# Vericidx

# Interim Results to 30 June 2023

October 2023

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Transforming kidney transplant outcomes

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### Clear market opportunity with compelling company positioning

Significant Unmet Need and Large Market	<ul> <li>Unacceptably high rate of transplant rejection (37-50%) with inadequate standard of care</li> <li>Large addressable market opportunity worth over \$5bn and growing</li> </ul>
Innovative Product Platform	<ul> <li>RNA signature-based transplant technology producing high performing and actionable diagnostics enabling accurate, data-driven support for critical decisions where there is now guesswork</li> <li>Three complementary tests covering full transplant lifecycle with expansion opportunities into new organs and technologies</li> </ul>
Strong Clinical Data and Validation	<ul> <li>Technology developed over 10 years with three peer reviewed publications and more expected within next year</li> <li>1 product in commercial launch, 1 completed validation and 1 product validation endpoint in 15 months</li> <li>Highly curated data within an innovative environment to promote collaboration and scalability</li> </ul>
Experienced Team and Accelerated Path to Market	<ul> <li>Experienced diagnostics and transplant teams and early adopting centers</li> <li>Accelerated regulatory &amp; reimbursement path for commercial launch within 24 months</li> </ul>



# What is the risk of rejection?

#### Current practice: Broad Clinical Factors/Score

- Too general and largely ignored
- No prognostic information
  - "One Size Fits All" therapy
     protocol



# Is the graft being rejected or damaged?

#### Current practice: Standard of Care

• Misses 30% of all cases

#### **Competitive tests**

- cfDNA is non-specific
- Measures the "debris" after damage has occurred

**Over-treatment** can result in **drug toxicity, viral infections and malignancy** 

Under-treatment can lead to Immune System-caused rejection

Clinicians needs better diagnostics to replace the guesswork

Through three foundational tests, enhanced end-to-end transplant testing for improved outcomes



# O) clarava<sup>™</sup>

### **Pre-Transplant Prognostic**

#### mRNA 10 gene Signature

#### <u>Advantages</u>:

- Provides risk score for early acute rejection within the first 6 months
- Informs therapeutic modulation
- No current competitors

Patients now can be prescribed treatment at an appropriate level

# (Otutivia<sup>™</sup>

### **Post-Transplant Prognostic**

#### mRNA 17 gene Signature

#### <u>Advantages</u>:

- Specific real time diagnostic of immune activation before irreversible damage occurs
- Sequencing is more accessible and stable than microarray

Fibrosis/Long-term Prognostic mRNA 9 gene Signature <u>Advantages</u>:

(Oprotega<sup>™</sup>

Replaces biopsy on a monitoring basis



#### • Two clinically validated products:

- **Tutivia** <sup>™</sup>: Positive clinician feedback following its commercial launch at the start of the year
  - Peer-reviewed publication imminent
- Clarava<sup>™</sup>: On track for initial US commercial use under prospective real-world evidence (RWE) studies
  - Abstract accepted
- Preliminary reimbursement rate of \$2,650 (median), above market expectations
  - For both Tutivia<sup>™</sup> and Clarava<sup>™</sup> via 'gapfill' method (valid for 3 years from January 2024)
- Further progress on Protega<sup>™</sup> product with patient enrolment completed
- Strong IP protection: portfolio of 18 patents across five patent families
  - includes two US patents protecting core technologies
- Achieved CLIA Certificate of Compliance in 49 states
- Medicaid approvals in 15 states with a further 12 pending, a key catalyst for driving adoption
- Continued development of our research collaborations including leveraging specimen and data assets



- Initial transplant centre adoption
  - Slower than anticipated
    - CMS "clarifications" caused short-term confusion. This appears to be resolving in Q3
    - Logistical issues around sample collection process now resolved with a new approach in operation
    - Commercial decision to operate with a very small sales team to focus on a high-quality customer experience while carefully managing COStS
- Technical Assessment ("TA") submission dependent upon peer-reviewed publication
  - Forms part of TA submission for Local Coverage Determination ("LCD") from Medicare
  - TA now expected in 2024 (vs. previous expectation Q4 2023)
- Revenue mix
  - Slower adoption of Tutivia<sup>™</sup> expected to be offset by income from research collaborations/ access to specimen and data assets
- Cash runway to mid 2024 (guidance unchanged)

