

# FY18 Results Presentation

12 months to 30 June 2018

Release date: 13 August 2018



# Investment Summary

All results presented in US\$

- Continued growth in Clinical Trials sales contracts and revenue delivered in FY18. Growth expected to continue into FY19.
- Notification of Clinical Trials study cancellations received July 2018. Despite this, contracted future revenue at 30-Jun-18 (\$28.4m) equivalent to prior year (\$28.7m)
- Strategic change implemented in respect of sales and marketing of Cognigram, removing significant costs from the business. Continued commitment to Cognigram opportunity through alternative distribution model.
- Overall restructure will remove over \$5m of costs from FY19 budget:
  - These costs accounted for \$3.46m of costs of sales and operating costs in FY18
  - 84% of costs removed were direct costs - Cognigram and Shared Services (legal, finance and admin)
  - 16% of cost removed were cost of sales : to balance cost of sales against contracted revenue position and ensure maintenance of gross margins
  - FY19 budget allows for increased Clinical Trials sales and marketing resources, compared to FY18
- Profit growth forecast for FY19



“

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.**”

# Investment Highlights

All results presented in US\$

## FY18

- \$36m clinical trials sales contracts; up 22%
- Revenue \$29m; up 10%
- Adjusted EBITDA\* from continuing operations \$3.6m; up 102%
- Profit before tax \$0.1m; \$0.77m improvement

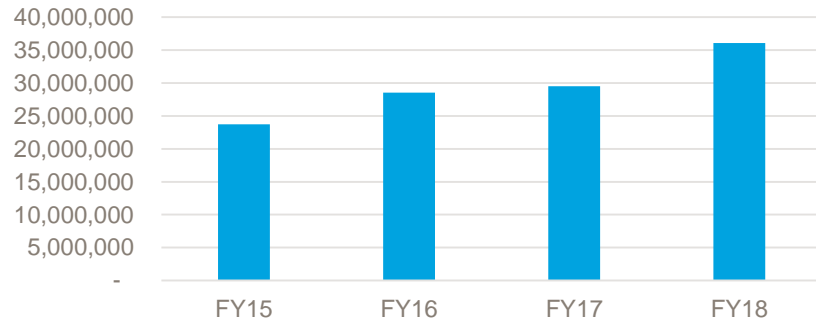
\* Adjusted EBITDA excludes share based compensation for purposes of annual comparison (see slide 31)

## Clinical Trials

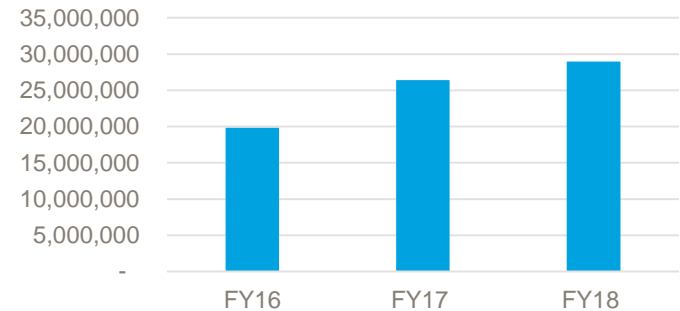
- Strong FY18 performance, impacted by cancellation of a small number of clinical trials in July 2018
- Contracted revenue backlog of \$28.4m at 30-Jun-18, down 1% from prior year
  - Contracted revenue impacted by cancellations of clinical trials (was \$34.8m before cancellations)
- Adjustment to staffing levels in Aug-18, balancing resources against contracted revenue
- Continue to see growth opportunities in Alzheimer's disease, where the number of phase 2 studies are increasing year-on-year : see slides 22 - 24
- Gaining traction in other key markets, such as pediatric safety studies

# Clinical Trials Sales and Revenue Growth

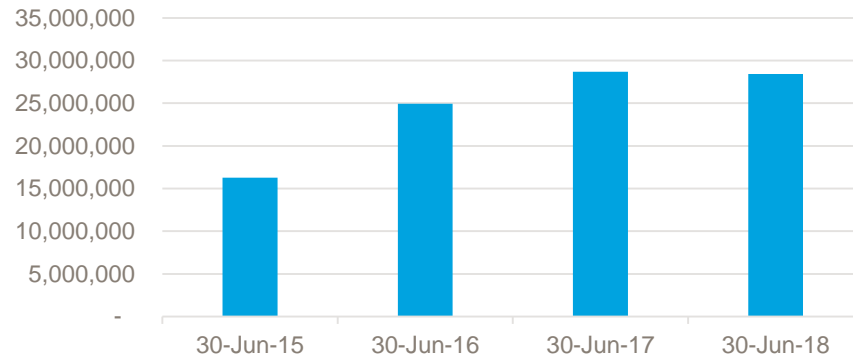
## Sales Contracts Executed, by Financial Year (US\$)



## Recognised Revenue, by Financial Year (US\$)



## Contracted Future Revenue, at 30-Jun (US\$)



30-Jun-18 contracted future revenue inclusive of impact of contract cancellations

# Investment Highlights

All results presented in US\$

## Healthcare

- Regulatory clearance achieved in US, EU, Canada & Australia
- Sales contracts \$0.7m, delivering revenue of \$0.4m
- Loss from operations \$1.9m, approx. double FY18 loss
- Strategy adjustment : will seek distribution and license of technology and discontinue direct sales activities
- Continued commitment to new and existing customers
- Major adjustment to staffing and commercial model executed, removing significant costs from the business

# Investment Highlights

All results presented in US\$

## Strategy Adjustment – Implementation of Restructure and Cost Reduction

- Significant restructure undertaken Apr-18 through Aug-18
  - Major impact in Healthcare (Cognigram) segment
  - Minor impact in Clinical Trials as well as Shared Services (legal, finance, admin)
- Removal of 30 full-time roles (17% of staff)
- Overall restructure will remove over \$5m of costs from FY19 budget:
  - These costs accounted for \$3.46m of costs of sales and operating costs in FY18
  - 84% of costs removed were direct costs - Cognigram and Shared Services (legal, finance and admin)
  - 16% of cost removed were cost of sales : to balance cost of sales against contracted revenue position and ensure maintenance of gross margins
  - FY19 budget allows for increased Clinical Trials sales and marketing resources, compared to FY18

# Investment Highlights

All results presented in US\$

## FY19 Guidance – Profit Growth

- Continued growth in Clinical Trials sales contracts and revenue delivered in FY18. Growth expected to continue into FY19.
- As a result of restructure, approx \$2m of non-recurring costs will be incurred in 1H19
- 1H19: expecting to record a loss overall, inclusive of non-recurring costs
  - 1H19 profit, if non-recurring costs are excluded
- Much improved profitability in 2H19
  - forecast revenue growth from 1H19 to 2H19
  - Full benefit of cost reduction measures delivered in 2H19
- Full year profit, inclusive of non-recurring costs



# Addressing an Unmet Need in Clinical Research



For **drug candidates that cross the blood-brain barrier**, pharmaceutical researchers need reliable and valid measures to understand how these drugs impact human cognition



There are traditional, paper-and-pencil neuropsychological assessments available for the many cognitive domains of interest, but without careful adaptation, training and monitoring, **these measures break down when applied to large global studies** : Cogstate has the technology & skills to manage these issues

- *Due to factors like practice effects, patient population differences in culture, language and education, and administration or scoring errors by raters*



Cogstate computerized measures were **specifically designed by cognitive researchers for cognitive research** to address these exact limitations and dramatically improve the sensitivity to even subtle cognitive change

- *Standardized administration, automated scoring, global, repeatable, sensitive, extensively normed and validated through years of research*

A man with a grey beard is wearing a VR headset and a maroon jacket. He is smiling and has his hands behind his head, suggesting he is enjoying the experience. The background is a light-colored wall. The image has a dark overlay and a colorful geometric shape in the bottom left corner.

