

CELLMID (

### **GENERAL MEETING**

21 May 2020

ASX: CDY

# CELLMID

#### **Forward looking statements**

This presentation contains forward-looking statements that are subject to risks and uncertainties. Such statements involve known and unknown risks that may cause the actual results, performance or achievements of Cellmid to be materially different from the statements in this presentation. Actual results could differ materially depending on factors such as the availability of resources, regulatory environment, the results of advertising, sales activities and competition.



# CELLMID (

### AGENDA

### Section 1: Cellmid operations: consumer health and biotech

- Advangen (consumer health): Resilient during pandemic
- Lyramid (biotech): Expansion of diagnostics to boost assets

### Section 2: Overview of COVID-19 diagnostics landscape

- COVID-19: What we know about the pandemic
- Three different testing approaches
- Analysis of PCR and antibody testing
- Why antibody testing is important

### Section 3: Upcoming Milestones



### **SECTION 1:** CELLMID OPERATIONS

CELLMID (

# Cellmid operations

### **ADVANGEN** (Consumer Health)

# évolis®

- First in class/best in class anti-aging hair care products
- Operations in Japan, Australia and USA
- Sales in Japan, China, Australia, USA and Europe





- Largest patent portfolio globally around the novel target midkine
- Midkine is implicated in a number of inflammatory diseases and cancer and Cellmid's antibodies have shown early efficacy
- Diagnostic patent licensed (CxBladder), MK-ELISA
- New product line: Wondfo antibody test



### Consumer health has been the major driver of revenue



- The consumer health division accounted for 89% of total \$8.35M Cellmid revenue in FY2019
- Year to Date (YTD) to 31 March 2020, the consumer health division accounted for 84% of total Cellmid revenue
- Staff is allocated to the consumer health and biotech segments in roughly the same proportion as the revenue split between the divisions with several shared functions

### 

### **Consumer health: resilient during pandemic**

The Consumer Health division has been resilient during the pandemic with several new sales channels active and slowly improving trading conditions in China, Japan and Australia.

- **JAPAN:** Japan remains on target to be profitable in FY2020 despite domestic salon sales ending lower and export sales to China delayed.
- AUSTRALIA: Australia is currently showing 40% revenue growth YTD from last year. This is a strong result in light of the delay in the evolis Professional product launch in Priceline stores. The growth is the result of higher retail sales during the second quarter, increasing online sales and successful television shopping campaigns.
- USA: The USA revenue is up 50% YTD from last year, however, it will be difficult to maintain momentum in the short term due to Neiman Marcus, our biggest customer, entering Chapter 11 proceedings.

Overall, we expect the Consumer Health division to report FY2020 results similar to FY2019\*

\*Revenue numbers and percentages are unaudited and may change during the remainder of the financial year.









### New product line: SARS-CoV-2 antibody test

- **Supply Agreement:** Cellmid signed an agreement with Australia Applications Pty Ltd on 22 March for the supply of the Wondfo SARS-CoV-2 antibody rapid diagnostic tests
- **Strong demand:** The Company received a large number of expressions of interests from industry and government organisations since 27 March 2020
- **Tests received:** First shipment of 12,000 tests received on 14 April 2020, some sold to customers others have been reserved for testing, collaborations and future sales
- Independent testing: Cellmid provided 500 tests to the TGA for testing at the Doherty Institute
- In-house testing: Cellmid commenced its inhouse 'ATLAS' study with participants including recovered COVID-19 patients and healthy volunteers:
  - To demonstrate the Wondfo test performance
  - To generate data on long term antibody status for those recovered from COVID-19
- Key Hires: Boosted capabilities by adding new senior business development manager
- New products and markets: Assessing other SARS-CoV-2 tests with the view to build a portfolio of complementary diagnostic products including IgM/IgG split antibody and rapid PCR tests plus pursue new geographies





SECTION 2: OVERVIEW OF COVID-19 AND DIAGNOSTICS LANDSCAPE



# COVID-19: What we know about the pandemic

#### Quick facts COVID-19 1.4-3.7% overall mortality ~20% EXPOSURE TO ONSET: NO SYMPTOMS 13% Average 5.2 days up to 3 weeks 80 YEARS + ONSET TO FIRST CLINIC VISIT: 6.5% 4.6 days 70-80 YEARS 13.8% 1.5% SEVERE DISEASE ONSET TO ICU: 60-70 YEARS 7-12 days 60.1% 0.4% MILD DISEASE **50-60 YEARS ONSET TO RECOVERY / DEATH:** 24.7 /17.8 days 6.1% 0.1% CRITICAL DISEASE <50 YEARS

• Mortality rates vary, depending on population dynamics and extent of testing. Very few governments have tested widely so mortality rates are inflated

• Data sourced from: Li et al., NEJM (2020), Park et al., JCM (2020), Verity et al., Lancet 2020, Phua et al., Lancet Resp Med., (2020), among others



### COVID-19: Three different diagnostic approaches – no perfect test

- 1. Look for the virus
  - Evidence of infection
  - Viral RNA in respiratory tract can be detected by polymerase chain reaction testing (PCR)
- 2. Look for the body's response to the virus
  - Evidence of exposure to the virus
  - SARS-CoV-2 specific antibody tests (IgA, IgG, IgM)
- 3. Look for distinct clinical evidence of disease
  - Patient history, symptoms such as loss of smell/taste, respiratory distress, CT lung imaging



#### Graph by Wondfo

#### Different tests are most useful in different phases of the infection.

### Diagnostic performance: terminology

### 



The accuracy of evaluation is strongly dependent on a welldefined test population. The tests should be assessed in terms of how well they perform for their intended use.

