



COGSTaTE

# INVESTOR MEETINGS

DECEMBER 2016

“

We believe that **brain health is profoundly important to quality of life** and should be easier to measure.

That's why we so passionately apply our expertise, access to data and flexible technology **to simplify the measurement of cognition.**

It's our core focus, and we won't stop until cognitive assessment—**anyone, anytime, anyplace**—is a routine exercise across healthcare and clinical research.”



# COMPANY SNAPSHOT

## CAPITAL STRUCTURE

Share Price (01 Dec 2016)	\$1.065
Fully paid ordinary shares	113m
Market Capitalisation	\$121m
Net Cash (30 Sep 2016)	\$4.7m

## MANAGEMENT & BOARD

Brad O'Connor	CEO / Managing Director
George Hunnewell	COO & President, Clinical Trials
Frank Cheng	President, Healthcare

Martyn Myer	Non-Executive Chairman
David Dolby	Non-Executive Director
David Simpson	Non-Executive Director
Richard Van Den Broek	Non-Executive Director

## SHAREHOLDERS

Board & Management	43.1%
Former Director (Finkel)	8.04%
Top 20	83.6%

## SHARE PRICE CHART



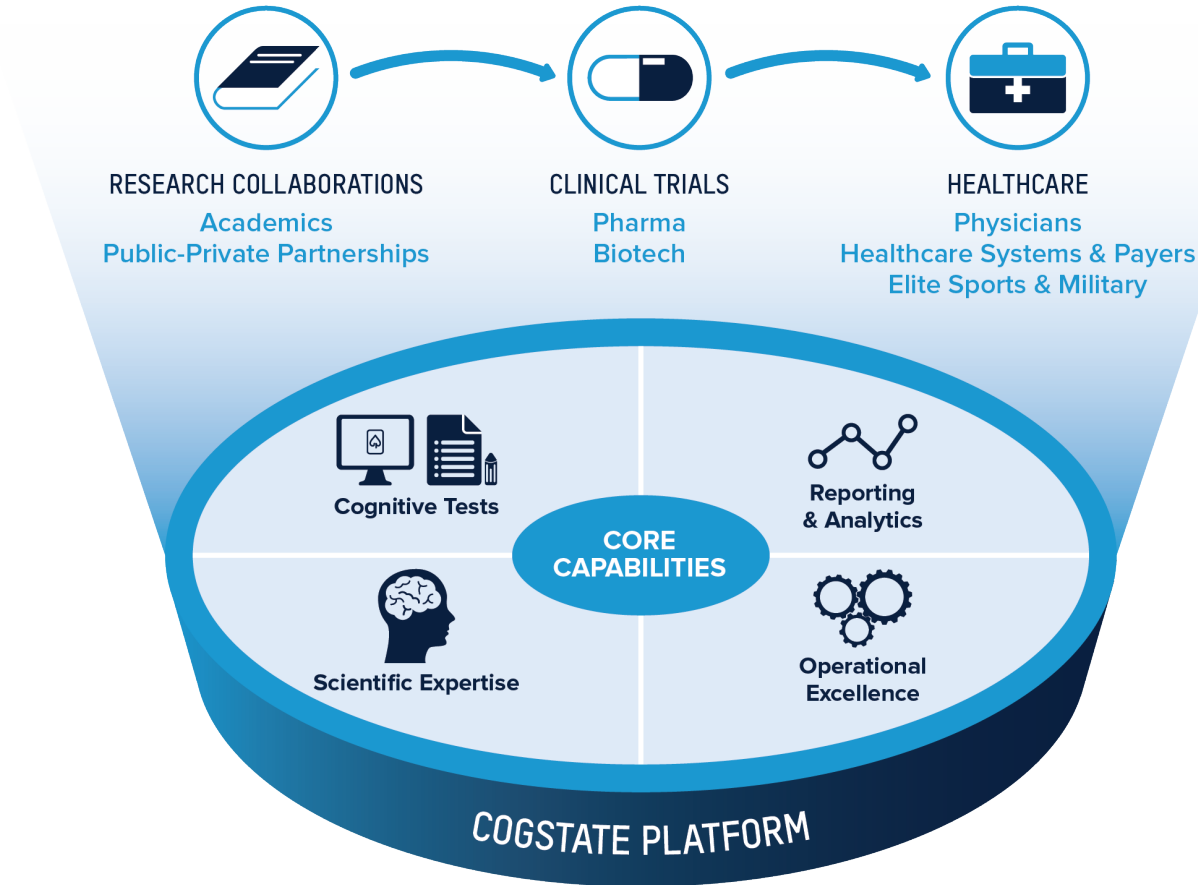


# COGSTATE HIGHLIGHTS

- Cogstate is a leader in Cognitive Assessment
- Clinical Trials market is immediate growth driver (99% of revenue), with further upside from opportunity in Healthcare
- Outsourcing growth trends to continue in Clinical Trials<sup>1</sup>
- Long life contracts in Clinical Trials (>12mths) provides revenue certainty; over \$55m of revenue backlog at 30 Sep
- Cogstate's customers are some of the world's largest pharmaceutical and biotech companies and CRO's
- Strong legacy of scientific excellence facilitating current focus on business development and product development
- FY16 results highlight Cogstate has transitioned to profitability and that strong growth momentum continues
- Key management appointments in November 2016 bring relevant commercial experience to drive further growth

1. The global clinical trial service market predicted to reach more than \$64B by 2020, representing CAGR of 9% with close to 75% of trial predicted to be outsourced to CROs. Source: Research and Markets "The New Trends of Global Clinical Development Outsourcing Market" – 30 June 2015.

