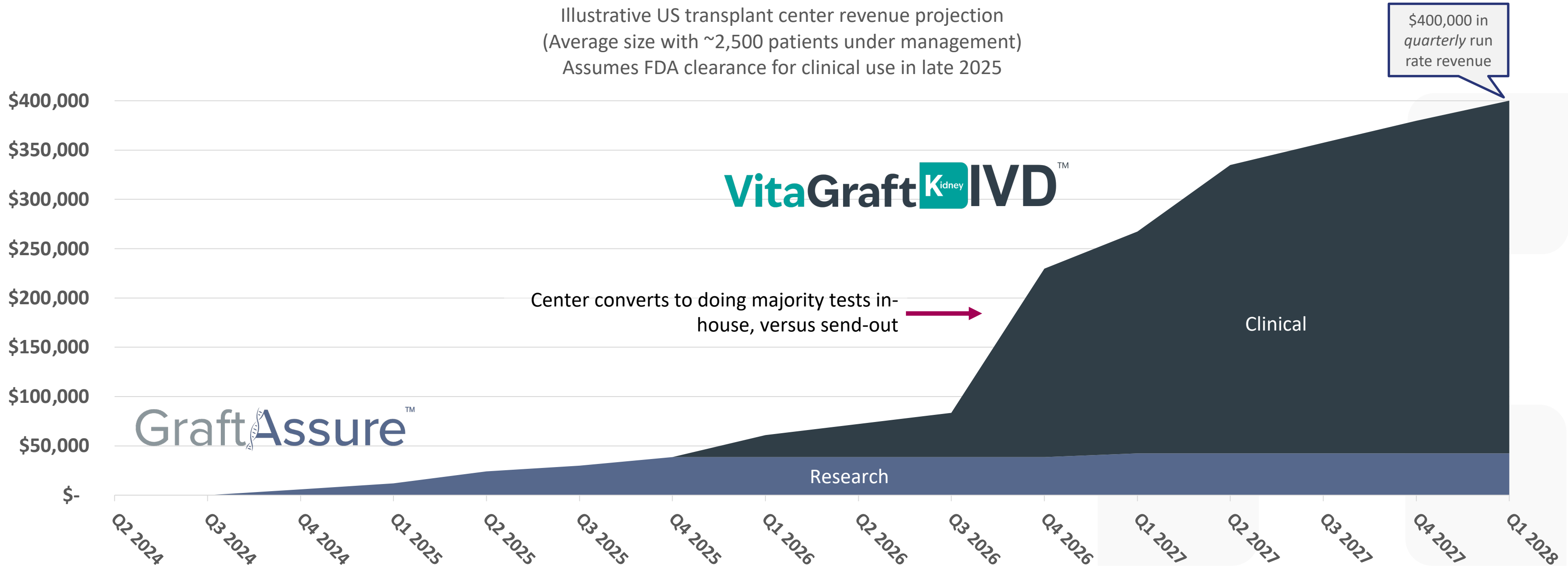
In Vitro
Diagnostics Kit
(IVD)