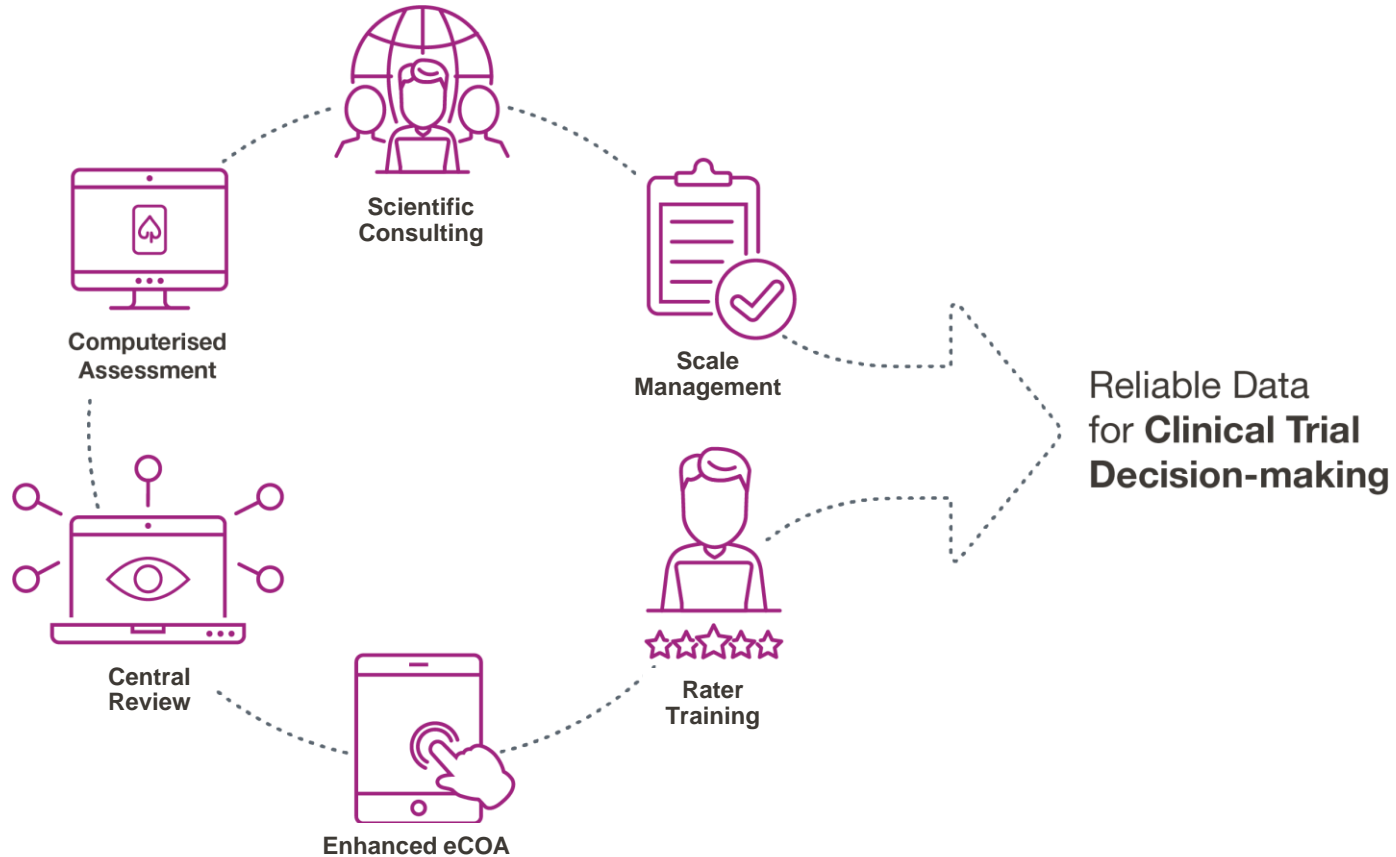
What is our unfair advantage?

# Improving Signal to Noise: Key Advantages of Cogstate Computerized Assessments

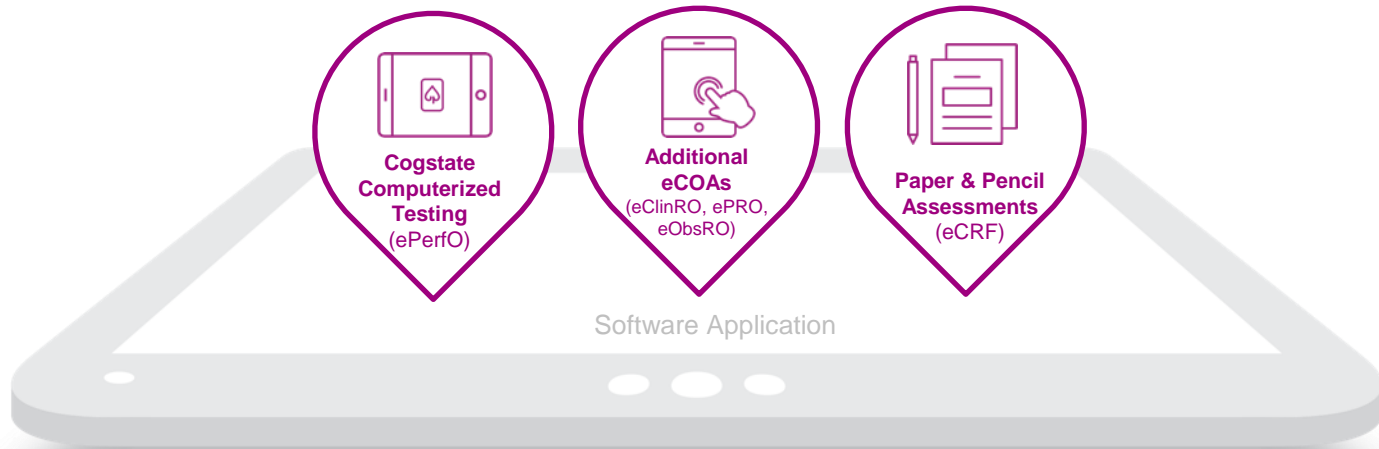
- Objective & standardized **administration by a non-psychologist**
  - *Eliminates the inter- and intra-rater variability that can compromise conclusive clinical trial outcomes*
- Assessments are **brief & repeatable**
  - *Each test takes 2-5 minutes*
  - *Controlled for practice effects*
- Demonstrated **sensitivity** to drug-related change in various populations and indications
  - *Validating data from 1,500 studies and 400 peer reviewed publications*
- **Eliminates errors** related to scoring and data entry
  - *Paper and pencil tests require that raters compute total scores or analyze performance, which increases the potential for error*
- **Regulatory acceptability**, as Cogstate data have been included as part of many regulatory submissions
  - *Including programs that went on to achieve marketing approval*