# SIMPLIFYING THE MEASUREMENT OF COGNITION IN:



# VALIDATED THROUGH USE IN OVER 1,500 STUDIES ACROSS ACADEMIC AND CLINICAL RESEARCH



54  
COUNTRIES



88  
LANGUAGES  
& DIALECTS



70  
INDICATIONS



>400  
PEER REVIEWED  
PUBLICATIONS

Cognition disorders **Alzheimer's disease** Heart failure  
**Major depressive disorder** Multiple sclerosis (MS) **Hepatitis C**  
Parkinson's disease Diabetic peripheral neuropathy **Mild cognitive impairment**  
Insomnia **Schizophrenia** Overactive bladder Stroke  
Obsessive compulsive disorder **Alcohol Toxicity** **Familial Hypercholesterolemia**  
Attention deficit hyperactivity disorder **Epilepsy** Prostate cancer Lung carcinoma  
Bipolar disorder **Glioblastoma** Tourette's syndrome **Paediatric Hyponatremia**  
Autism spectrum disorders **Healthy Population** Anemia **HIV**  
**Pain** Fragile X **Cardiovascular Risk** **NSCLC** **Down syndrome** Depression



# SUMMARY OF FY16 FINANCIAL PERFORMANCE



## RECORD REVENUES & POSITIVE EBIT

DELIVERED ON GUIDANCE WITH EBIT OF A\$1.0M



## MAINTAINED GROSS MARGIN

EVEN AS HEADCOUNT GREW TO KEEP PACE WITH DEMAND



## FINANCIAL LEVERAGE

THE INCREASE IN REVENUE HAS DELIVERED SIGNIFICANT EBIT IMPROVEMENT

	<b>FY16</b> A\$ millions	<b>FY15</b> A\$ millions	<b>Change</b> A\$ millions
<b>Clinical Trials &amp; Precision Recruitment Revenue</b>	27.14	15.70	11.46
<b>Total Revenue</b>	27.25	16.07	11.18
<b>EBIT</b>	1.04	-3.05	4.09
<b>Net Profit After Tax*</b>	2.64	-5.06	7.70

\* FY16 includes Income Tax Benefit of \$1.6M



# BUSINESS UPDATE Q1 FY17



## RECORD REVENUE

Q1 revenue was a record A\$11.1M

Up 82% on Q1FY16, and up 59% on last quarter (Q4FY16)



## RECORD SALES

Largest quarter of new contract signings

US\$17.3M of contracts signed since 1 July 2016



## RECORD BACKLOG

Record high contracted future revenue position

Contracts totaling A\$55.5m, of which A\$28.7m will be recognised in FY17



## MANAGING CASHFLOW

A Net Operating Cash Outflow of -A\$2.78m

Cash receipts from customers expected to improve Q2 FY 17



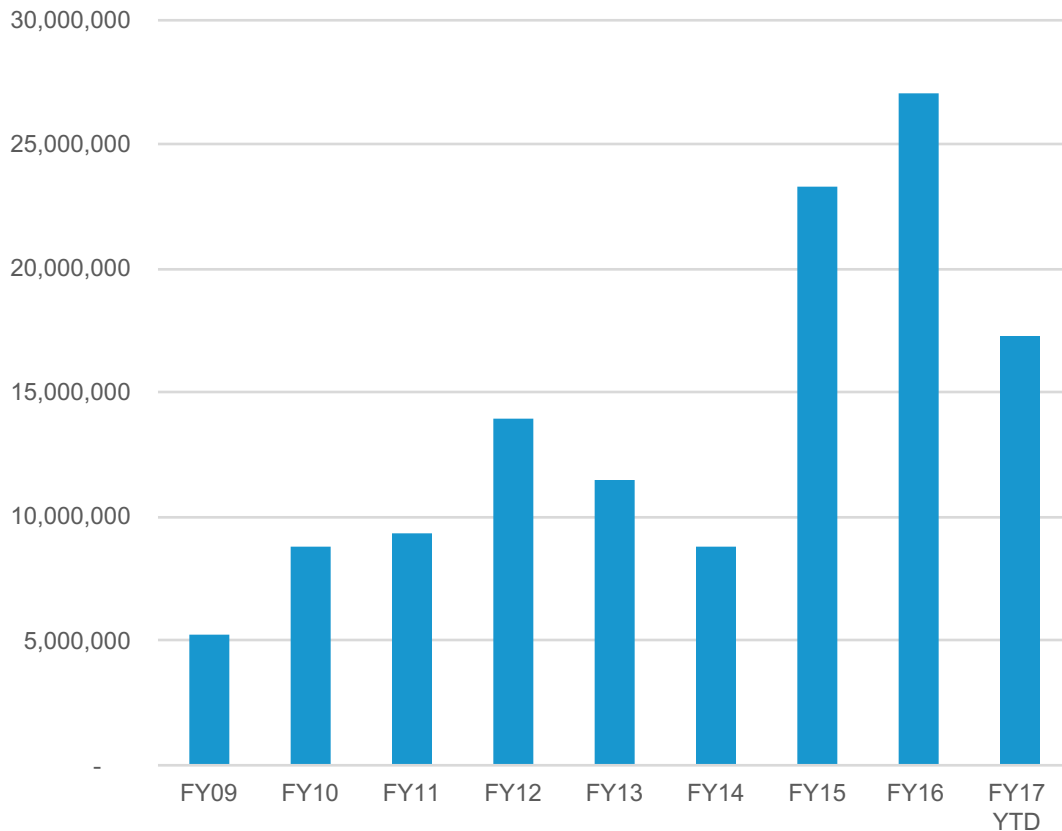
## CONTINUED PROFITABILITY

Positive EBIT recorded for the quarter

Guidance provided for positive EBIT for the first half of the FY17



# CONTINUED GROWTH IN SALES CONTRACTS



## Q1 RECORD FOLLOWS STRONG GROWTH IN FY16

US\$28.5M of sales contracts signed during FY16

A record US\$17.3M of sales contracts signed during the first quarter of FY17.

# GROWTH IN CONTRACTED REVENUE



## RECORD CONTRACTED REVENUE BACKLOG

### FY16:

- Began year with A\$10.9M of contracted revenue.
- An additional A\$16.3M of revenue was recognised as a result of signing US\$28.5M of sales contracts throughout the year.

### FY17:

- Began year with A\$17.5M of contracted revenue.
- An additional A\$11.2M of revenue will be recognised as a result of signing US\$17.3M of sales contracts in Q1.



## CLINICAL TRIALS

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Solutions to accelerate  
recruitment and  
measure drug efficacy  
and safety in cognition



# NEW APPOINTMENT

## GEORGE HUNNEWELL

Chief Operating Officer & President, Clinical Trials

- 2IC to CEO, Brad O'Connor
- Full P&L responsibility for the Clinical Trials division
- Oversee operations including:
  - Quality Assurance (regulatory compliance);
  - Product Development (software engineering, quality control);
  - HR (attract and retain employees, global footprint)
- US based role, in line with Cogstate staffing footprint.