Main long-term focus

\$1 billion global TAM today
Can expand to \$2 billion with claims expansion

Beta customer revenue path

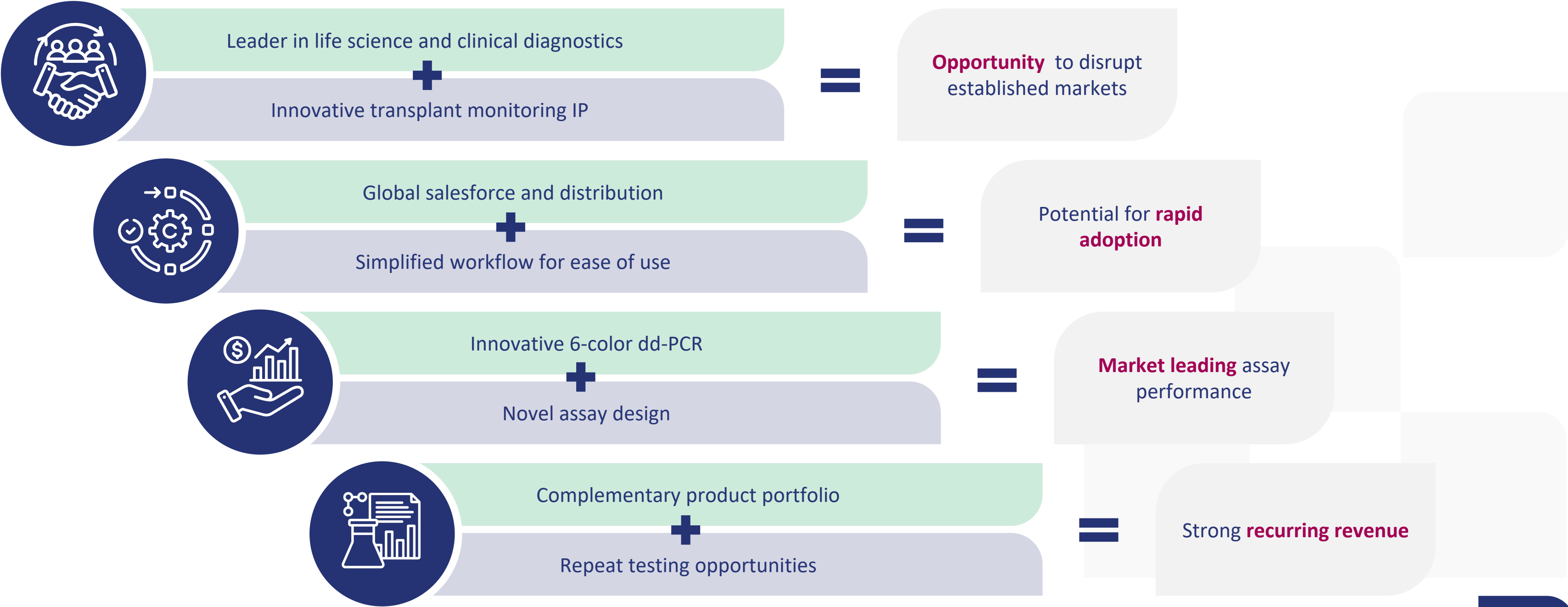
Illustrative US transplant center revenue projection
(Average size with ~2,500 patients under management)
Assumes FDA clearance for clinical use in late 2025



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

Where
Tomorrow
LIVES

ONCOCYTE™ / BIO-RAD Partnership



ONCOCYTE™ / Partnership

- BioRad (NYSE: BIO) became second largest shareholder 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

What comes after transplant?

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

GraftAssure™
VitaGraft^Kidney™
Personalized Transplant Monitoring
VitaGraft^Liver™
Personalized Transplant Monitoring
VitaGraft^Kidney IVD™

DETERMA^{IO}™
DETERMA^{CNI}™
OncoTIME™

Transplant

Oncology



Oncocyte's second strategic market

Oncology

oncocyte.com

Oncology Pipeline

DETERMA ™

\$2 billion TAM (US only)

2.6 million annual global testing opportunities

Sources: Haslam, et al. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7063495/> 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 (<https://acsjournals.onlinelibrary.wiley.com/doi/10.3322/caac.21820>). (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 opportunities of 872,000/year and estimated reimbursement ASP of \$2,400/test. $872k \times \$2,400 = \2 billion

Oncology Pipeline

Tumor Immune Micro- Environment

DETERMA  TM

Will patient benefit from immuno-therapy?

 **OncoTIME** TM

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 expected summer 2024

Oncology Pipeline

DETERMA ™

\$4 billion TAM (US Market)

7.8 million annual global testing opportunities

Haslam, et al. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7063495/> Study estimates 43.6% of all cancer cases are eligible for immunotherapy and CNI IO therapy monitoring. American Cancer Society estimates 2.0 million new cancer cases in United States in 2024 (<https://acsjournals.onlinelibrary.wiley.com/doi/10.3322/caac.21820>). 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)

Oncology IP Pipeline

Copy Number Instability (CNI)

DETERMA CNI™

Is the cancer therapeutic drug working?

MolDX: Minimal Residual Disease Testing for Cancer, Local Coverage Determination:
<https://www.cms.gov/medicare-coverage-database/view/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

Oncocyte Investment Summary

✓ **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

Thank You



 **ONCOCYTE™**



 **ONCOCYTE™**



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

Transplant: US research market share potential

GraftAssureTM

(RESEARCH USE ONLY)

~800,000

testing
opportunities US
market

~2 million

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

* Home - GODT (transplant-observatory.org)

* [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

VitaGraftTMK_{idney} + **VitaGraftTMK_{idney}IVD**

~\$500 million

US revenue currently generated by competitors

VitaGraft Kidney LDT

US Reimbursement –

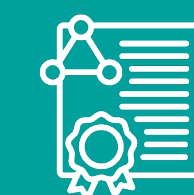
\$2,222 first contact**, **\$1,030** repeat