# Beyond Computerized: End-to-End Solution for Reliable Measures of Cognition



# Cogstate eSource Platform



# Cogstate eSource Platform



Cloud-based Data Management System



**Cogstate  
Computerized  
Testing**  
(ePerfO)



**Additional  
eCOAs**  
(eClinRO, ePRO,  
eObsRO)

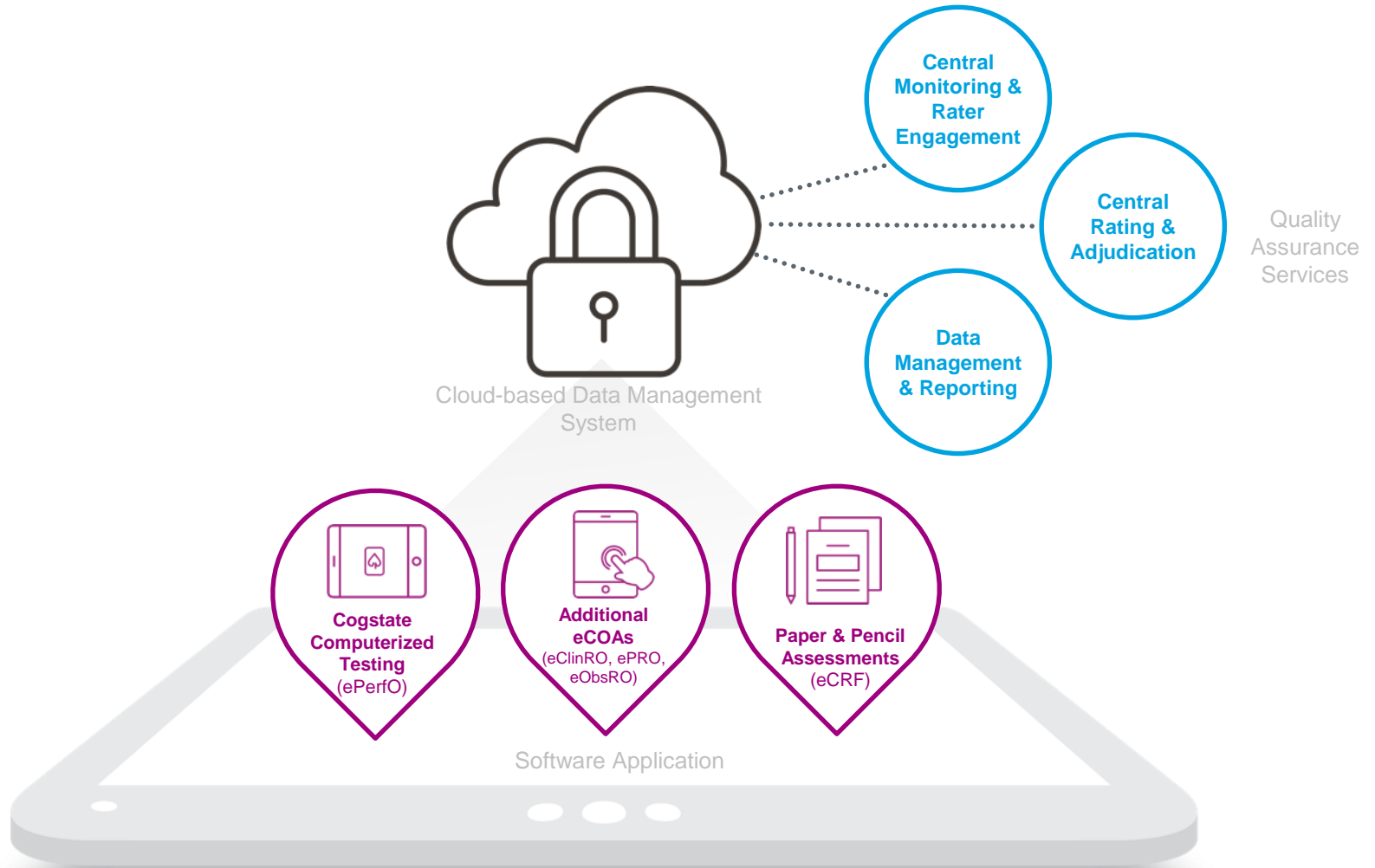


**Paper & Pencil  
Assessments**  
(eCRF)

Software Application



# Cogstate eSource Platform



A woman with long blonde hair in a braid, wearing a dark blue button-down shirt, is standing in a classroom. She is holding a white marker and writing on a whiteboard. The whiteboard has various handwritten notes and diagrams, including a pie chart and a list of items. The background shows a classroom setting with desks and chairs. The image has a dark overlay and a colorful geometric shape in the bottom left corner.

# The Market Opportunity



# Large & Growing Cognitive Assessment Market

**\$4.1**  
**BILLION**

Forecasted Market  
Size for **Cognitive  
Assessment and  
Training** in 2021

- Research Cosmos forecasts the market size for cognitive assessment and training in healthcare to grow from USD 962.0 Million in 2016 to USD 4,127.2 Million by 2021, at a CAGR of 33.8%.
- “The applications segment [represented in this forecast] includes clinical trials, screening & diagnostic, brain training, and academic research”
- The aging population and rise in brain fitness awareness are the major factors driving growth

# Large & Growing Cognitive Assessment Market

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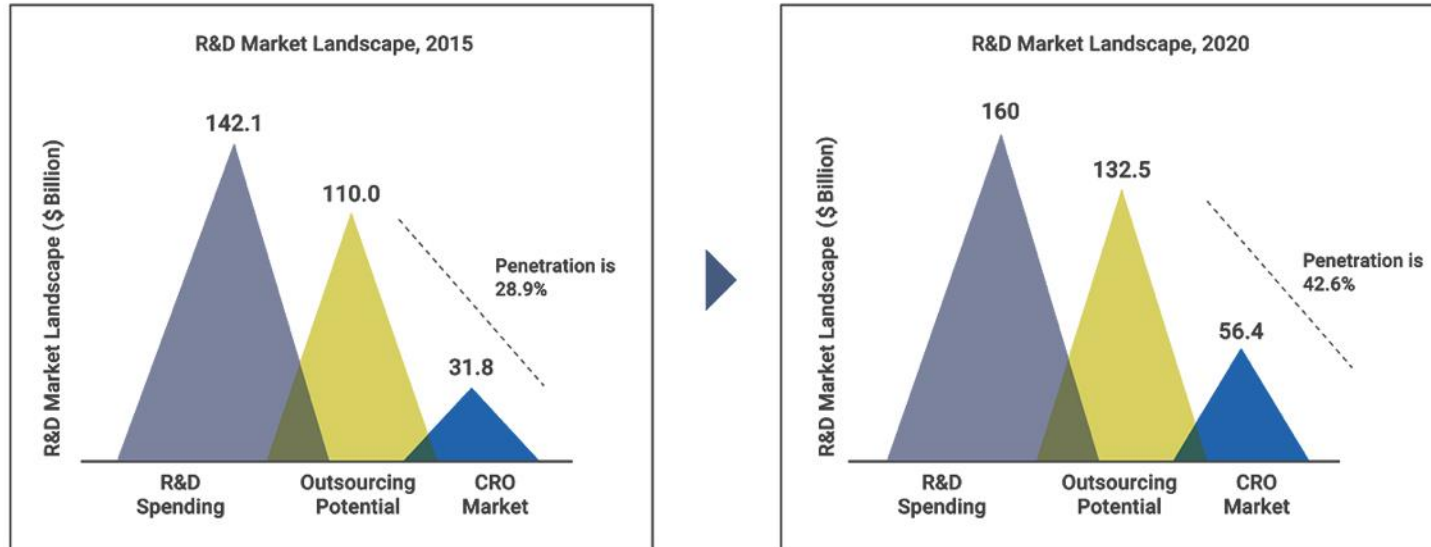
- Research Cosmos forecasts the market size for cognitive assessment and training in healthcare to grow from USD 962.0 Million in 2016 to USD 4,127.2 Million by 2021, at a CAGR of 33.8%.