# GEORGE HUNNEWELL

## Background

- Parexel International for approx 15 years
- Parexel are one of the largest CROs in the industry, running thousands of clinical trials on behalf of pharmaceutical companies. It is headquartered near Boston, but operates in 85 locations in 51 countries and has over 18,000 employees.
- Mostly recently held the role of Corporate VP, Clinical Research Services where he was responsible for operations improvements in the Clinical SBU (\$1.4b revenue, 10,000 FTE)
- Previously oversaw worldwide M&A, working closely with CEO, CFO and business unit Presidents
- Co-founder of Parexel Informatics; a member of the executive team that spun out the Informatics business from Parexel when it was 75 people in 2000. Helped grow it to 450 people and sold back to Parexel in 2005.
- Parexel grew from 3,000 FTE to nearly 20,000 FTE during his time.
- AB in Mechanical Engineering from Harvard. MBA from MIT Sloan School of Management.

# FULL SERVICE SOLUTION FOR MEASURING COGNITION IN CLINICAL TRIALS



DESIGN



RECRUIT



TRAINING



MEASURE



DELIVER



ANALYSE

“ From well-validated computerized batteries to expert support for traditional paper and pencil tests, science and excellence in delivery are at the core of everything we do. ”

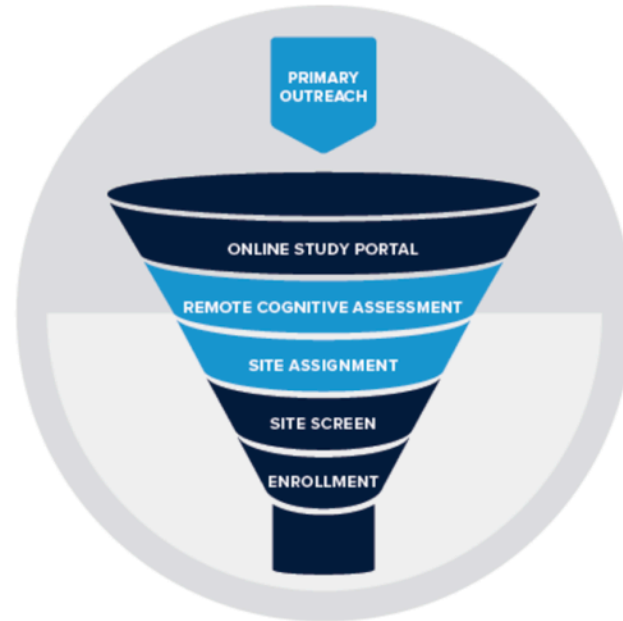
# CLINICAL TRIALS SOLUTIONS

**COGSTATE  
PRESCREEN**

**COMPUTERIZED  
ASSESSMENT**

**SCALES  
MANAGEMENT  
& RATER  
TRAINING**

**ONLINE SCREENER THAT ACCELERATES  
CLINICAL TRIAL RECRUITMENT USING REMOTE  
COGNITIVE ASSESSMENTS**





# CLINICAL TRIALS SOLUTIONS

COGSTATE  
PRESCREEN

COMPUTERIZED  
ASSESSMENT

SCALES  
MANAGEMENT  
& RATER  
TRAINING

## RAPID, SENSITIVE AND RELIABLE TESTS DESIGNED FOR CLINICAL RESEARCH

- Screening criteria, Safety and efficacy endpoints
- Computerized cognitive tests dramatically increase the sensitivity and specificity of the measurement of human cognitive processes
- Designed, developed and validated to withstand the numerous operational challenges of conducting clinical trials, such as testing patient groups with unique characteristics, working with sites in countries or cultures with limited experience with cognitive testing and protocol schedules where there is often limited time available for assessment.
- Currently available on iPad with plans underway to integrate onto the Clinical Ink tablet and platform.



# CLINICAL TRIALS SOLUTIONS

**COGSTATE  
PRESCREEN**

**COMPUTERIZED  
ASSESSMENT**

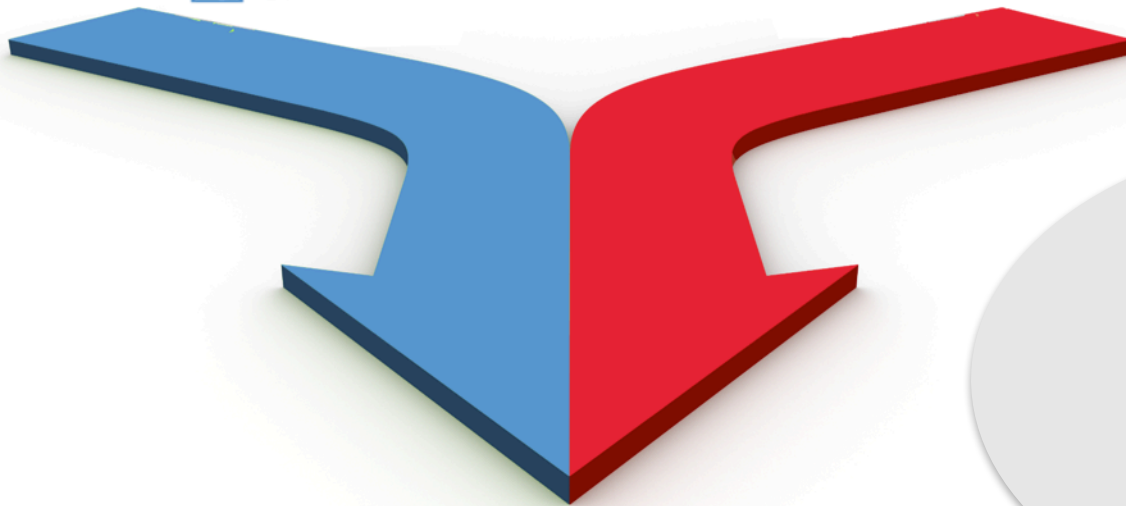
**SCALES  
MANAGEMENT  
& RATER  
TRAINING**

