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Cogstate (CGS)

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Speculative Investment

Recommendation: Outperform

ERT partnership plus Cognigram blue sky

Our View

Cogstate is well positioned for continued revenue growth in FY21, supported by a record contract book of $39.4m at the start of the financial year. The recently signed preferred partnership with ERT should allow Cogstate to further broaden the market penetration of its core clinical trial cognition assessment business, particularly in assessment of cognition as a safety endpoint. The FDA approval decision on Biogen/Eisai's Alzheimer's drug aducanumab is due by March 2021; we see potential for a deal which would enable Biogen to use Costate technology as a screening tool to improve the detection and diagnosis of Alzheimer's, as part of its marketing preparations. We increase forecast growth in Clinical Trial contract sales by 5% p.a. to reflect the ERT opportunity, which increases our valuation, excluding the Cognigram opportunity, to A$0.93/sh (vs A$0.76/sh) or A$0.92/sh fully diluted. Our scenario analysis indicates that if a disease modifying Alzheimer's drug such as Biogen/Eisai's aducanumab is approved, the Cognigram opportunity could plausibly be worth A$1.07/sh. Our risk-weighted valuation of the Cognigram opportunity is A$0.32/sh.

Key Points

ERT partnership opens a new sales channel. Cogstate's preferred partnership with ERT, a global leader in clinical trial data management, provides an additional distribution channel which should further increase uptake of Cogstate computerised cognitive assessments in clinical trials. ERT will provide access to trials that the Cogstate business development team would not normally encounter, particularly in indications such as oncology where cognition is assessed as a safety endpoint. We estimate that the sales opportunity for cognition as a safety endpoint that Cogstate will be able to access via the ERT partnership could be worth in the range of US$20-40m, ie similar to its current annual contract sales. We will watch closely to see whether the preferred partnership can deliver on this opportunity.

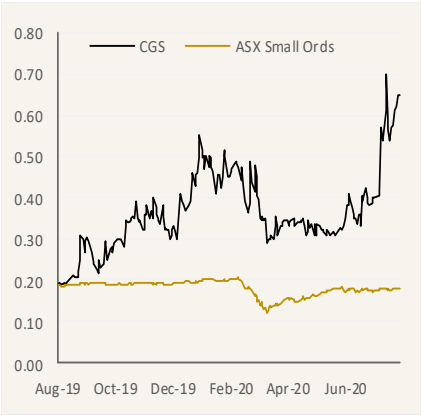
The clock is ticking on Biogen's Alzheimer's marketing preparations. Biogen/Eisai's Alzheimer's drug aducanumab was recently granted a Priority Review by the US FDA, with an approval decision due by 7 March 2021. With less than 7 months until the FDA approval decision, we expect Biogen to accelerate its preparations for a potential US launch of aducanumab. We expect these preparations to include strategies to improve the awareness and diagnosis of early Alzheimer's and see a high probability for a deal to give Biogen access to Cogstate technology for this purpose. Cogstate's Cognigram tool is easy to use and can be administered either in-clinic or at home, while also showing greater sensitivity to cognitive change in early Alzheimer's disease than other widely used assessment tools, which makes it ideal for identifying patients with mild early stage Alzheimer's disease and who might benefit from treatment with aducanumab (if approved). Biogen's partner Eisai has already entered an exclusive licence for Cognigram in the Japanese market.

Our conservative FY21 forecasts leave room to upgrade. Globally, clinical trial recruitment rates recovered strongly in June, although they remained 30% below pre-pandemic levels. Reflecting this recovery, Cogstate reported strong interest in Clinical Trial proposals in July. Despite this recovery in interest, we continue to apply a 10% discount to modelled FY21 revenue in deriving our forecasts, in order to allow for the uncertainty around the future course of the covid-19 pandemic. Separately, we assume that the US$2.4m loan under the US Payroll Protection Program will need to be repaid in FY21, although there seems to be a high chance that the loan will be forgiven. If either of these assumptions is too conservative, Cogstate could return to profitability in FY21.