#### Sensitivity

Measures the accuracy of the test in identifying true positives which is important in acute diagnosis

#### Specificity

Measures the accuracy of the test in identifying true negatives, which is important in determining prevalence, long term treatment and monitoring

#### **Negative Predictive Value** Probability of true negatives and

false negatives

### **Positive Predictive Value** Probability of true positives and false positives

### Polymerase Chain Reaction (PCR) based testing

#### Polymerase chain reaction (PCR) – why use it?

- PCR is used to detect viral nucleotide (DNA or RNA)
- PCR is very good at amplifying small amounts of virus from a sample, as little as 5-10 virus particles
- Highly specific depending on probe choice

#### PCR – challenges

- Requires several steps that introduce variability before the test is done sampling, storage, extraction, PCR
  - False negatives from wrong sampling site or processing error
  - False positives from cross contamination
- Can detect dead virus impacts clinical utility
- Narrow window of use
- Some reported "reinfections" have been shown to be incorrect PCR results
- PCR accuracy was recorded as low as 63% in nasal swabs and 32% in throat swabs in COVID-19 patients.\*



\*Wang et al JAMA 2020

CELLMID

### SARS-CoV-2 antibody testing – an overview



#### Background

Originally developed in February 2020 to assist in acute testing in China and S Korea due to <u>shortage</u> <u>of PCR capability</u>, needed <u>rapid deployment</u> of <u>highly specific tests</u> to triage population and <u>overcome</u> <u>false negative</u> issues with PCR.

Serology – Detection of antibodies specific to SARS-CoV-2

- Specific to virus
- Fast and easy to implement
- Large window of detection
- Can determine past infection
- Can determine if the body has developed an immune response

#### Serology – challenges

- Does not tell if you have an active infection
- Window period before antibodies rise are variable patient to patient, so not a standalone acute diagnostic tool
- Depends on the individual's immune response a very small number may not produce the right kind of response (current data suggest this is less than 1% of convalescent patients\*)
  \*Wajnberg et.al, Icahn School of Medicine at Mount Sinai, New York, NY



an hu

IgM is the EARLIEST antibody produced by human body after infection



IgG is the most abundant antibody (75%∼80%) and persists for a long time.

### Three reasons why antibody tests are misunderstood

### CELLMID (



- 1. Antibody tests are often compared to PCR, an imperfect standard
- PCR is evaluated against other PCR tests inherent false positives and negatives are undetected
- The inaccuracies of PCR are misclassified as incorrect results in serology

#### 2. Intended use is not as a stand alone for acute diagnosis

- Evaluation at timepoints outside of relevant usage window skews results (day 2 of symptoms — No antibodies — Negative antibody test in COVID-19 patient)
- New disease = unknowns: the only way to learn is by testing
- At early stages of the pandemic, the rate of antibody response and development of immunity was unknown
- Latest evidence shows the vast majority of patients (>99%) develop specific antibody and memory immune responses\*

\*Wajnberg et.al, Icahn School of Medicine at Mount Sinai, New York, NY

### Why use antibody tests?

## 

#### **Combining PCR and serology improves detection**

To improve the accuracy of detection by using in conjunction with other diagnostics\*

#### Post recovery surveillance

• To determine whether the body has developed an immune response and how long it lasts

#### **Population screening**

 To determine the actual exposure rate in the population and how many are potentially at higher risk if the virus re-emerges

#### Risk management in combination with social distancing, face masks and/or hygiene

To assist in return to work scenarios, particularly with high contact and mobile workforce

#### Vaccine development

- 159 vaccine candidates under development
- Very large and long term trials will be needed
- All studies will require monitoring of both antibodies and cell mediated immunity



Guo, Li, et al. "Profiling early humoral response to diagnose novel coronavirus disease (COVID-19)." Clinical Infectious Diseases (2020).

Combining PCR and antibody detection significantly improved overall accuracy from 51.9% (PCR alone) to 98.6% (PCR and antibody test)



### Wondfo SARS-CoV-2 Antibody test (lateral flow method)



- **Experience:** Wondfo has been manufacturing POCT for >25 years, e.g. AIDS, pregnancy, hepatitis tests
- Highest quality: Internationally certified facility (MDSAP, ISO13485, 1SO9001)
- **High capacity:** 1.5M tests strips per day
- Regulatory approvals: NMPA approved for export, CE marked, ARTG
- Independent evaluation: Sensitivity > 80% (11+ days from symptoms), specificity > 98% (11+ days from symptoms)\*
- **Supply agreement** until 30 June 2020, may be extended subject to approval by Wondfo.

#### \*Whitman et al, University of California, San Francisco (published)

llondfo

#### 

#### **Doherty Institute Testing**

- The COVID-19 pandemic led to the fast track emergency registration of many devices with the TGA
- Post market review applies to all medical devices (for SARS-CoV-2 Antibody devices it is Doherty Institute testing)

#### What do we consider to be a very good testing result for Wondfo?

- Consistent with manufacturer's claims and user instructions
- Specificity 97% +
- Sensitivity at early onset, days 0-7 of symptoms, of between 25-40%
- Sensitivity from days 8-14 of 70%
- Sensitivity for days 15+ of 80%+



CELLMID (



### SECTION 3: UPCOMING MILESTONES

### 

# UPCOMING MILESTONES

#### Consumer health

- Continue to expand e-commerce in key markets
- Grow Chinese distribution of heritage brands
- Opening new sales channels
- Increase sales into existing channels

#### **Diagnostics**

- Results of the TGA testing by the Doherty Institute
- Results of the ATLAS study
- Broaden diagnostic portfolio and geographic rights
- Antibody test sales and commercial partnerships