## **REDUCING TRIAL RISK WITH HIGHER QUALITY OUTCOMES**

- Specialists in cognitive and behavioral scales
  - Scales selection/consultation and management (permissions and licenses, source docs, translations, logistics)
  - Rater training and training materials development (didactic slides, videos, quizzes, scoring exercises, audio/video recorded practice, etc.)
  - Central monitoring (forms, data-based, audio, video)
- Enhanced tablet-based eSource data capture with Clinical Ink Sure Source
- Global capabilities and extensive network of expert consultants in over 30 countries



COGSTATE



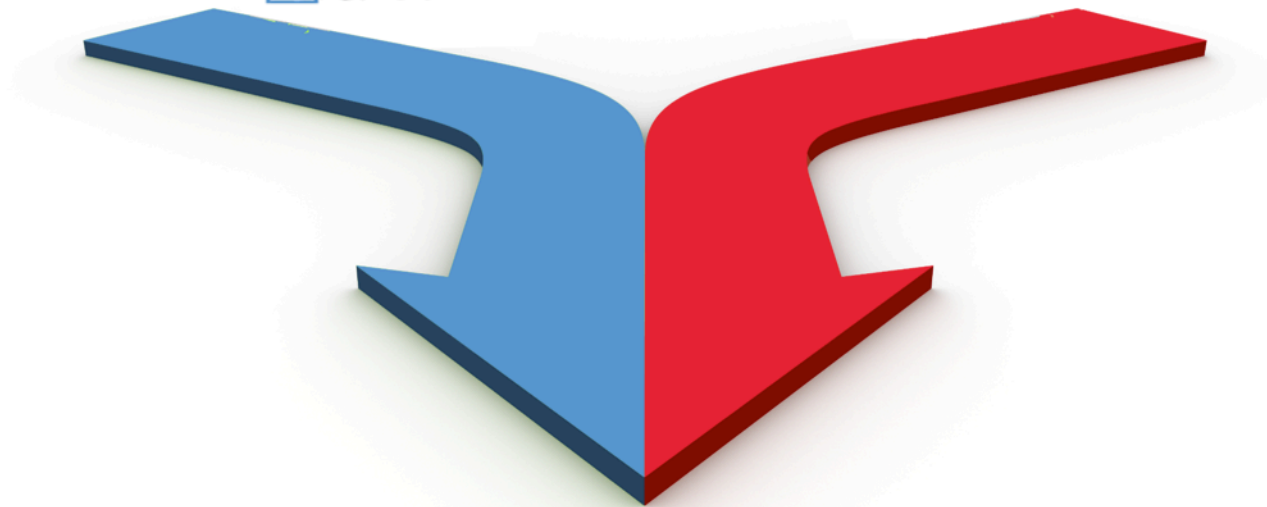
## ENHANCED TABLET-BASED SCALES

Electronic Scales on the leading eSource platform, enhanced by clinical science and rater training experts to elevate endpoint quality in CNS trials.

*Cogstate and Clinical Ink have formalized our long-standing relationship with a strategic alliance to deliver enhanced tablet-based scales assessments for CNS clinical trials. The alliance combines, in a single solution, the **scientific and adult learning expertise** at Cogstate with the **market-leading eSource data capture platform** from Clinical Ink.*



COGSTATE



### JOINT SOLUTION DELIVERS:

1

Custom edit checks, programmed workflows, and automated scoring that prevents clerical errors and miscalculations

2

Same day access to cleaner source data for central monitoring by Cogstate's network of local expert advisors (LEADs), with custom flagging algorithms designed by clinical scientists for rapid identification of rater variance

3

Rater training that reaches beyond the investigator meeting and eLearning platform by elegantly incorporating rater guidance into the rating scale instrument for more accurate, standardized administration

4

Growing library of enhanced electronic scales ready for study-specific licensing and protocol customization

# CLINICAL RESEARCH – eSOURCE MODEL

The screenshot shows a digital form for recording vital signs. It includes fields for patient information (Site # 001, Protocol # HJH-57, Screening # 462798, Visit # 2), a date and time (12/23/2008, 1:30 PM), and instructions for blood pressure measurement. The form contains several input fields for numerical data, some with dropdown menus for units or options. A handwritten note in the center reads: '\* Subject ran in from car - was out of breath.' The form is titled 'Vital Signs' and 'Vital Signs - Page 2'.

Field	Value	Unit/Option
Arm Used:	Left	Left/Right
Cuff Size Used:	Regular	Regular/Large
Blood Pressure #1:	100 / 60	mmHg
Blood Pressure #2:	100 / 55	mmHg
Blood Pressure #3:	100 / 75	mmHg
Mean Blood Pressure:	133 / 63	mmHg
Sitting Pulse Rate:	72	beats/min
Respiration Rate:	20	breaths/min
Temperature:	99.0	F
Height:	75.0	in
Weight:	190.0	lbs
Body Mass Index:	23.8	kg/m <sup>2</sup>



# Days	Task	Benefit
Same Day	Record Patient Data On <u>Digital</u> Forms	No Paper
	<u>Automatically</u> Record To Database	No Errors
	<u>Remotely</u> Review Source Documentation On Portal	No Travel

