



HY24 Results and Business Update July 2024

Transforming kidney transplant outcomes

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A black and white photograph of a hand pointing at a DNA double helix structure on a laptop screen. The laptop keyboard is visible in the foreground. The image is partially overlaid by a vertical bar with blue and green segments.

Business Update

Sara Barrington, CEO

Strong scientific platform provides multiple opportunities for further development and revenue generation

AUTO-IMMUNE DISEASES

PRE-TRANSPLANT | EARLY-STAGE DAMAGE | LATE-STAGE DAMAGE

clarava → tutivia™ → protega

New Technology (curved arrow pointing up)

Other development e.g. Urine Program

Clinician's Platform

New Technology (curved arrow pointing up)

Core Kidney Transplant business

Opportunity to expand into Other Organs

Data generated can be used for Research Collaborations

Core Testing Business

PRE-TRANSPLANT

EARLY-STAGE DAMAGE

LATE-STAGE DAMAGE

☑️ clarava

- Deceased Donor
- Living Donor

Licensing Revenues

☑️ tutivia™

- Existing claims
- Delayed Graft Function (DGF)
- Monitoring

Direct Revenues

protega

- Fibrosis and long term outcome

To Be Determined

Services Business


Research Asset

- Wet Lab
- Samples and Data
- Other RNA-based
- Other Bioinformatic

Services Revenues

Other product development: Urine program, other organs, autoimmune

INCOME STREAMS

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H1 2024 Review

Sara Barrington, CEO

Licensing Revenues



- Completed transfer milestones for Clarava™ to Thermo Fisher, generating cash inflows and recognised revenue.
- Thermo Fisher presented the rebranded Pre-Transplant Risk Assessment (“PTRA”), formerly Clarava™, to the clinical community at the American Transplant Conference (“ATC”) in June.
- Remaining milestones on track, subject to launch plans of Thermo Fisher.

Direct Revenues



- Tutivia™ ordering centres now increased to 15 with Company focus on both new and repeat ordering.
- Presented new data at ATC on the usefulness of Tutivia™ in the setting of delayed graft function (DGF), where there is unmet clinical need and interest from practitioners.
- Timing of revenue recognition from test sales is affected by conclusion of LCD determination process.
 - Submitted the Technical Assessment (“TA”) File for Tutivia™, an important step in the pathway for reimbursement coverage from Medicare. Determination decision expected by the end of 2024.
- Completed the CLIA application for the final US state, New York, where there were several additional stages to complete prior to submission. When granted, testing will be possible for patient samples from all US states.
- Experienced commercial team of 5, deployed between commercial and medical affairs
- Key opinion leader (KOL) education program initiated.
- New “Patient journey” resources launched.

Other Revenues (source to be determined)

↳ protega

- 12-month visits complete.
- Team now in the process of data cleaning with analysis due in 1H 2025.
- Cohort expanded for the 24-month visits and some samples already collected.

Urine program, other organs, autoimmune

- Medium to longer term product development.

Services Business


- Completed transfer milestones for urine samples to Thermo Fisher, generating revenues.
- Collaboration announced: The Westmead Institute for Medical Research (“WIMR”) based in Sydney, Australia:
 - Research project funded via a 4-year federal research grant to the WIMR.
 - Verici Dx approach deployed across diverse patient groups from 3 centres.
- Further revenue generation opportunities on track:
 - Dedicated sales resource.
 - Other collaborations at various stages.

Regulatory

- FDA oversight extended to include CLIA process.
- Verici Dx is compliant.
- Future phased rollout includes an alignment with the NY State process, potentially simplifying our ongoing compliance.

Reimbursement

- Following submission of our TA file, we are now in an active review process.
- Following confusion in 2023 regarding the MoDx changes to the Local Coverage Determination (“LCD”) process, amended rules will be released this year. These are expected to be in line with the previous clarifications issued and as such are already factored into our plans.
- If required, we would be able to address any potential LCD regulatory changes into our TA file as part of this process.

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H1 2024 Results

David Anderson, CFO

- Revenues of \$3.3m in the period (FY 23: \$1.0m)
 - Product licensing revenues relating to the transfer of Clarava™
 - Services revenues relating to the urine data asset licensing
 - \$2.8m received to date under the agreement with Thermo, with a further \$1.5m invoiced at period end
- EBITDA loss of \$1.1m (30 June 2022: loss of \$4.9m, year to 31 December 2023: loss \$8.0m)
- Cash balance at 30 June of \$7.0m (31 December 2023: \$2.6m)
- £6.5m (\$8.2m) in gross proceeds (£6.0m / \$7.5m net) via a Placing and Retail Offer in early 2024
- Commercial transaction and the successful fundraise mean that cash runway has been extended into 2026
 - This reflects a number of assumptions including those relating to the timing and/or quantum of additional milestone payments under the Thermo Fisher Scientific transaction; the ongoing rollout of Tutivia™; other licensing revenues; services income and other research collaborations

Cash Flow Statement



Six months to June 2024	2024 \$'000
Net outflow from operating activities	(3,177)
Investing activities	(95)
Financing activities	7,536
Net increase (decrease) in cash	4,264
Cash at 30 June	7,015

Comments

- Operating outflow: of the \$3.3m revenue, \$1.5m was received in 2023 and held as deferred revenue, so not all flowing into cash in this period.
- Investing: minimal capital spend in year.
- Financing: February funding of \$7.5m net.
- Continuing to deploy cash carefully in line with our commercial objectives.

Income Statement



Six Months to June 2024	2024 \$'000
Revenue	3,339
Administrative expenses	(4,368)
Depreciation and amortisation	(388)
Share based payments charge	(36)
Interest expense	(13)
Interest income	118
Loss for the period	(1,348)

Comments

- Revenue: milestone payments on transfer of assay and urine samples
- Admin:
 - Staff costs \$1.9m
 - R&D costs \$1.0m
- Operational headcount of 14 at year end 2023
- Now 19 heads with new commercial and bioinformatics team members

Balance Sheet



As of 30 June 2024	2024 \$'000
Tangible assets	1,073
Intangible assets	2,084
Receivables	1,934
Cash at bank	7,015
Trade and other payables	(1,787)
Lease and right of use	(458)
Net assets	9,861

Comments

- Tangibles: minimal spend in year
- Intangibles: \$1.5m cost of original license from Renalytix plus additional spend on licenses and patents
- Receivables: \$1.5m trade receivables and \$386k in prepayments
- Payables: includes accruals \$1.1m, with main component being \$745k in trial sites costs not yet billed
- Leases: finance lease for sequencer (\$120k) and right of use asset for property lease (\$338k)

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Summary and Outlook

Sara Barrington, CEO



Strong track record of delivery



Tests commercialized with pipeline



Diversified revenue streams



Large addressable market and critical need



Advanced regulatory and reimbursement



aims to be at the centre of RNA Signature testing



clarava™

tutivia™

protega™

Q&A