- “The market is expected to be dominated in the near-term by clinical trials, followed by cognitive training, and cognitive assessment. Clinical Trials projected to be largest segment in near-term at **\$1.36B**.”

growth

# Macro Tailwinds for Increased Pharma R&D Spend & Outsourcing Penetration

Figure 2: Total CRO Market, R&D and Clinical Research Outsourcing Landscape, Global 2015-2020F



Note: F: Forecasted;

Source: Frost & Sullivan Global CRO Report, 2016

# Application in Alzheimer's Disease & Well Beyond

## Safety

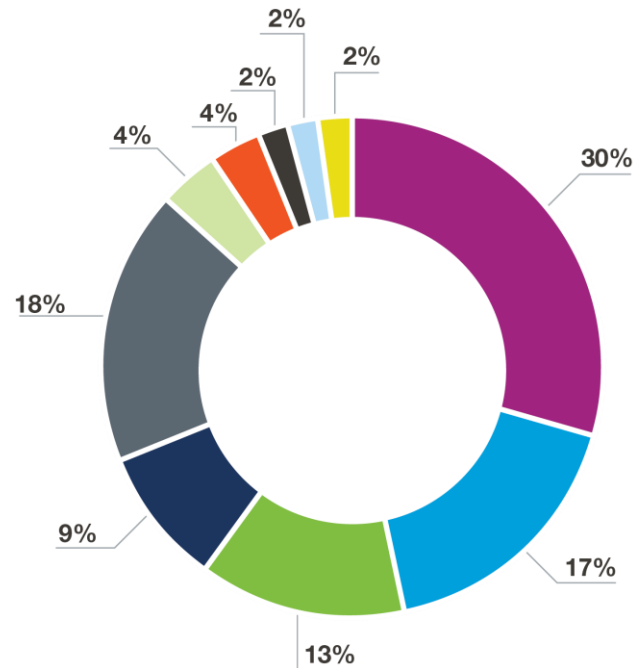
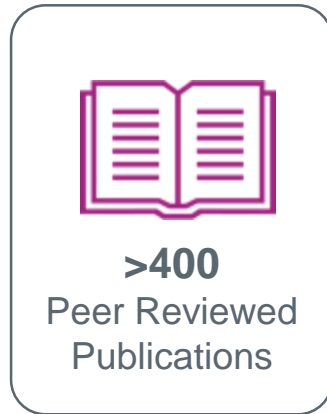
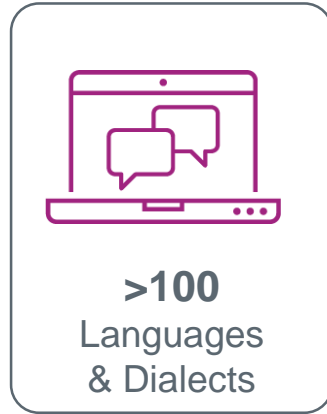
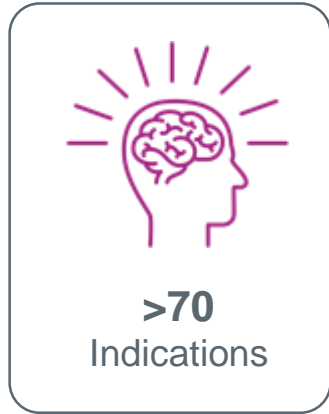
Does the therapy negatively impact aspects of thinking?  
*e.g. oncology*

## Efficacy

Does the therapy improve aspects of thinking?  
*e.g. Alzheimer's disease*



# Application in Alzheimer's Disease & Well Beyond



## Indications

- Alzheimer's disease & other dementias
- Schizophrenia
- Safety & Tolerability Studies
- Depressive disorders
- Other (including genetic disorders, Autism spectrum disorders, diabetes, stroke, heart failure, Attention deficit hyperactivity disorder (ADHD), Concussion & Traumatic brain injury, Pain, Sleep disorders, Fragile X syndrome and Blood disorders)
- Epilepsy
- Glioblastoma & other cancers
- HIV
- Parkinson's disease (PD)
- Hypercholesterolemia

# Alzheimer's Disease Market is Still Growing

- Despite repeated failures, the number of drugs entering phase 2 clinical trials continues to grow
- With improved knowledge and biomarkers of disease, focus has switched to new mechanisms of action
- Pharma companies continued commitment to R&D reflective of huge societal need and associated commercial opportunity

PHASE 2 FACTS 2018		Percent Change from 2017
Number of Drugs: 68	↑	17%
<b>Commercial Launch:</b> 8 drugs could reach the market in the next five years		0%
Number of Symptomatic Drugs: 13	↓	-24%
Number of Disease Modifying Drugs: 55	↑	34%
Prevention Trials: 2 drugs are in prevention trials		0%
<b>Mechanism of Action:</b> 11 drugs are classified as Tau 12 drugs are classified as Amyloid	↑ ↑	57% 20%

PHASE 3 FACTS 2018		Percent Change from 2017
Number of Drugs: 31	↓	-3%
<b>Commercial Launch:</b> 25 drugs could reach the market in the next five years	↓	-7%
Number of Symptomatic Drugs: 12	↑	20%
Number of Disease Modifying Drugs: 19	↓	-14%
Prevention Trials: 7 drugs are in prevention trials		0%
<b>Mechanism of Action:</b> 14 drugs are classified as Neurotransmission	↑	27%

# Changes in AD Study Design Requires New Thinking on Endpoint Selection

## AD Research is Focusing Earlier in the Disease

- More “prevention trials” that are seeking to measure cognitive change very early in the disease when the changes in cognition are most subtle
- This strategy requires a shift away from the cognitive tests that were designed for more advanced disease and most commonly used in clinical trials
- Cogstate is well positioned for growth in this environment, particularly given the sensitive nature of its computerised tests.
  - Cogstate computerised tests used in large longitudinal prevention studies like A4 and DIAN

# Changes in AD Study Design Requires New Thinking on Endpoint Selection

## AD Research is Focusing Earlier in the Disease



**11<sup>th</sup>**  
edition of  
**Clinical Trials  
on Alzheimer's Disease**

**Preliminary Program**  
PALAU DE CONGRESSOS DE CATALUNYA  
Barcelona, October 24-27, 2018

seeking to measure cognitive change very early in  
n cognition are most subtle

ay from the cognitive tests that were designed for  
st commonly used in clinical trials

5.00 - 6.00 p.m.

### Symposium 4 Endpoints for early Alzheimer's disease clinical trials: Interpretation and application of the draft FDA guidance

Symposium moderator: Eric Siemers, MD, Cogstate Ltd, New Haven, CT, USA

#### Communication 1: Clinical Endpoints in Stage 1, 2 and 3 Disease

Reisa Sperling, MD<sup>1</sup>, Ronald C. Petersen, MD, PhD<sup>2</sup>, Gary Romano, MD, PhD<sup>3</sup>, Paul Maruff, PhD<sup>4</sup>  
<sup>1</sup>Department of Neurology, Brigham and Women's Hospital, Boston, MA, USA <sup>2</sup>Department of Neurology, Mayo Clinic, Rochester, MN, USA  
<sup>3</sup>Janssen R&D, Titusville, NJ, USA <sup>4</sup>Cogstate Ltd, Melbourne, Victoria, Australia

#### Communication 2: Biomarkers in Stage 1, 2 and 3 Disease

Samantha Budd Haerberlein PhD<sup>1</sup>, Jose Luis Molinuevo, MD, PhD<sup>2</sup>, Christopher C. Rowe, PhD<sup>3</sup>, Maria C. Carrillo PhD<sup>4</sup>,  
Clifford R. Jack, Jr., MD<sup>5</sup>  
<sup>1</sup>Biogen, Cambridge, MA, USA <sup>2</sup>BarcelonaBeta Brain Research Center, Pasqual Maragall Foundation and Hospital Clinic-IDIBAPS,  
Barcelona, Spain <sup>3</sup>Department of Molecular Imaging, Austin Health, University of Melbourne, Melbourne, Australia <sup>4</sup>Alzheimer's  
Association, Chicago, IL, USA <sup>5</sup>Department of Radiology, Mayo Clinic, Rochester, MN, USA