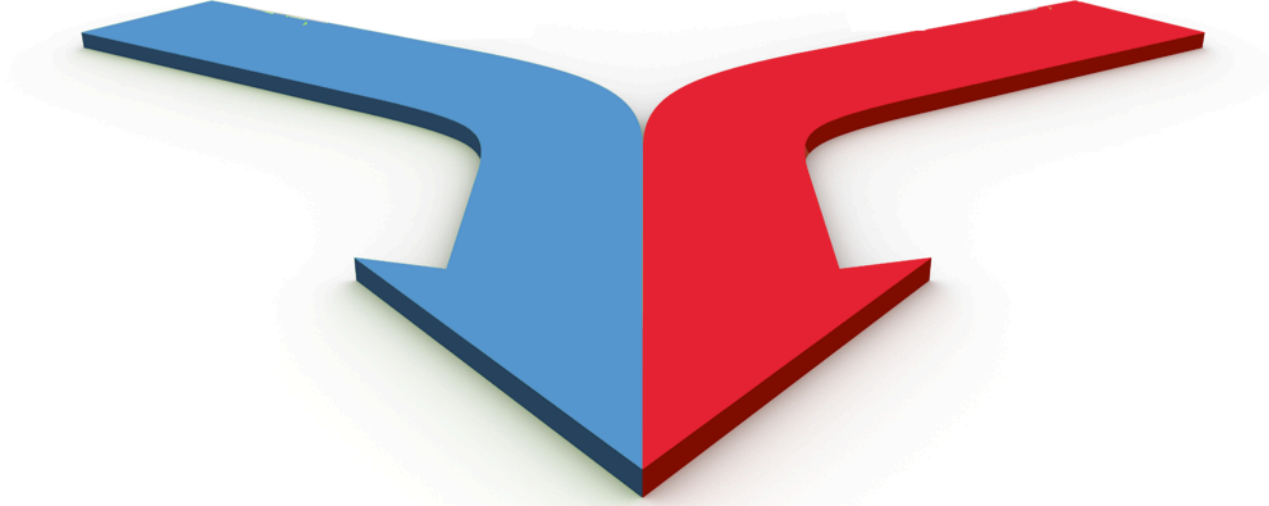
# KEY DIFFERENTIATORS

- The most widely adopted eSource solution, supported 1,000+ studies in 40 countries
  - Capable of full study data collection beyond eCOA
- Ensure protocol adherence with programmed workflows, branching and edit checks to prevent many errors
- “Paper-like” experience, captures handwritten notes
- Embed audio, video and photography on the forms
- Successful Inspections by MHRA, FDA and EMA
- Full off-line functionality: Workflows and edit checks run without internet connectivity
- Enables the review of all source and data in near real time with advanced algorithms designed by Cogstate scientists to detect errors





COGSTATE



## WELL RECEIVED BY CUSTOMERS

Cogstate's ability to offer eCOA has been positively received, allowing us to bid on new projects as reflected by the 7 outstanding joint proposals totaling over \$62M





## HEALTHCARE

Tools to detect cognitive  
change and impairment in  
patients (COGNIGRAM™)

# NEW APPOINTMENT

## FRANK CHENG

President, Healthcare

- Reporting directly to CEO, Brad O'Connor
- Full P&L responsibility for the Healthcare division
- Oversee preparations for launch of Cogstate tech into healthcare market:
  - Seeking regulatory approval (FDA 510k, EU CE Mark, plus other jurisdictions);
  - Market access & reimbursement;
  - Management of discussions / negotiations with potential launch partners;
  - Product launch & adoption;
- US based role, in line with Cogstate staffing footprint.

# FRANK CHENG

## Background

- 22 years experience within diagnostic / device industry:
  - Executive roles (including President / CEO roles)
  - Business Development and marketing roles
- Most recently Senior VP with NASDAQ listed robotic heart surgery company, where he led worldwide marketing, business development, training, clinical research, operations as well as Asia Pacific P&L
- Extensive medical device experience, having achieved regulatory clearance and reimbursement for multiple devices and diagnostics across international jurisdictions including the USA, the EU, Canada, China & Japan.
- Previous experience includes roles at both GE Healthcare and Roche Diagnostics (where he was VP, Global Business Development)
- BBA in International Finance from Wuhan University in China. MBA from Vanderbilt University.

# Current State of Diagnosis of Cognitive Decline in Primary Care:

Need for early-diagnosis vs. current clinical practice

1

## SKILL GAP

Not all primary care physicians are trained and/or confident in diagnosing

2

## TIME GAP

Cognitive assessment is time intensive

3

## STANDARDS GAP

Lack of consensus on the appropriate tools to detect and diagnose cognitive impairment

4

## REIMBURSEMENT GAP

Lack of support by global health systems...  
**COVERAGE & PAYMENT**





Welcome to COGNIGRAM, a test of cognitive function prescribed by your clinician.

To get started, confirm your details:

First Name

Last Name

First Name

Last Name

Date of Birth

MMM

DD

YYYY

☐ I understand and accept the [Privacy Policy](#).