Summary (AUD)

Market Capitalisation	**$111M**
Share price	**$0.65**
52 week low	$0.19
52 week high	$0.80
Cash at 30 June 2020	approx. A$15M

Share price graph (AUD)



Key Financials (USD)

	FY19A	FY20F	FY21F
Revenue	22.1	23.6	25.2
COGS	(12.0)	(11.3)	(12.3)
SG&A	(13.6)	(13.1)	(12.7)
EBITDA	(2.3)	(0.8)	0.1
Reported NPAT	(2.5)	(2.6)	0.8
NPAT Adj.	(1.3)	(2.6)	(1.6)
EPS Adj. (c)	(2.1)	(1.6)	(1.0)
PE ratio (x)	n/a	n/a	n/a
DPS (c)	0.0	0.0	0.0
EV/Sales	n/a	n/a	n/a
EV/EBITDA (x)	n/a	n/a	n/a
ROE	n/a	n/a	n/a

Cogstate - Summary of Forecasts — CGS $ 0.65

PROFIT & LOSS SUMMARY (US$m)

Year end June	FY19A	FY20F	FY21F	FY22F
Sales revenue	21.8	23.6	25.2	33.4
Other	0.3	0.0	0.0	0.0
Total Revenue	**22.1**	**23.6**	**25.2**	**33.4**
Growth (pcp)	-23.7%	6.8%	6.6%	32.5%
Cost of sales	(12.0)	(11.3)	(12.3)	(14.1)
SG&A expenses	(13.6)	(13.1)	(12.7)	(13.1)
EBITDA	**(2.3)**	**(0.8)**	**0.1**	**6.2**
Dep'n/Other Amort'n	(0.2)	(1.8)	(1.8)	(1.9)
EBIT	(2.5)	(2.6)	(1.7)	4.3
Net Interest	(0.1)	0.0	0.1	0.1
Pre-Tax Profit Adj.	(2.7)	(2.6)	(1.6)	4.4
Tax Expense	1.4	0.0	0.0	0.0
Minorities	0.0	0.0	0.0	0.0
NPAT Adj.	**(1.3)**	**(2.6)**	**(1.6)**	**4.4**
Growth (pcp)	n/a	n/a	n/a	n/a
Adjustments	(1.2)	0.0	2.4	0.0
NPAT Reported	(2.5)	(2.6)	0.8	4.4

PER SHARE DATA

Year end June	FY19A	FY20F	FY21F	FY22F
EPS (c) - Reported	**(2.1)**	**(1.6)**	**0.5**	**2.6**
Growth (pcp)	n/a	n/a	n/a	458%
EPS (c) - Adjusted	(1.1)	(1.6)	(1.0)	2.6
Growth (pcp)	n/a	n/a	n/a	n/a
Dividend (c)	0.0	0.0	0.0	0.0
Franking	0.0	0.0	0.0	0.0
Gross CF per share (c)	0.4	(0.2)	(1.2)	3.8
NTA per share (c)	4.3	5.8	6.3	8.9

KEY RATIOS

Year end June	FY19A	FY20F	FY21F	FY22F
Net Debt : Equity (%)	-26.8%	-49.9%	-27.2%	-47.3%
Net Debt: EBITDA (x)	1.2	8.7	(36.4)	(1.5)
Current ratio (x)	1.1	1.8	1.8	2.2
ROE (%)	-22.9%	-21.0%	5.2%	24.6%
ROIC (%)	n/a	n/a	n/a	n/a
Dividend Payout Ratio (%)	n/a	n/a	n/a	n/a

VALUATION MULTIPLES

Year end June	FY19A	FY20F	FY21F	FY22F
PE Ratio (x)	**n/a**	**n/a**	**139.8**	**25.0**
Dividend Yield (%)	**0.0%**	**0.0%**	**0.0%**	**0.0%**
EV/Sales (x)	n/a	n/a	n/a	n/a
EV/EBITDA (x)	n/a	n/a	n/a	n/a
EV/EBIT (x)	n/a	n/a	n/a	n/a