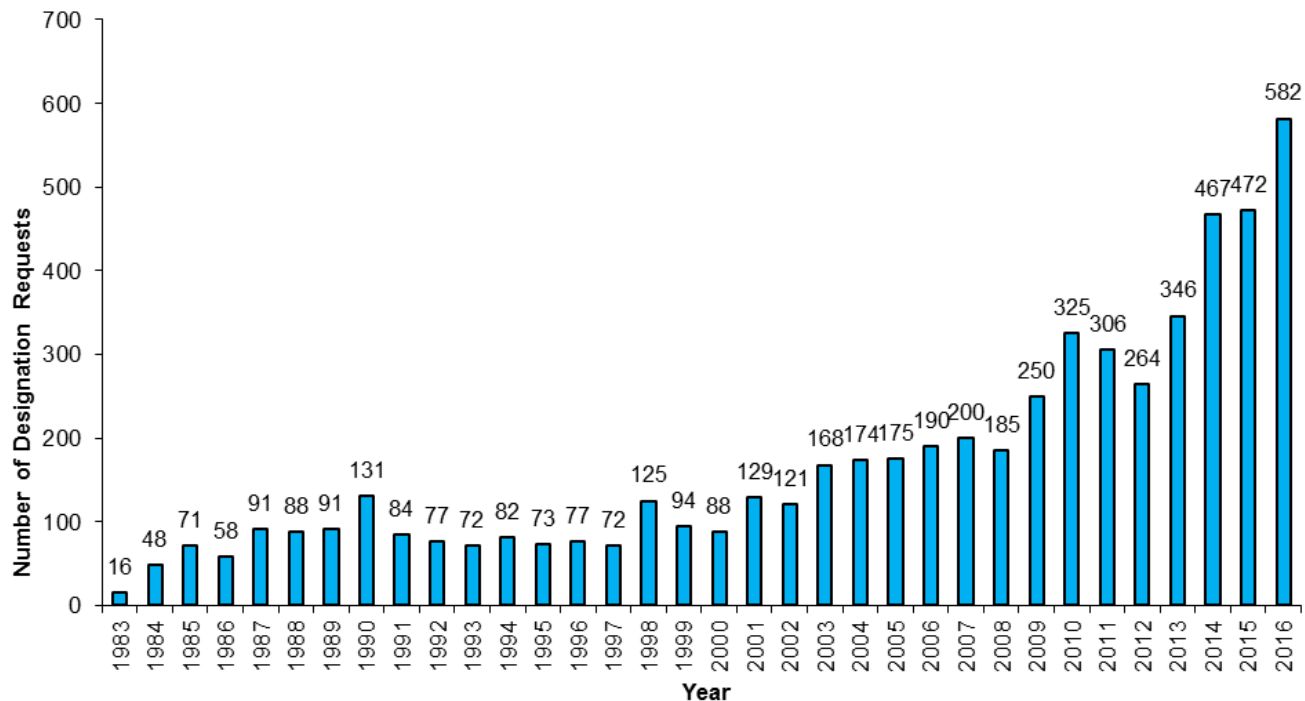
#### Communication 3: Approaches to Establishing the Meaningfulness of Treatment Effects

Chris J. Edgar, PhD<sup>1</sup>, George Vradenburg, JD<sup>2</sup>, Jason Hassenstab, PhD<sup>3</sup>  
<sup>1</sup>Cogstate Ltd, London, UK <sup>2</sup>UsAgainstAlzheimer's and Alzheimer's Disease Patient and Caregiver Engagement (AD PACE), Chevy Chase,  
MD, USA <sup>3</sup>Department of Neurology, Washington University School of Medicine, St. Louis, MO, USA



# Cogstate Has Successfully Pushed into Rare Diseases – a Growing Market Opportunity

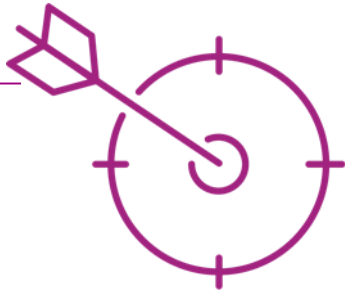
Number of Orphan Drug Designation Requests by Year



Source: <http://www.fdalawblog.net/2017/01/orphan-drug-approvals-and-designations-dipped-slightly-in-2016-but-orphan-drug-designation-requests/>

# Strategy for Growth





Cogstate will continue to support large pharma (currently work with 14 of the top 15 by R&D spend), but **small and mid-size pharma** also represent major growth potential.

- It's estimated that 60 to 80% of the intellectual property in the industry resides within these smaller companies\*
- We've established a strong commercial strategy and flexible, full-service solution to cater to these small and mid-sized companies -- providing them with the right level of support and services to conduct complex and global programs



Full suite of solutions for **single-site to large global studies**

- Expanded scientific leadership team in AD, pediatric and rare disorders for early-stage consultancy and trial design input
- New, more flexible technology platform to support more types of assessments
- Established key vendor alliances to provide a one-stop solution to sponsors



Continuing **and expanding our strategic academic partnerships** in high-growth areas, as we've done in AD and pediatric oncology. Cogstate's role in these studies puts us at the center of important KOL research.



# Case Study: Building a Better Verbal Memory Test

- The International Shopping List Test (ISLT) is a 12-word, 3-trial word learning test developed by Cogstate with established validity and reliability for the detection of memory impairment in even the early stages of Alzheimer's disease
- The unique design of the ISLT allows the assessment of memory in individuals from different languages, cultures or geographic regions without the need for the complex translations or cultural adaptations that must be applied to other verbal memory tests (such as the Free and Cued Selective Reminding Test or Wechsler Memory Scale Logical Memory Test), which were developed and validated in well-educated, middle-class, English-speaking settings
- The ISLT has now been used extensively by pharmaceutical sponsors to measure the magnitude and nature of memory impairment in global clinical studies; as well as to screen individuals' memory for entry into clinical trials in prodromal (early) AD







# Rare Disease Case Study: New Novel Measures for Uncharted Territory

- Current outcome assessments for CNS-based trials have clear limitations which are further magnified in rare disease trials. Small sample sizes mean outcome measures must be refined to be highly targeted to the indication and drug mechanism in order to detect a signal (i.e., detect a potential change in functioning).
- To address this challenge in one rare disease trial of Fragile X syndrome, we integrated our clinical expertise and clinical trial experience to modify a commonly used assessment methodology (Visual Analog Scale) to accurately and efficiently measure behavior and cognition in the population.
- The scale has been approved for use by regulators, is under review for academic publication, and is currently a key outcome measure in multiple Fragile X trials.
- The novel methodological approach we used to develop this modified rating scale is highly relevant to rare disease trials as a whole and is being employed as a model approach for additional indications and scales.

An overhead view of five people sitting around a white circular table in a meeting or study session. They are surrounded by laptops, open books, papers, and sticky notes. The scene is set on a grey concrete floor. A decorative graphic with blue and purple geometric shapes is in the bottom-left corner.