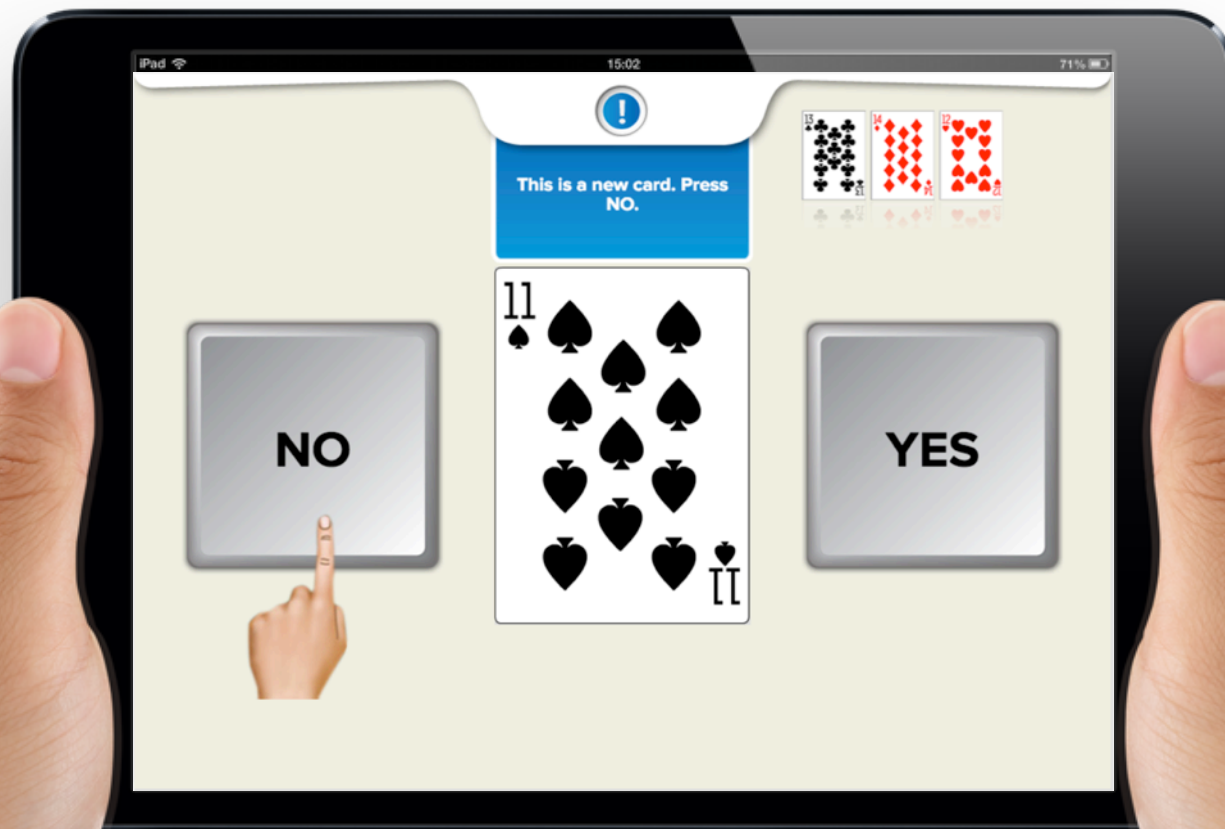
Confirm Details

**COGNIGRAM is a brief and simple test to measure your cognitive function. It allows for regular and standardized testing to assist your clinician in the early detection of changes that could signify the need for further evaluation.**

[Privacy](#) | [Terms of Use](#) | [FAQ](#) | [About COGNIGRAM™](#)

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Software Version 3.0

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One Card Learning

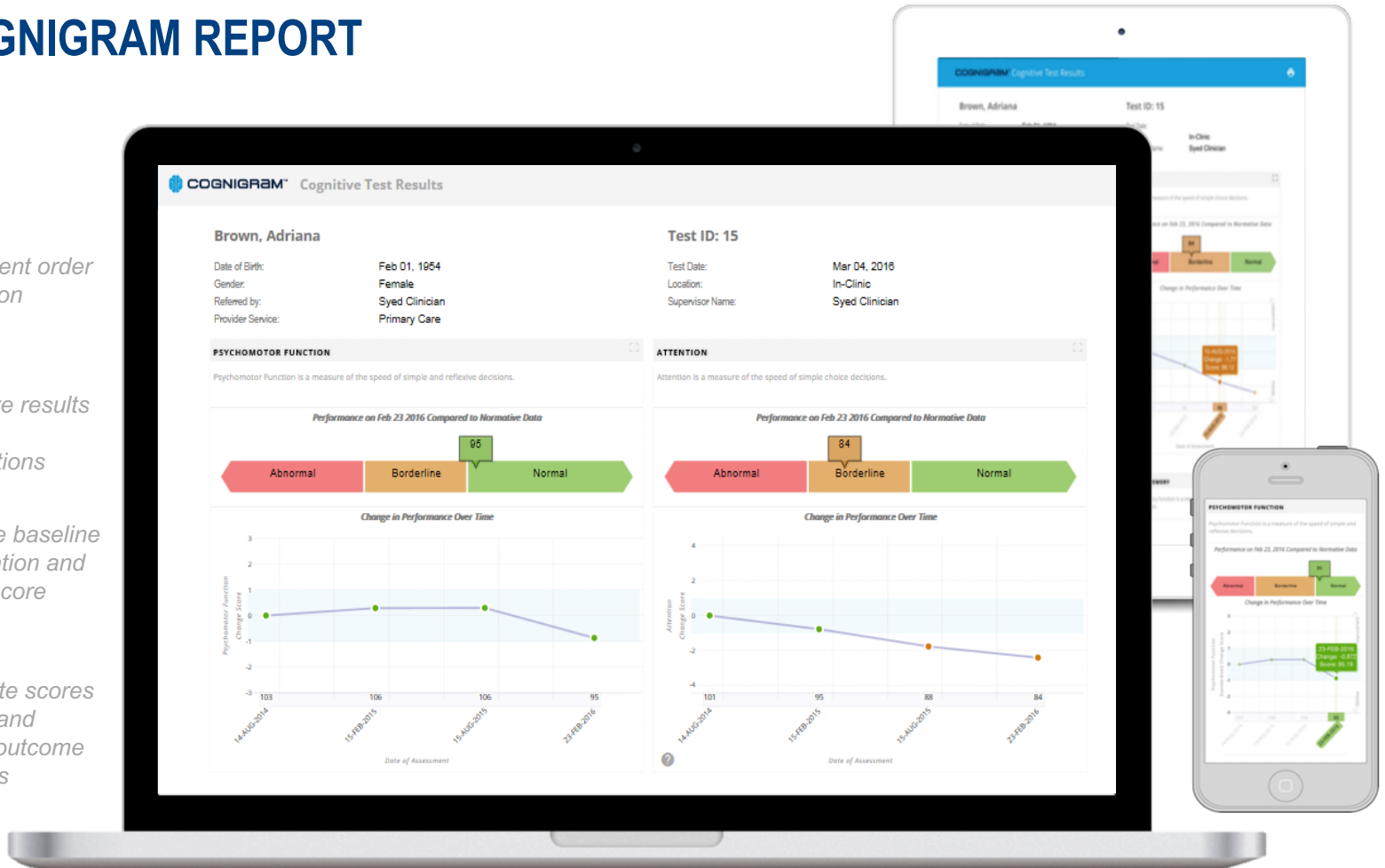
# COGNIGRAM REPORT

*Patient & assessment order Information*

*Interactive results and data visualizations*

*Real-time baseline configuration and change score analysis*

*Composite scores (shown) and detailed outcome measures*





# Leveraging Technology to Realise Effective Cognitive Assessment Tools for Primary Care



## **SENSITIVITY**

High sensitivity and specificity in AD and prodromal disease



## **EASE OF USE**

Standardised, rapid, self administration and/or non-expert administration.

