ASX: CC5

AI-powered microbiology

Revolutionising microbial quality control in pharmaceutical manufacturing

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CLEVER CULTURE SYSTEMS

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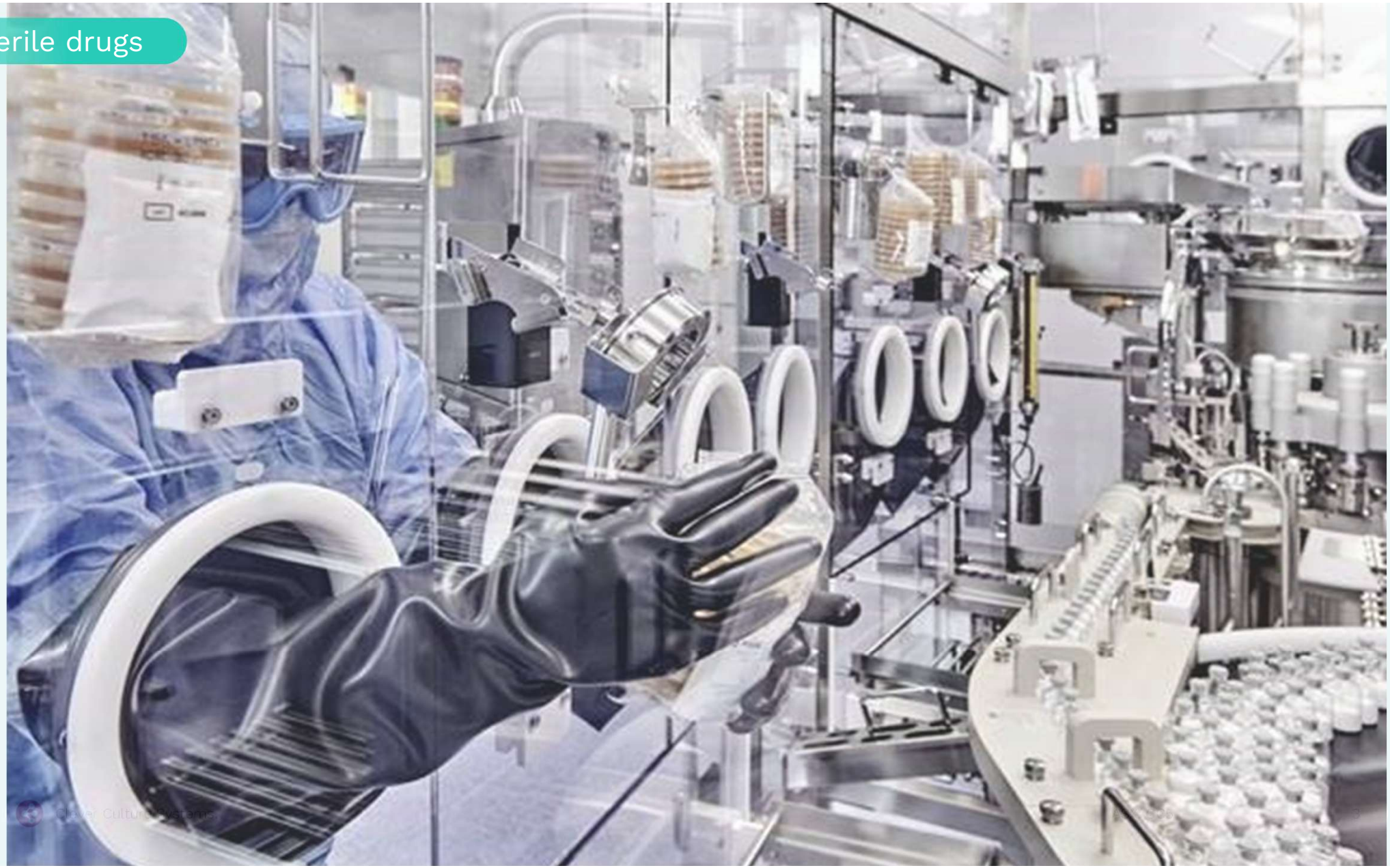
Sterile drugs



Problem

Millions of culture plates are manually read and reported annually during pharmaceutical manufacturing

Incorrect results costly

High cost of failure

Up to US$1bn lost revenue[1]

Failed results in pharmaceutical manufacturing can lead to substantial revenue losses. Catastrophic impact is patient death

Regulatory scrutiny

116% regulatory increase[2]