BALANCE SHEET SUMMARY

Year end June	FY19A	FY20F	FY21F	FY22F
Cash	3.2	10.3	7.2	12.4
Receivables	4.3	4.2	4.5	6.0
Inventories	0.0	0.0	0.0	0.0
Other	1.8	1.8	1.8	1.8
Total Current Assets	9.3	16.4	13.5	20.2
Inventories	0.0	0.0	0.0	0.0
Property Plant & Equip	1.3	1.3	0.7	0.0
Intangibles	4.9	4.9	4.9	4.9
Other	3.7	3.7	3.7	3.7
Total Non-Current Assets	10.0	10.0	9.3	8.7
TOTAL ASSETS	**19.2**	**26.3**	**22.8**	**28.8**
Accounts Payable	6.5	6.9	5.0	6.7
Borrowings	0.5	0.5	0.5	0.5
Provisions	1.8	1.8	1.8	1.8
Other	0.0	0.0	0.0	0.0
Total Current Liab	8.8	9.2	7.3	9.0
Borrowings	0.0	2.4	2.4	2.4
Provisions	0.0	0.0	0.0	0.0
Other	0.4	5.3	5.3	5.3
Total Non-Current Liab	0.3	2.8	2.8	2.8
TOTAL LIABILITIES	**9.1**	**12.0**	**10.1**	**11.8**
TOTAL EQUITY	**10.1**	**14.3**	**12.7**	**17.1**

CASH FLOW SUMMARY

Year end June	FY19A	FY20F	FY21F	FY22F
EBIT (excl Abs/Extr)	**(2.5)**	**(2.6)**	**(1.7)**	**4.3**
Add: Dep'n & Amort'n	0.2	1.8	1.8	1.9
Other non-cash items	(5.2)	(4.2)	(1.4)	(2.6)
Less: Tax paid	0.0	0.0	0.0	0.0
Net Interest	0.1	0.0	0.1	0.1
Change in Rec.	2.1	0.0	(0.3)	(1.5)
Change in Inv.	0.0	0.0	0.0	0.0
Gross Cashflows	0.4	(0.4)	(1.9)	6.4
Capex	(2.4)	(1.8)	(1.2)	(1.2)
Free Cashflows	(0.1)	(0.8)	(3.1)	5.2
Share Issue Proceeds	0.9	7.3	0.0	0.0
Other	(1.9)	0.6	0.0	0.0
Dividends Paid	0.0	0.0	0.0	0.0
Net Cashflows	**(1.2)**	**7.1**	**(3.1)**	**5.2**
FX Effect on Cash	0.0	0.0	0.0	0.0

ERT adds another dimension to Clinical Trials opportunity

Cogstate announced on 23 July that it has entered into a preferred partnership with ERT, which is a global leader in clinical endpoint data collection. Cogstate's computerised cognitive assessments will be deployed in clinical trials on ERT's electronic Clinical Outcome Assessment (eCOA) technology platform.

ERT is a major player in data collection and management for clinical trials, with 75% of all FDA drug approvals in 2019 coming from studies supported by ERT. It has 1,930 employees and generated EUR500m of revenue in 2019. The private equity investor Nordic Capital acquired 70% of ERT in 2016 for an enterprise value of US$1.8bn.

Cogstate's partnership with ERG provides an additional distribution channel which should further increase uptake of Cogstate's computerised cognitive assessments in clinical trials, particularly in trials where cognition is assessed as a safety endpoint (ie where there is a concern that the drug might have a negative impact on cognition). ERT will provide access to trials that the Cogstate business development team would not normally encounter. For example, ERT has a strong presence in oncology trials, which will enable it to bring to Cogstate opportunities to assess cognition as a safety endpoint in these studies. The Cogstate business development team will then work up a proposal and pricing to bid for the cognition assessment work, which ERT will include in its overall proposal to the potential client. Cogstate does not pay any margin away to ERT, although there is nothing to stop ERT imposing an additional margin on top of the price that Cogstate nominates.

In turn, ERT gains increased access to central nervous system trials, where Cogstate has a strong market presence.

The Cogstate cognitive assessment tools have already been integrated into the ERT eCOA technology platform and are currently available to be deployed at clinical trial sites. Validation studies have been run to ensure that the system functions as intended.

One of the advantages for the customer from integration of the Cogstate technology into the ERT platform is that no additional devices or technology are needed. There is a single management system, a single device and log-in and a single point of contact. The integrated system supports in-clinic or remote assessments with automated, error-free reporting of results.