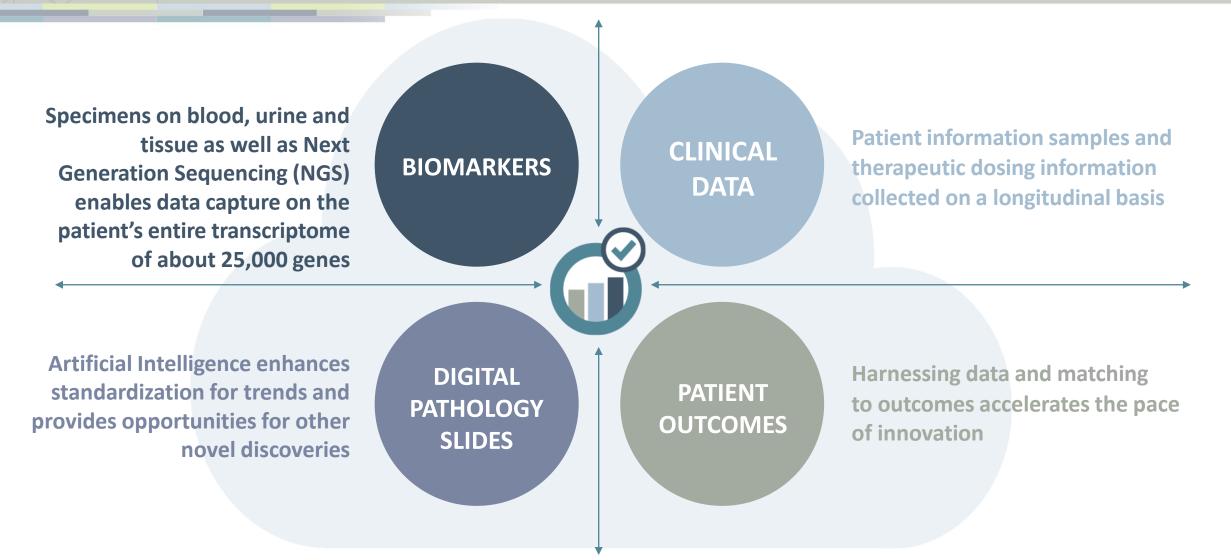
#### Positive operational and commercial outlook



- Tutivia<sup>™</sup>: Increasing adoption and tests ordered
  - Doubled the number of centers in the early adoption programme through Q3
  - Excellent clinical feedback follow us on Social Media (e.g. LinkedIn, X etc.) for clinician video interviews
  - Medicare and private payor pricing and coverage submission for Tutivia<sup>™</sup> still expected this year
- Clarava<sup>™</sup>: Progressing towards initial US commercial launch after clinical positioning
- Option for a distribution partner or a modest direct sales force of around 10 to 12 individuals, to facilitate more ambitious targets over time
- Progress on publications, with final responses submitted for peer-reviewed publication on the Tutivia<sup>™</sup> clinical validation
- Options to monetize research opportunities Directors believe that the commercial value of specimen and data assets exceeds total cash raised to date

#### Underpinned by an unparalleled data set for leading competitive advantage





DELIVERING INCREASINGLY PERSONALISED TRANSPLANT MEDICINE



#### **Cash Flow Statement**



#### Six months to 30 June 2023

Unaudited	\$'000
Net outflow from operating activities	(4,766)
Investing activities	(106)
Financing activities	28
Net decrease in cash	(4,844)
Cash at 30 June 2023	5,249

#### Comments

- Operating outflow in H1 2022 of \$5.0m.
- Investing flows: capex (\$23k) and spend on patents (\$83k).
- Financing flows: interest (\$122k), interest and lease repayments (\$94k).
- With revenue expectations and higher than expected research-related revenues, cash runway to mid 2024.



#### **Income Statement**



#### Six months to 30 June 2023

Unaudited	\$'000
Gross margin	16
Administrative expenses	(4,825)
Depreciation and amortisation	(472)
Share based payments charge	(99)
Finance income	122
Finance expense	(15)
Loss for the period	(5,273)

#### Comments

- Revenues of \$19k
- Largest items of expenditure:
  - Wages: \$1.8m with average 14 members of staff – prior period \$1.3m with average 10 members of staff
  - R&D: \$1.6m prior period \$2.3m.



#### **Balance Sheet**



#### As of 30 June 2023

Unaudited	\$'000
Tangible assets	1,641
Intangible assets	2,037
Trade and other receivables	426
Cash at bank	5,249
Trade and other payables	(2,044)
Lease and right of use	(621)
Net assets	6,688

#### Comments

- Tangibles: includes \$823k spent over the period on CLIA lab
- Intangible: \$1.5m cost of original license from Renalytix and additional spend on patents
- Receivables: mainly prepayments \$288k
- Payables: mainly accruals \$1.0m, of which main component (\$788k) is costs from trial sites not yet billed
- Leases: finance lease for sequencer (\$200k) and right of use asset for property lease (\$421k)



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### Appendix

- Board
- Scientific Advisory Board

#### Experienced Leadership for developing and commercializing kidney transplants assays





Julian Baines Non-executive Chairman EKF Diagnostics, BBI



#### Sir Ian Carruthers Senior Independent Non-executive Director Chancellor UWE, Snr Director NHS



Lorenzo Gallon Independent Non-executive Director, Chair of SAB NorthWestern Medical Prof.



**Erik Lium** *Non-executive Director* President, Mount Sinai Innovation Partners



James McCullough Non-executive Director Renalytix AI, Exosome Diagnostics



Sara Barrington CEO LungLife AI, BBI, Exosome Diagnostics

\* Chair of the Samuel Bronfman Department of Medicine, Dean for Clinical Integration and Population Health Management at the Icahn School of Medicine at Mount Sinai

#### Multinational Science Advisory Board of Key Opinion Leaders

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Lorenzo Gallon, MD (Chair)

Tony Dorling, MD

Richard Formica, MD

Roslyn Mannon, MD

Peter Nickerson, MD

Philip O'Connell, MD

Emilio Poggio, MD

David Rothstein, MD

Kathryn Wood, Dphil

Weijia Zhang, PhD



King's College Hospital NHS NHS Foundation Trust











- Five (5) past presidents of major international Transplant organizations (AST, TTS, ASTS)
- Current President of American Society of Transplantation
- Represent transplant centers processing about 2,000 transplants annually

- TTS: The Transplantation Society
- ASTS: American Society of Transplant Surgeons