Rise in regulatory observations to drug establishments creates compliance challenges

Inefficient

Up to 98% zero growth plates[3]

Millions of plates reviewed annually, majority of plates have no growth yet require dual analyst verification, wasting resources

Workflow

Environmental monitoring today

Mandatory process in every pharmaceutical manufacturing facility globally

Culture plates

Environmental monitoring

Cleanrooms
(pharmaceutical manufacturing)

Incubation (3-7 days)

Critical decision point

Culture plate reading, reporting. Result to release pharmaceutical product

No Growth
➔ Batch release

Growth detected
➔ Batch held
➔ Investigation

Solution

Digital disruption

APAS INDEPENDENCE

Solution: APAS

Automated Plate Assessment System

Cutting edge AI technology
Machine learning for microbiology applications

Demonstrated performance
Extensive scientific data, faster than microbiologist

Improved data integrity
Automatic data trails and audit reports

Easy integration and user operation
Simple plug and play technology

Workflow

Environmental monitoring with APAS

Mandatory process in every pharmaceutical manufacturing facility globally

Culture plates

Environmental monitoring

Cleanrooms
(pharmaceutical manufacturing)

Incubation
(3-7 days)

Critical decision point

Automated culture plate reading

No Growth >90%
➔ Batch release automatically

Growth detected
~2-10% reviewed manually

Revenue

Up to $1.2M revenue per APAS Independence sale[4]

Includes up-front Capex and Annual Recurring Revenue (ARR) streams

Product / Service	Description	Revenue Model	Approx. Split
APAS® Independence	Laboratory Instrumentation	Upfront Capex *(inc. financing options)*	40%
APAS Apps®	AI Software Licence	ARR	40%
APAS Service[2]	Support and maintenance services	ARR	15%
Implementation Services	Instrument connectivity, technical data and validation support	One-off	5%

Opportunity

Total addressable pharmaceutical market – $2.8B[4]

Market Opportunity – sterile pharmaceutical manufacturing

Market CAGR growth >8%[5]

Annual SaaS Opportunity

$230M ARR[6]

$1.6B[4]
SaaS / ARR

Annual AI software license + hardware maintenance over 7 years

$1.2B[4]
Up-front CAPEX

Instrument hardware

Every instrument sale worth up to $1.2M[4] over 7 years

Commercial progress against TAM

Current sales ✓

22 Instruments

10 customers

~$1.3M[7] ARR

Qualified Opportunity: 180 instruments

Expand with current customers

100[8]
Instruments

+

Qualified pipeline (active engagement)

80[9]
Instruments

$216M total value

$19M ARR

TAM Penetration

~9%[10]

of TAM are already customers and part of qualified pipeline

Sales Strategy

Land & Expand with global pharmaceutical customers

How it works

1 LAND
1-2 instruments at a global pharma site

2 VALIDATE
Technology proven in routine operations

3 EXPAND
Roll out across global sites

AstraZeneca: 12 instruments purchased across global locations

Current global pharmaceutical customers

- **AstraZeneca** — 12 instruments – global sites
- Pfizer — Global pharma customer
- Bristol Myers Squibb — Global pharma customer
- Novo Nordisk — Global pharma customer
- Boehringer Ingelheim — Global pharma customer
- CSL Behring — Global pharma customer
- Thermo Fisher (Patheon) — Global pharma CDMO customer
- Global pharma customer — *Confidential*

Expand opportunity – global pharma customers

~100	~$51M	~$10M ARR
APAS instruments	CAPEX Opportunity	SaaS / Recurring

Competition

Different automation approach

Incubation and reading technologies

- Requires continuous reading between incubator and imaging platform
- Incubation size restricts volume capacity (60-132 plates per day capacity)

3P System – bioMerieux
(Interscience OEM)

Incubator capacity **300** plates
~60 plates per day[1]

Growth Direct – Rapid Micro Biosystems
(NASDAQ::RPID)

Incubator capacity **~660** plates
~132 plates per day (5-day incubation time)