# FY18 Results

# Financial Analysis

All results presented in US\$

- Clinical Trials sales contracts \$36.1m, up 22%
- Revenue \$28.96m, up 10%
- Maintenance of margins within the Clinical Trials division
- Adjusted EBITDA from continuing operations \$3.56m (FY17 \$1.76m)
- Profit before tax from continuing operations \$1.96m (FY17 \$0.27m)
- Investment in Cognigram will significantly decrease in FY19 as a result of the restructure implemented

	Full Year Ended	
	30-Jun-17	30-Jun-18
<b>Revenue from operations</b>	<b>26,404,953</b>	<b>28,956,884</b>
<b>Clinical Trials</b>		
Revenue	26,187,137	28,080,187
<b>Clinical Trials EBITDA</b>	<b>14,861,048</b>	<b>15,905,193</b>
	56.7%	56.6%
<b>R&amp;D (incl. academic research studies, normative data studies and new technology validation)</b>		
<b>R&amp;D EBITDA</b>	<b>(568,061)</b>	<b>(326,981)</b>
Total Other Expenditure (Net)	(12,529,553)	(12,014,677)
<b>Adjusted EBITDA from continuing operations, excluding shre based compensation</b>	<b>1,763,434</b>	<b>3,563,535</b>
Share based payments (expense of employee options)	(721,724)	(953,003)
Depreciation and Amorization	(771,593)	(651,718)
<b>Profit before tax from continuing operations</b>	<b>270,117</b>	<b>1,958,814</b>
<b>Investment in Cognigram (start-up)</b>		
<b>Cognigram EBIT</b>	<b>(931,562)</b>	<b>(1,852,597)</b>
<b>Net Profit / (Loss) before tax</b>	<b>(661,445)</b>	<b>106,217</b>

# Restructure

All results presented in US\$

- Annualised staff costs in excess of \$5m removed from the business through restructure implemented from April 2018 – July 2018
  - These costs accounted for \$3.46m of costs of sales and operating costs in FY18
- In total, 30 roles removed from the business
  - 17% of total staff headcount
- Significant strategy change in respect of Cognigram
  - Seeking distribution and licensing arrangements rather than direct selling
  - Immediate impact is to significantly reduce expenditure
  - Continue to support existing and new customers
  - Will continue to seek revenue growth, but through alternative distribution model
- Full impact of savings realised in 2<sup>nd</sup> half of FY19
  - Approx \$2m of non-recurring costs (salaries, severance payments and other close-out costs) will be incurred in the July – December 2018 half year
  - Non-recurring costs removed completely from January – June 2019 half year



# FY19 Guidance

All results presented in US\$

- Contracted revenue position is consistent with the prior year
  - Even after taking into account recent contract cancellations due to failure of two potential Alzheimer's disease therapies
- Sales growth prospects are good, but even at flat sales, profit is projected to increase due to restructure and associated cost reduction
- Specific guidance:
  - As a result of restructure, approx \$2m of non-recurring costs will be incurred in 1H19
  - 1H19 expecting to record a loss overall, inclusive of non-recurring costs
    - 1H19 profit if non-recurring costs are excluded
  - Much improved profitability in 2H19
    - Forecast revenue growth from 1H19 to 2H19
    - Full benefit of cost reduction measures delivered in 2H19
- Guiding for profit growth for FY19 year, inclusive of non-recurring costs



