

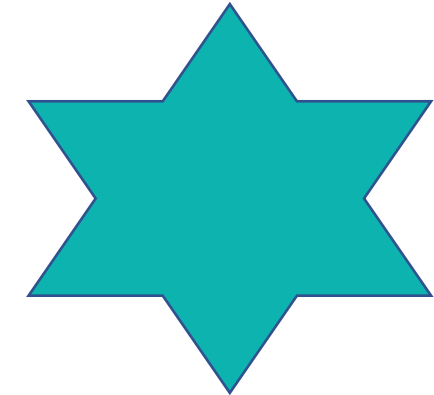
Mission:

To smooth ovarian cancer patients' journey with accurate, fit-for-purpose blood tests



QIMR Berghofer
Medical Research Institute

Michelle Hill, PhD



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Ovarian cancer surgery is conducted before diagnosis



Patients with pelvic mass

- Presented with symptoms
- Incidental finding

~10% of women will undergo surgery for pelvic mass in their lifetime¹



Clinical risk assessment

- Age, risk factors
- Ultrasound, CA125 blood test

None of the current tests are specific to ovarian cancer

High risk of cancer



Surgery and tissue histology

>200,000 surgeries per year in the USA, only ~20% of those will have ovarian cancer².

¹ Bullock et al. 2022 Front. Med. 9:913549

² Bast et al. 2013 Int J Gynecol Cancer. 22: S5

Market size, segment & challenges

- Global ovarian cancer diagnostics market expected to grow with a CAGR of 7% from US\$6.5 billion in 2022 to reach US\$11.6 billion by 2030
- Key segments
 - By geography: North America, Europe, APAC
 - By test type: Gene mutation, Imaging, Blood marker test
 - By indication: Risk assessment, (diagnostic, screening)
- Key challenges
 - Different regulation and regulatory bodies for each country
 - Lack of tests/biomarkers specific for ovarian cancer, and suitable for early detection



Sources: Data Bridge Market Research & Fact.MR

Approach & value proposition: Differentiated biomarker panels for diagnosis and screening



UKCTOCS

United Kingdom
Collaborative Trial
of Ovarian Cancer
Screening

UKOPS

United Kingdom
Ovarian Population
Study



Biomarker discovery &
validation in 155 samples
include pre-symptomatic
women and benign tumours

Blood markers that can

- ✓ distinguish cancer from benign ovarian mass
- ✓ be detected months prior to symptom onset and diagnosis by current protocol

Differentiated
technology, directly
deployable as LDT

Oesophageal cancer
blood markers licensed
to Proteomics
International in 2022

Accurate, fit-for-purpose blood tests



Aspira Women's Health

Primary care diagnostic Test Cancer vs (benign + healthy)	Validation cohort ¹ 90.7% specificity, 70.4% sensitivity for 10-marker panel	Clinical study ² 87% specificity, 40% sensitivity for 7 marker plus age and menopause status
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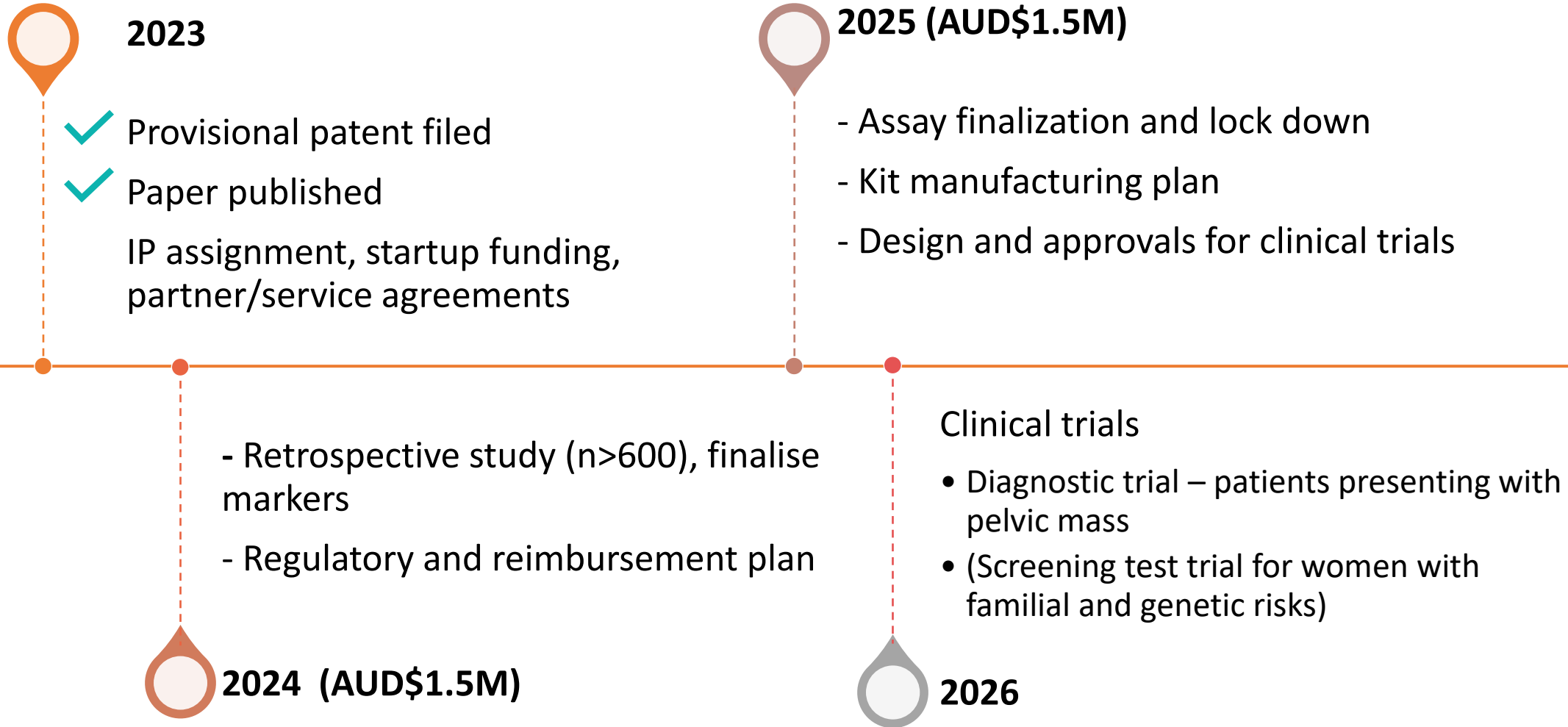
Early Detection
(Screening) Test