Integration into electronic health records



## **CUTURALLY NEUTRAL**

Available in all languages and appropriate for any level of education



## **IMPAIRMENT & CHANGE**

Measure impairment on single assessment but also measure change over time

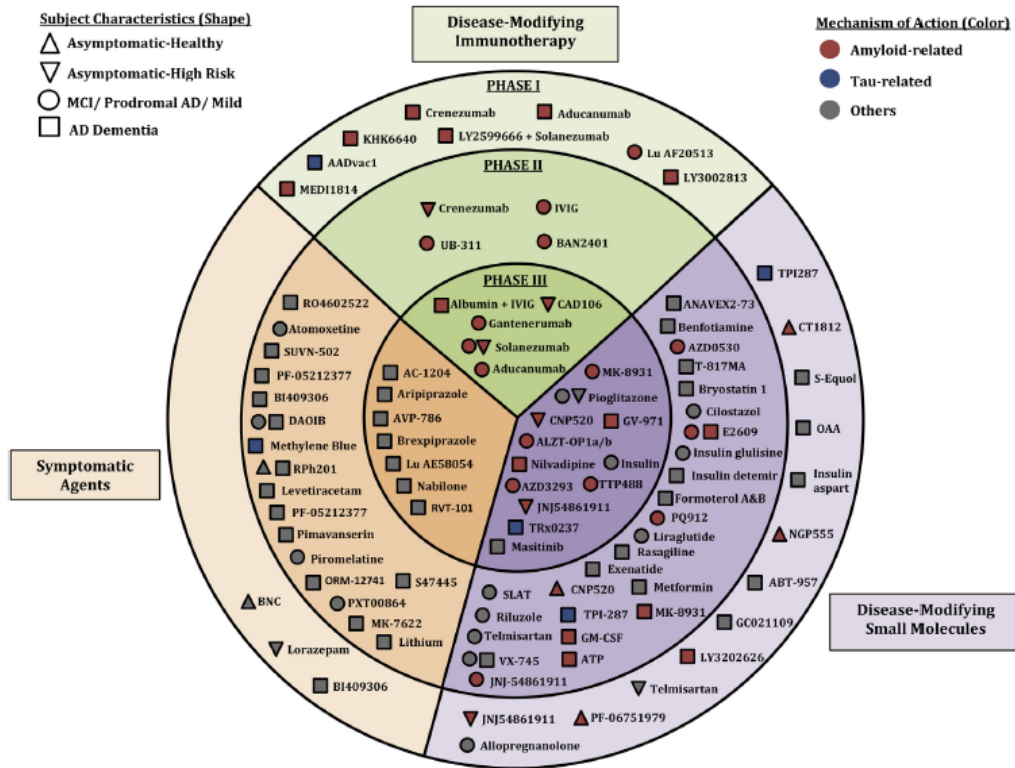


## **HEALTHCARE & TRIALS**

Adoption in primary care & research studies, allowing payers to measure treatment effect data in individuals

# POTENTIAL SOURCES OF THERAPEUTIC BREAKTHROUGH

## AD Drug Pipeline



# COGSTATE IN PRIMARY CARE : NOT LIMITED TO AD

## Hospital-based assessment of cognition

- based upon concerns about post-operative cognitive decline
- especially important within a US “total cost of care” model

## Concussion

- Concerns about “return to play” decisions and legal / insurance risk are real
- In US, the concept of mass baseline testing is hindered by lack of FDA approved device that can test remotely and link directly into electronic health records

# AFTER LILLY'S RESULT...WHAT NEXT

- Starting earlier
  - A4 & DIAN studies are measuring the impact of therapy before symptoms but when amyloid is present (Cogstate is an endpoint in both studies)
- Other drugs...those getting the most attention include:
  - BACE inhibiting drugs being developed by Merck, Lilly & AZ jointly, Biogen & Eisai jointly. Merck's results are due mid-late 2017.
  - Biogen's aducanumab is also a amyloid beta antibody but Biogen has pointed out previously that it has a different method of action to Lilly's solanezumab
  - Many other drugs, including symptomatic treatments
  - Tau focused therapies

# COGSTATE SUMMARY

- Positive EBIT expected for H1 FY17, based on strong Q1 performance
  - September quarter sales results reinforces the exciting growth profile
  - Strong backlog of contracted future revenue provides visibility into revenue growth for FY17
- Partnership with Clinical Ink provides additional scope for new opportunities and further growth in the Clinical Trials business
- Key senior appointments bring extensive commercial and management experience as well as domain expertise
- Q2FY17 high level results released in January 2017 with audited results to follow in February 2017
- Roadshow, including new senior executives, Jan/Feb 2017