Cogstate and ERT have compared the deployment of the integrated system to the deployment of standard cognitive assessments. They found that the ERT + Cogstate technology results in a:

- 33% reduction in start-up timelines
- 66% reduction in test administration time
- 98% reduction in administration, recording and scoring errors
- 50% reduction in placebo response rate.

Putting the ERT opportunity in context

We believe that the biggest benefit to Cogstate from the ERT collaboration will be the opportunity to substantially increase its penetration into the measurement of cognition as a safety endpoint in clinical trials.

To put this in context, we note that Cogstate has been successful in recent years in increasing its penetration into clinical trials for paediatric and rare diseases, to the point where this area represents 20-25% of new clinical trials contracts by value. Management indicated that about 70% of the rare diseases work is assessing cognition as a safety endpoint; which would equate to ~15% of annual contract revenue or US$6-7m per year.

Oncology accounts for 32% of clinical trials recorded by the World Health Organisation (WHO), over three times more than the next most common fields, which were diabetes (9%) and cardiovascular disease (8%). Studies categorised as mental health or mental disorders accounted for 3.2% and 2.5% of trials registered, respectively.

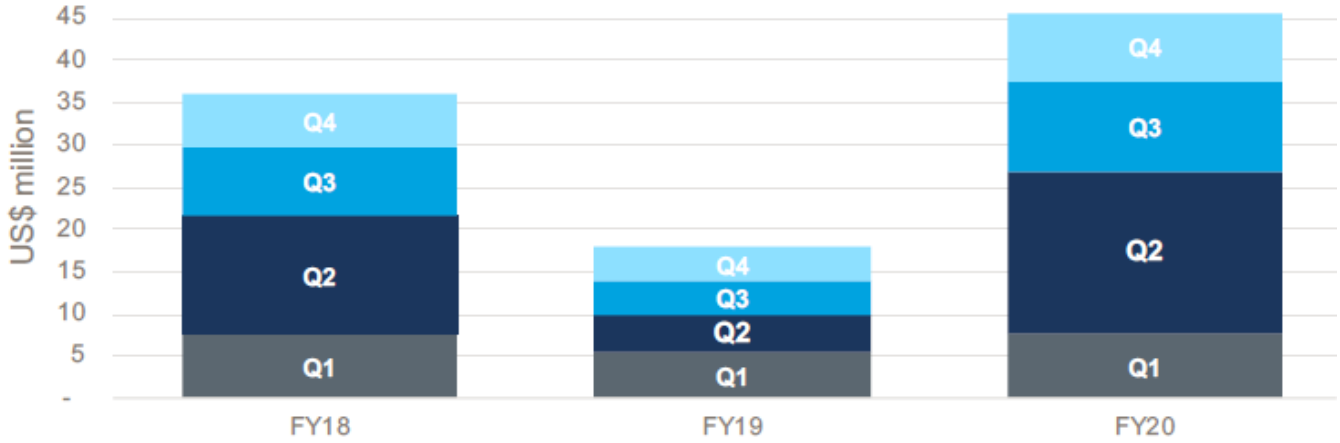
While the WHO does not list any categories that would equate to paediatric and rare diseases, we expect that the number of trials would be several fold lower than the number of oncology clinical trials. Therefore, we assume that the sales opportunity for cognition as a safety endpoint that Cogstate will be able to access via the ERT partnership will be several fold higher that the US$6-7m that it is currently achieving for this indication in paediatric and rare diseases, perhaps in the range of US$20-40m. We will watch closely to see whether the preferred partnership can deliver on this opportunity.

The collaboration could see some services such as data management transition from Cogstate to ERT. This work is not high margin and the transfer would allow Cogstate to focus on higher margin business, such as software licence fees.

Record contract book underpins FY21 revenue growth

Cogstate reported record Clinical Trials contract sales of US$46.0m for the full FY20 financial year, compared to US$17.9m in FY19 and the previous record of US$36.1m in FY18. Exhibit 1 shows the quarterly Clinical Trials new contract sales for the past 3 years. Record sales were reported in the December, March and June quarters of FY20.