APAS Independence: end point reader

APAS delivers scale

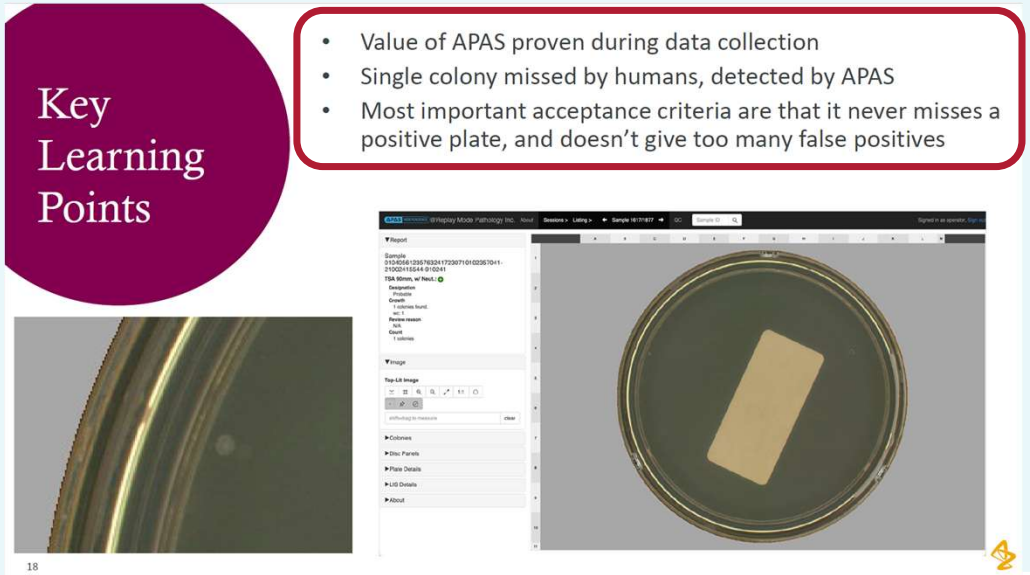
- 1 APAS instrument automates 1,600 plates per day
- Customers use their existing low-cost, high-volume incubators

Customer

AstraZeneca Case Study

Enterprise customer – Standardisation across multiple global sites

- ~1,000 plates per day at large AZ sites
- >98% of plates are negative
- Occasionally humans make mistakes
- APAS resolves data integrity challenges