COGSTATE

ASSESS • MONITOR • IMPROVE

# APPENDIX 1

## CONTRACTED REVENUE PIPELINE

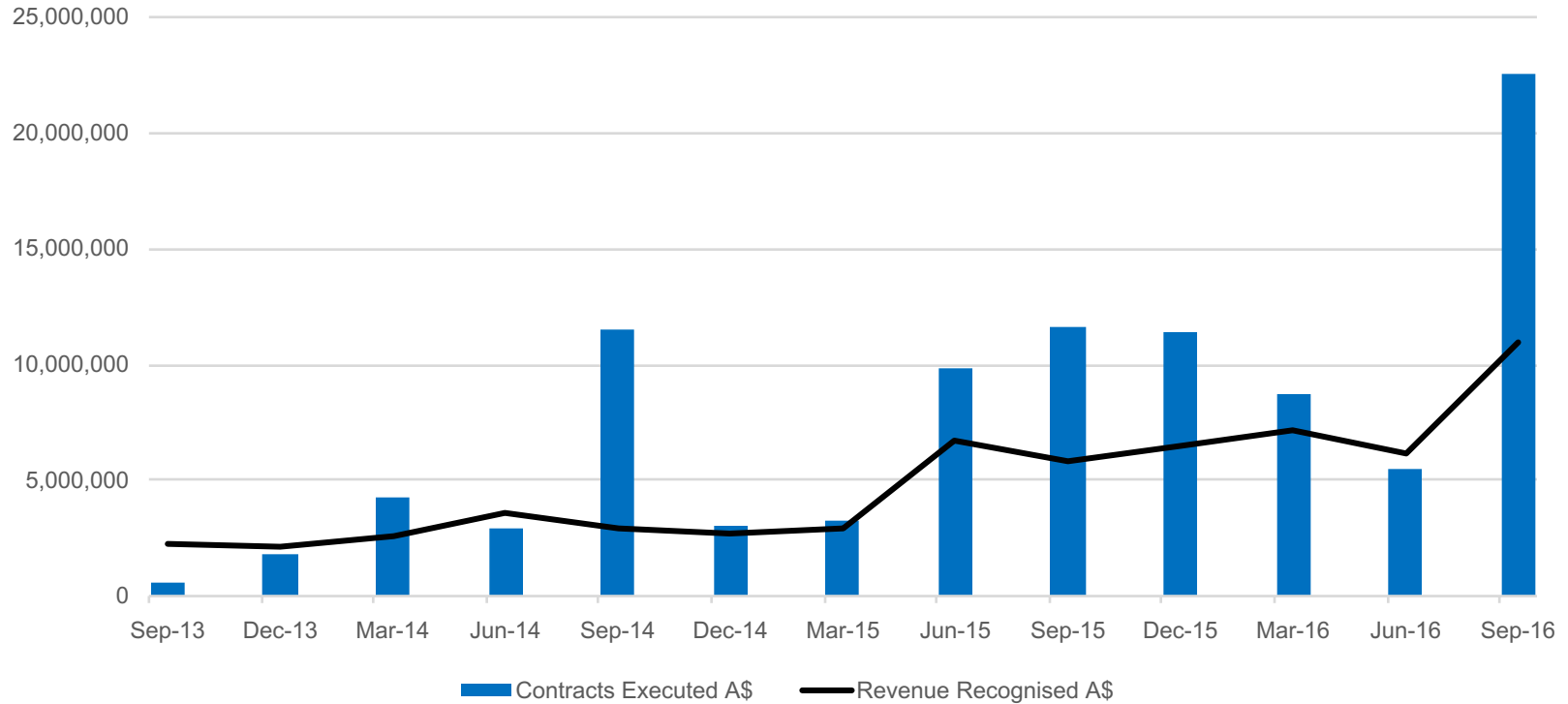
US\$17.3m of new sales contracts signed since 1 July 2016 have added an additional A\$11.2m to FY17 contracted revenue. This is in addition to the A\$17.5m that was secured at 1 July 2016:

	As at 30 Sept 2016		As at 30 June 2016		As at 22 Oct 2015	
Year 1	FY17	A\$28.7m	FY17	A\$17.5m	FY16	A\$18.7m
Year 2	FY18	A\$14.3m	FY18	A\$ 9.7m	FY17	A\$ 9.2m
Year 3-5	FY19-FY22	A\$12.5m	FY19-FY22	A\$ 6.7m	FY18-FY20	A\$ 7.5m
Total		<b>A\$55.5m</b>		<b>A\$33.9m</b>		<b>A\$35.4m</b>

Contracts are denominated in US\$. Spot rate at 30 September 2016 has been used to calculate the A\$ equivalent. The rate used at 30 September 2016 was 0.763, the rate used at 30 June 2016 was 0.743 and the rate used at 22 October 2015 was 0.732.

## APPENDIX 2

# CONTRACTS SIGNED VS. REVENUE, PER QUARTER

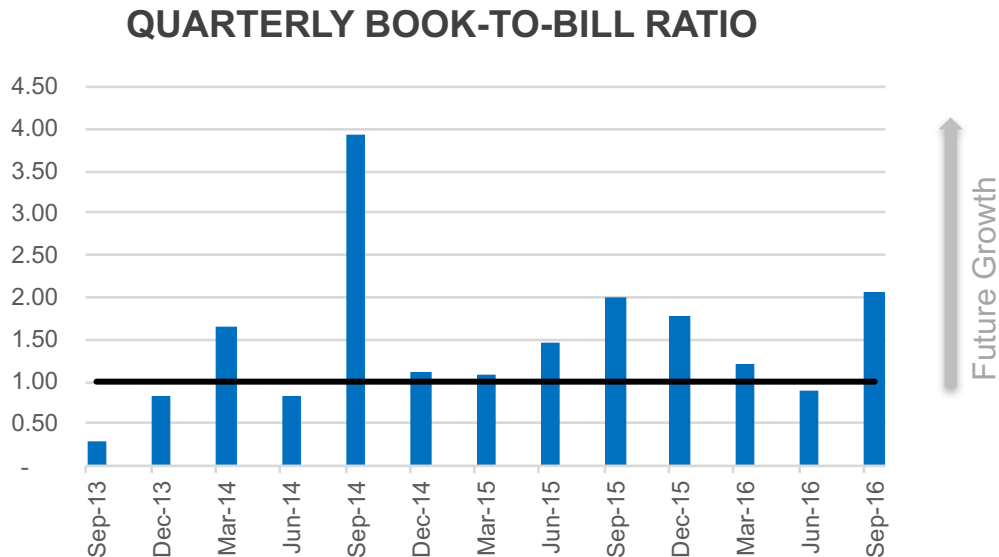




## APPENDIX 3

# QUARTERLY BOOK-TO-BILL RATIO

New contract signings in 1Q17 of A\$22.6m exceeded the A\$11.1m of revenue in the same period by **2.04x (Book-to-Bill ratio)**. New contract signings have exceeded revenue (Book-to-Bill ratio >1) in 8 of the last 9 quarters, indicating growth in the revenue pipeline.



*At 1.00, contracts signed = revenue and future contracted revenue is constant.*

*When Book-to-Bill > 1.00 contracted future revenue increases.*

# APPENDIX 4

## SUMMARY BALANCE SHEET

	30 JUNE 2016 A\$'000,000	30 JUN 2015 A\$'000,000
<b>Assets</b>		
- Cash and cash equivalents	7.47	5.50
- Trade and other receivables	5.26	4.90
- Other current assets	0.94	0.46
- Property, plant and equipment	1.71	1.12
- Deferred tax assets	3.85	1.94
- Intangible assets	0.40	0.40
<b>Total Assets</b>	<b>19.63</b>	<b>14.31</b>
<b>Liabilities</b>		
- Trade and other payables	3.39	2.55
- Provisions	1.72	1.15
- Deferred tax liabilities	0.72	0.49
<b>Total Liabilities</b>	<b>5.83</b>	<b>4.19</b>
<b>Net Assets</b>	<b>13.80</b>	<b>10.11</b>