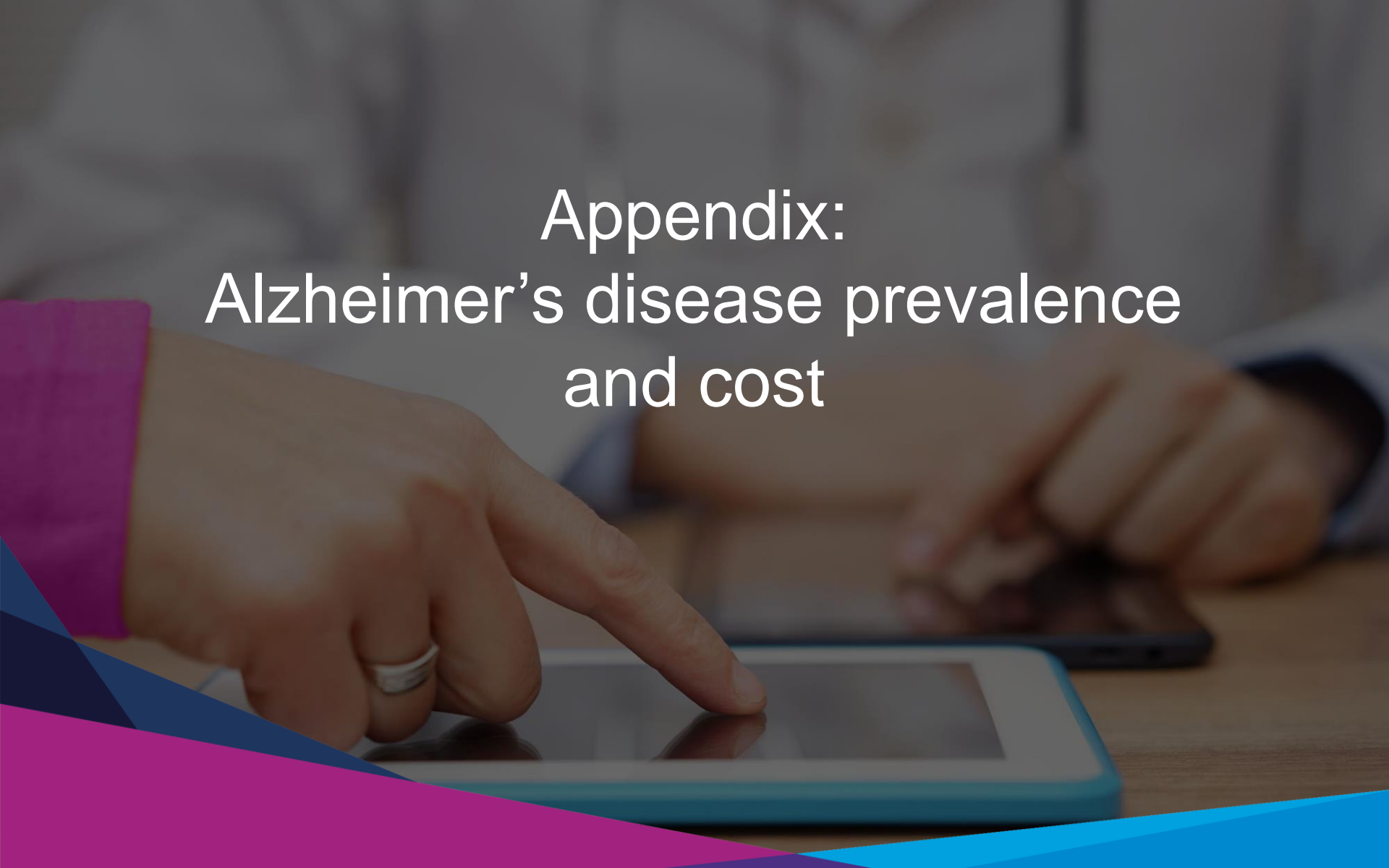
Cogstate

# Financial Analysis

All results presented in US\$

Data from Slide 31, presented in expanded form

	Full Year Ended	
	30-Jun-17	30-Jun-18
<b>Revenue from operations</b>	<b>26,404,953</b>	<b>28,956,884</b>
<b>Clinical Trials</b>		
Revenue	26,187,137	28,080,187
Cost of sales (excluding dep'n)	(8,191,704)	(8,548,455)
<b>Gross Margin</b>	<b>17,995,433</b>	<b>19,531,732</b>
Selling, General & Admin costs	(3,171,244)	(3,626,539)
Pass-through costs, net of recovery	36,859	0
<b>Clinical Trials EBITDA</b>	<b>14,861,048</b>	<b>15,905,193</b>
	56.7%	56.6%
<b>R&amp;D (incl. academic research studies, normative data studies and new technology validation)</b>		
Revenue	12,771	491,768
Cost of sales	(68,407)	(30,447)
Other operating expenditure - Salaries & Wages	(512,425)	(788,302)
<b>R&amp;D EBITDA</b>	<b>(568,061)</b>	<b>(326,981)</b>
Product Development & Quality Assurance Expense	(4,133,870)	(1,632,705)
IT Infrastructure	(1,184,634)	(1,662,058)
Office & Facilities	(814,449)	(1,144,918)
Other operating expenditure	(6,082,420)	(7,553,069)
Other Income	0	0
Interest Income / Expense	56,154	38,796
Net foreign exchange losses	(370,334)	(60,723)
Total Other Expenditure (Net)	(12,529,553)	(12,014,677)
<b>Adjusted EBITDA from continuing operations, excluding shre based compensation</b>	<b>1,763,434</b>	<b>3,563,535</b>
Share based payments (expense of employee options)	(721,724)	(953,003)
Depreciation and Amorization	(771,593)	(651,718)
<b>Profit before tax from continuing operations</b>	<b>270,117</b>	<b>1,958,814</b>
<b>Investment in Cognigram (start-up)</b>		
Revenue	205,045	384,929
Cost of sales	(844,605)	(494,608)
Other operating expenditure	(292,002)	(1,742,918)
<b>Cognigram EBIT</b>	<b>(931,562)</b>	<b>(1,852,597)</b>
<b>Net Profit / (Loss) before tax</b>	<b>(661,445)</b>	<b>106,217</b>



Appendix:  
Alzheimer's disease prevalence  
and cost

# Increasing prevalence

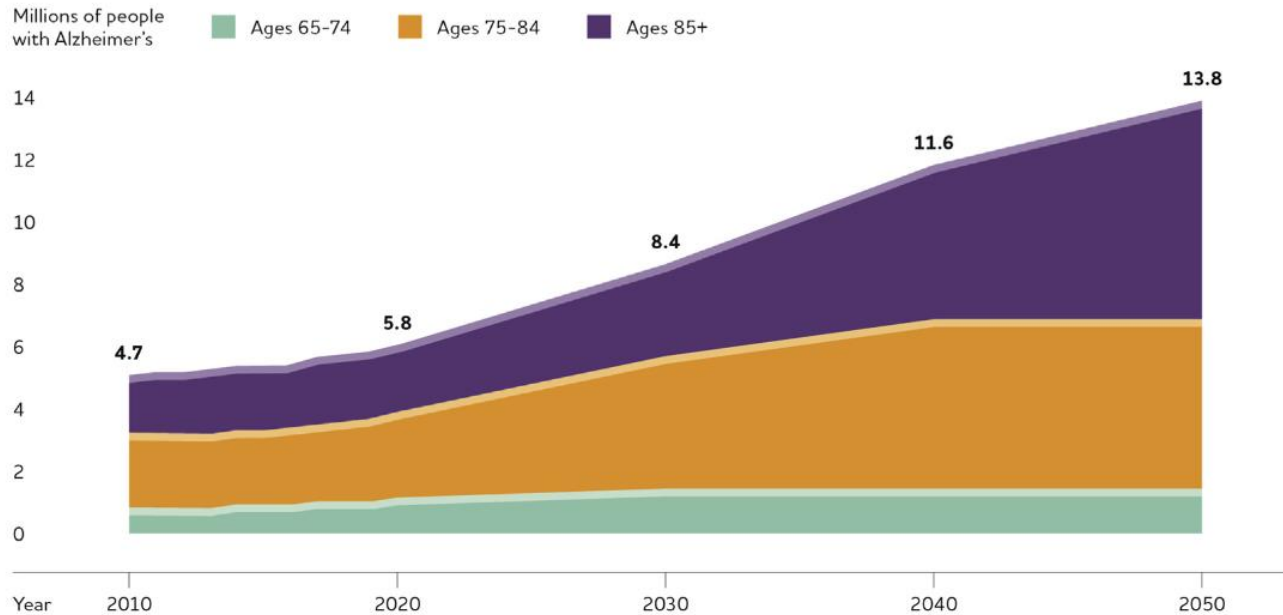


Fig. 4. Projected number of people age 65 and older (total and by age) in the U.S. population with Alzheimer's dementia, 2010 to 2050. Created from data from Hebert and colleagues [30].<sup>A11</sup>

# Increasing mortality

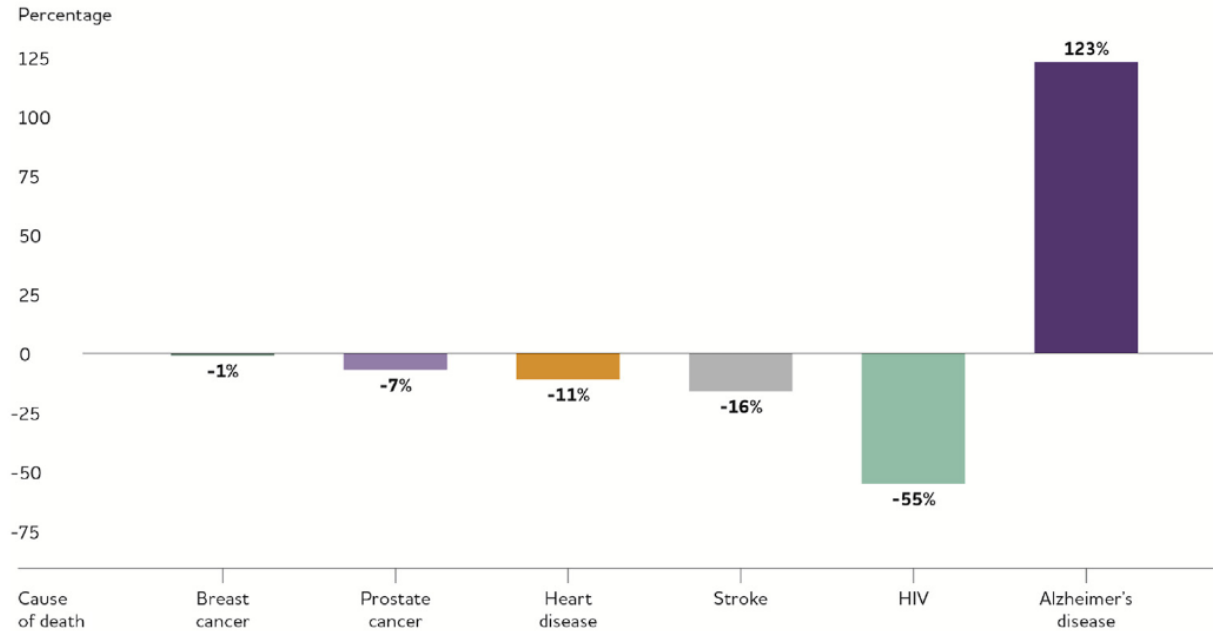


Fig. 5. Percentage changes in selected causes of death (all ages) between 2000 and 2015. Created from data from the National Center for Health Statistics [232,243].