¹ Dutt et al. 2023
Proteomics Clin App
<https://doi.org/10.1002/prca.202200114>

² Reilly et al. 2023 *Front. Med.* 10:1102437

³ Klein et al. 2021 *Ann. Oncol.* 32: 1167-1177.

Development plan & investment proposal



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Acknowledgements



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FDA-cleared blood tests for ovarian cancer risk assessment pre-surgery, to determine whether surgery should be performed by gynecologic oncologist (5-8 months survival benefit) or general gynecologist – new ACOG guidelines, 2016¹

Test	Company	Analytes	FDA	Cost/reimbursement
ROMA	Fujirebio	ARCHITECT CA125 II™ assay and microplate spectrophotometer at 620 nm or 405 nm for the HE4 EIA, menopausal	510(k) Class II, Substantial equivalence, predicate OVA1 test (2011)	\$260 Medicare Reimbursement rate
OVA1	Aspira	Apo A-1, B2M, Tfr, TT on Siemens BN™ II, CA125 on Roche Elecsys® 2010	510(k) Class II (2009)	2017: \$897 (CMS code 81503) 2013 Quest: \$650 (\$540 Medicare)
OVERA	Aspira	Apo A-1, CA125, FSH, HE4, Tfr on Roche cobas 6000	510(k) Class II, Substantial equivalence, predicate OVA1 test (2016)	Not reimbursed

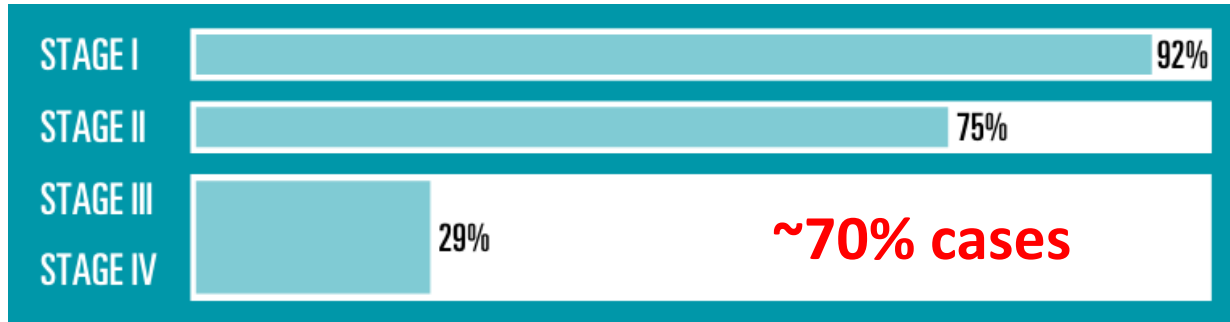
¹American College of Obstetricians and Gynecologists' Committee on Practice Bulletins—Gynecology. Practice Bulletin No. 174: evaluation and management of adnexal masses. *Obstet Gynecol.* 2016;128(5):e210-e226

Ovarian cancer, the silent killer

 Ovarian cancer is the most lethal gynaecological cancer.

EVERY YEAR, AROUND 1,800 AUSTRALIAN WOMEN ARE DIAGNOSED WITH OVARIAN CANCER

5 YEAR SURVIVAL RATES, BY STAGE OF DIAGNOSIS



Source: Ovarian Cancer Research Foundation website, International Federation of Gynecology and Obstetrics (FIGO)

In the USA:

22,000

new cases are diagnosed each year

50% diagnosed are at least 60 years old

Every 24 minutes marks another diagnosis of ovarian cancer in the United States

15,500

women will die each year

1 : 95 women will die from ovarian cancer

<http://smrfteal.org/about-ovarian-cancer/facts/>

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