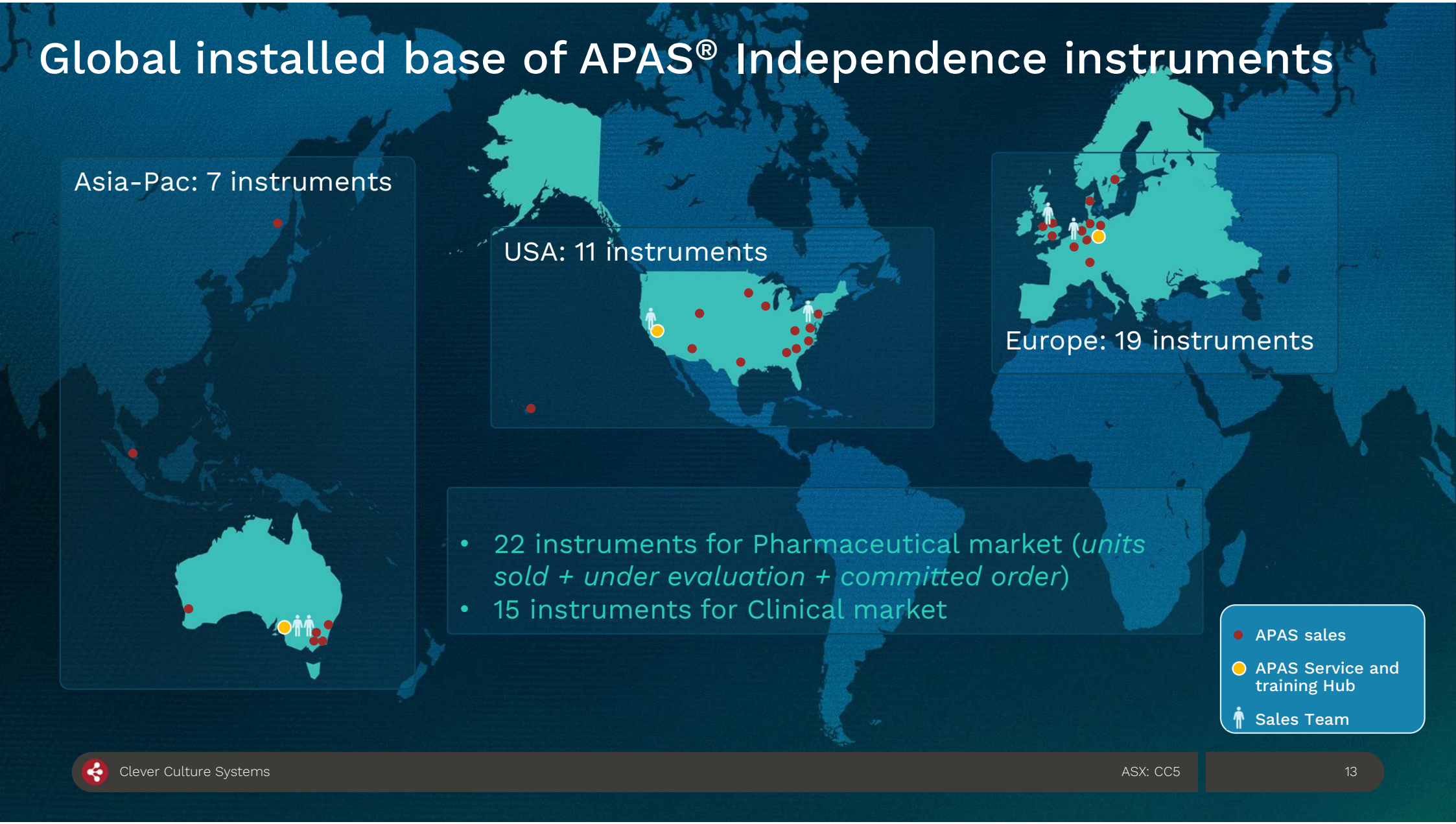


AstraZeneca

12 instruments purchased and installed

- Multiple global manufacturing locations
- Advocates of technology presenting at multiple conferences
- Validated technology for routine use

Global installed base of APAS® Independence instruments



- 22 instruments for Pharmaceutical market (*units sold + under evaluation + committed order*)
- 15 instruments for Clinical market

Experienced

Board and Management

Focused on expansion into pharmaceutical manufacturing industry

- Board and Management shareholding 20%+
- International experience with healthcare, technology and pharmaceutical manufacturing expertise
- Extensive public listed ASX experience in micro-cap and high-growth companies

Brent Barnes
CEO and MD, AU
Aug-16 start

Rebecca Wilson
Chair, AU
Jul-23 start

Dan Hill
NED, AU
Dec-23 start

Ian Wisenberg
NED, US
Oct-24 start

Ray Ridge
CFO and CoSec, AU

Outlook

Strong product-market fit evidenced by 8 leading global pharmaceutical companies
Land-and-expand commercialisation strategy

Capital efficient growth model driven by existing customers + qualified pipeline
Potential revenue $216M + $19M ARR

High margin SaaS model
Growing installed base underpins financial outlook

Step-change sales increase anticipated in FY27
Expected to deliver financial growth

References:

[1] www.researchandmarkets.com, Global Pharmaceuticals Market Report 2021: Covid-19 Impact and Recovery to 2030.

[2] https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/inspection-references/inspection-observations

[3] https://www.cleverculturesystems.com/scientific-library/apas-pharmaqc-ai-culture-plate-reading

[4] Australian dollars (USD:AUD: 1.4). Market opportunity of AU$2.8B based on 2,300 APAS® Independence over expected 7 years based on internal Company market research

[5] Compound Annual Growth Rate of 8.1% from 2026 to 2033 (https://www.coherentmarketinsights.com/market-insight/sterile-injectables-market-201)

[6] AUD$100,000 ARR per APAS® Independence sold multiplied by TAM of 2,300 APAS® Independence instruments = AUD$230M

[7] AUD$1.3M ARR expectations based on current installed base due to product sales mix. Lower ARR for Clinical market sales and lower ARR for the 12 AstraZeneca pharmaceutical market instrument sales to compensate for the >AUD$1M pre-payment for R&D services (https://cdn.prod.website-files.com/6615dec696e9446eaf6b7c32/671f16ceaf350741abc9e900_9-January-2023-AstraZeneca-Partners-LBT-for-APAS%C2%AE-Pharma-Development.pdf) [8] The 100 APAS® Independence instrument potential is a Company estimate of the opportunity with existing global pharmaceutical customers: AstraZeneca, Novo Nordisk, Bristol Myers Squibb, Pfizer, Thermo Fisher (Patheon), Boehringer Ingelheim, CSL, un-named Top-20

[9] The 80 APAS® Independence instrument potential is a Company estimate of the opportunity from the current customer qualified pipeline

[10] The TAM penetration calculation is 22 + 180 APAS® Independence instruments divided by the TAM of 2,300

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