# Substantial caregiver impact

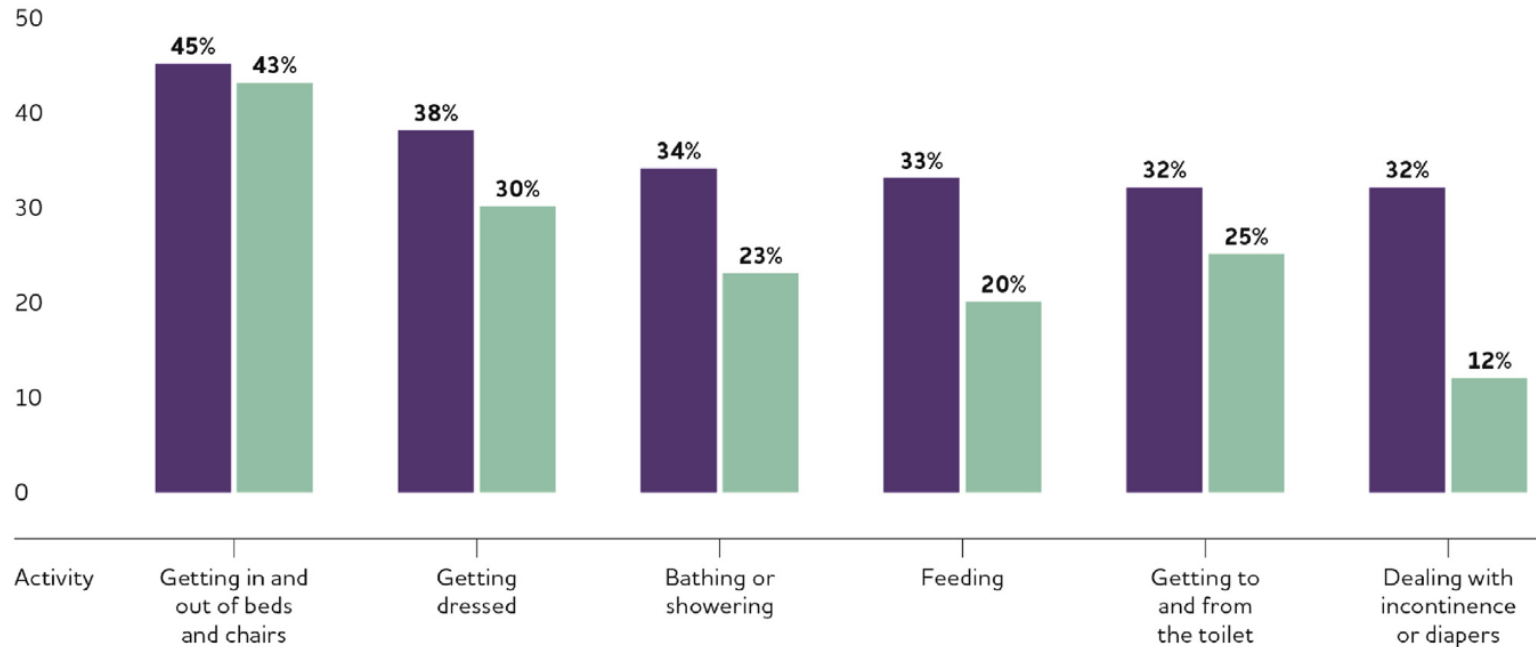


Fig. 7. Proportion of caregivers of people with Alzheimer's or other dementias versus caregivers of other older people who provide help with specific activities of daily living, United States, 2015. Created from data from National Alliance for Caregiving and AARP [268].

# Substantial societal impact

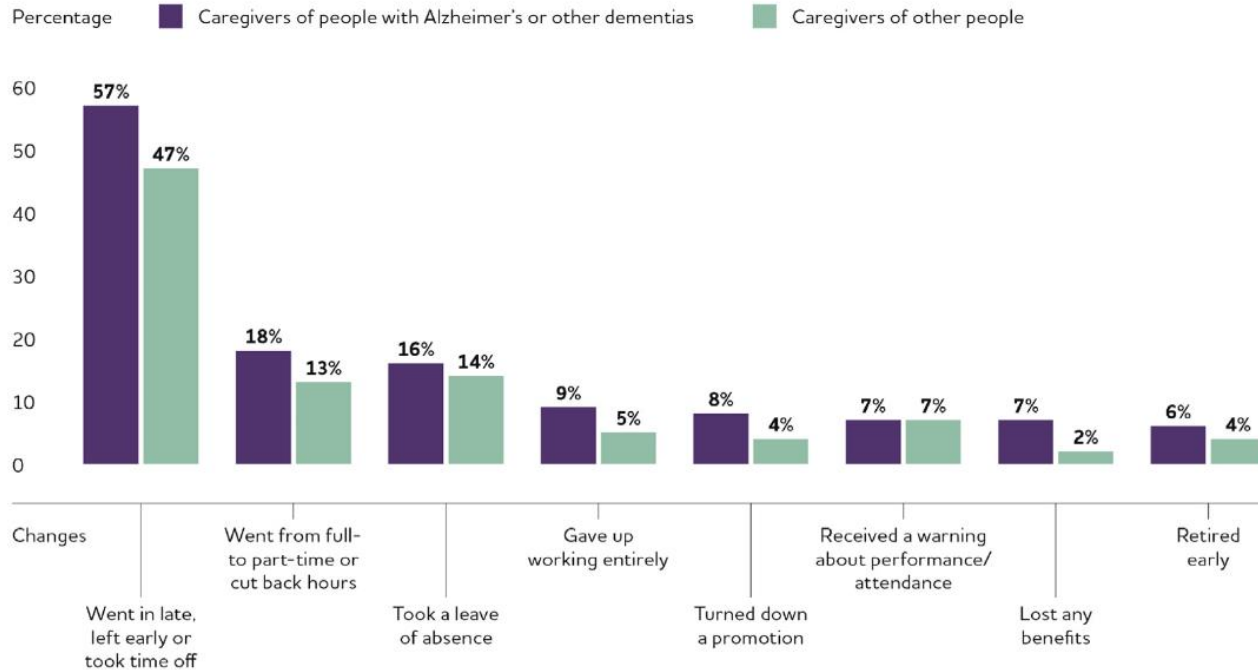


Fig. 9. Work-related changes among caregivers of people with Alzheimer's or other dementias who had been employed at any time since they began caregiving. Created from data from the National Alliance for Caregiving and AARP [268].



# Huge cost to healthcare systems

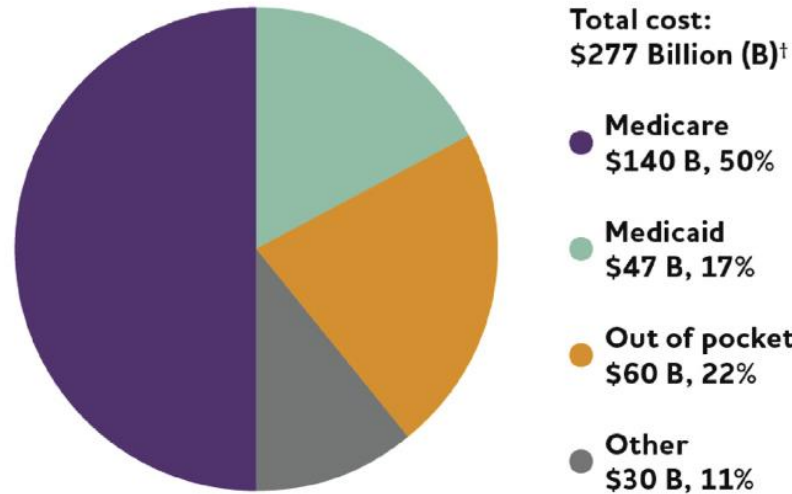


Fig. 10. Distribution of aggregate costs of care by payment source for Americans age 65 and older with Alzheimer's or other dementias, 2018. Data are in 2018 dollars. Before rounding, Medicare and Medicaid payments combined total \$186 billion, and out-of-pocket and other expenses combined total \$91 billion. "Other" payment sources include private insurance, health maintenance organizations, other managed care organizations and uncompensated care. Created from data from the Lewin Model.<sup>A19</sup>