Mature clinical market, with strong reimbursement



Growing demand for decentralized testing at local lab

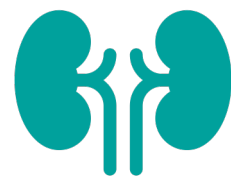
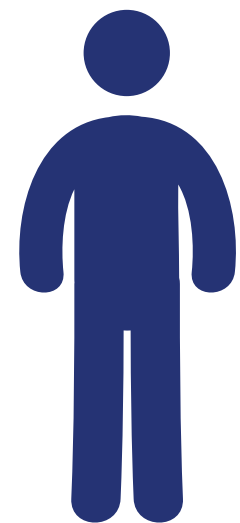


Single-site de novo pathway to establish predicate device at FDA

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

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

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



Elevated
Kidney Function
Tests



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



Up to 86%

(lower CI: 59%)

of biopsies in patients with elevated Creatinine may possibly be avoided by using VitaGraft¹

1. Oellerich 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.



Q2 2024 GAAP & Non-GAAP P&L

\$'s in thousands

Significantly reduced operating losses compared with prior years through prudent capital management and financial discipline ahead of revenue ramp.

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NET REVENUE

Cost of revenues
Cost of revenues – amortization of acquired intangibles
Gross profit

OPERATING EXPENSES

Research and development
Sales and marketing
General and administrative
Change in fair value of contingent consideration
Impairment losses
Impairment loss on held for sale assets

Total operating expenses

Loss from operations

Total other income (expenses), net

Loss from continuing operations
Loss from discontinued operations

NET LOSS

NON-GAAP LOSS FROM OPERATIONS

Loss from operations
Stock-based compensation
Depreciation and amortization expense
Change in fair value of contingent consideration
Impairment losses
Impairment loss on held for sale assets
Non-GAAP loss from operations, as adjusted

	Three Months Ended June 30,		Six Months Ended June 30,	
	2024	2023	2024	2023
NET REVENUE	\$ 104	\$ 463	\$ 280	\$ 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 losses	-	-	-	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)
Total other income (expenses), net	102	(39)	240	70
Loss from continuing operations	(4,530)	(8,333)	(13,659)	(2,374)
Loss from discontinued operations	-	-	-	(2,926)
NET LOSS	\$ (4,530)	\$ (8,333)	\$ (13,659)	\$ (5,300)
NON-GAAP LOSS FROM OPERATIONS				
Loss from operations	\$ (4,632)	\$ (8,294)	\$ (13,899)	\$ (2,444)
Stock-based compensation	386	816	804	1,650
Depreciation and amortization expense	326	457	661	929
Change in fair value of contingent consideration	(1,031)	1,795	2,281	(16,512)
Impairment losses	-	-	-	4,950
Impairment loss on held for sale assets	-	-	169	1,283
Non-GAAP loss from operations, as adjusted	\$ (4,951)	\$ (5,226)	\$ (9,984)	\$ (10,144)

Where
Tomorrow
LIVES



Condensed Consolidated Balance Sheets

\$'s in thousands

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CURRENT ASSETS

Cash and cash equivalents
Accounts receivable, net
Other current assets
Assets held for sale

TOTAL CURRENT ASSETS

NONCURRENT ASSETS

Fixed assets and leases, net
Intangible assets, net
Other noncurrent assets

TOTAL ASSETS

CURRENT LIABILITIES

Accounts payable
Accrued liabilities from acquisition
Other current liabilities
Current liabilities of discontinued operations

TOTAL CURRENT LIABILITIES

ROU lease liabilities, noncurrent
Contingent consideration liabilities, noncurrent

TOTAL LIABILITIES

Series A Redeemable Convertible Preferred Stock

SHAREHOLDERS' EQUITY

Common Stock
Accumulated other comprehensive income
Accumulated deficit

TOTAL SHAREHOLDERS' EQUITY

TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY

	June 30, 2024	December 31, 2023
	\$ 9,256	\$ 9,432
	85	484
	595	643
	32	139
	<u>9,968</u>	<u>10,698</u>
	5,938	5,436
	56,551	56,595
	2,263	2,163
	<u>\$ 74,720</u>	<u>\$ 74,892</u>
	\$ 1,051	\$ 953
	2,314	2,314
	3,833	3,882
	-	45
	<u>7,198</u>	<u>7,194</u>
	2,638	2,204
	42,181	39,900
	<u>52,017</u>	<u>49,298</u>
	-	5,126
	326,201	310,295
	37	49
	(303,535)	(289,876)
	<u>22,703</u>	<u>20,468</u>
	<u>\$ 74,720</u>	<u>\$ 74,892</u>

Where
Tomorrow
LIVES