Exhibit 1: Clinical Trial sales contracts executed

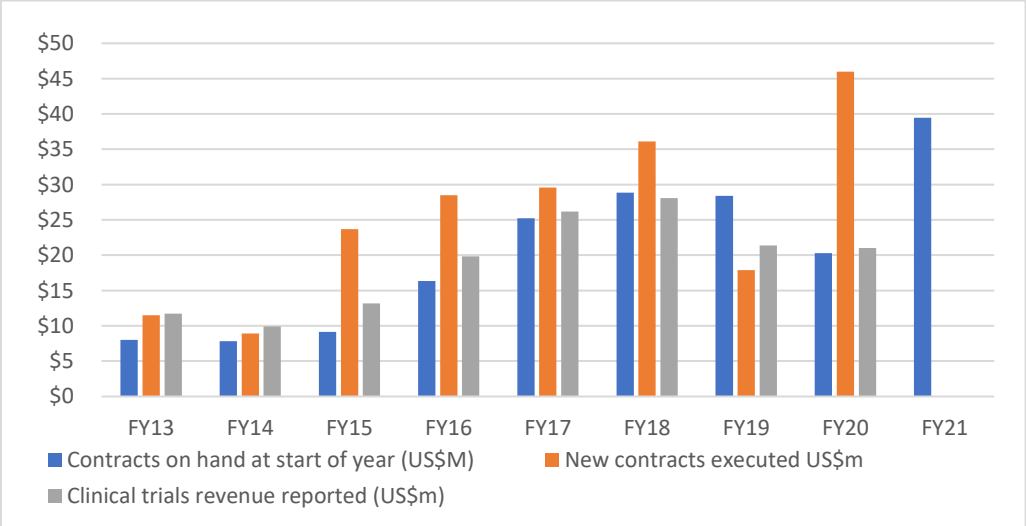


Source: Cogstate.

The record new contract sales in FY20 has lifted the contracted future revenue (backlog) to US$39.4m at 30 June 2020, vs US$20m at the start of FY20 (Exhibit 2). This is the highest level that the contract book has ever been at the start of a financial year.

Despite the record new contract sales in FY20, the low contract back log at the start of the year meant that the Clinical Trials revenue booked was 2% below the previous year (US$21.0m vs US$21.4m in FY19). Total revenue, including the Healthcare and Research segments, rose 8% to US$23.6m.

Exhibit 2: Contract backlog, sales and revenue



Source: Cogstate, Taylor Collison analysis. Note: data for FY13-FY16 converted from A$ to US$ at prevailing exchange rates. Cogstate changed its reporting currency from A$ to US$ in FY18.

We expect the record contract backlog to underpin a return to revenue growth in FY21. Exhibit 3 shows that Cogstate expects to book US$15.35m of revenue in FY21 from the US$39.4m of contracts in place at the start of the financial year, as the contracted services are delivered and invoiced. This compares with guidance for US$10.83m of revenue to be derived from the contract book in FY20.

Exhibit 3: Expected run-off of contracted clinical trials revenue and historical comparison

Source: Cogstate.

We leave our forecast that New Clinical Trials contract sales will be US$36.1m in FY21 unchanged; this represents a 22% decline on the record sales achieved in FY20. We have increased our forecast for the growth rate in new contract sales in FY22 to FY25 from 5% to 10%, to reflect the potential benefit of the new preferred partner status with ERT.

Impact of Covid-19 on clinical trial activity appears to be diminishing

The covid-19 pandemic has had a dramatic impact on global clinical trial activity, but the impact appears to be diminishing. The clinical trial technology company Medidata reported that the number of new subjects entering clinical trials fell to a low point of 70% below normal levels in April, but has since rebounded to be 30% below normal levels in June.

The impact of the pandemic on Cogstate's new contract sales appears to be following a similar trajectory, with a sharp downturn from March to mid-June. While new contract sales of US$8.4m in 4Q20 were a record for the June quarter, over US$5.4m of the US$8.4m sales were recorded in the first two weeks of the quarter. Over the remainder of the June quarter Cogstate executed less than US$0.5m of contracts for new trials, but approximately US$2.5-3.0m for increased services for ongoing trials to facilitate virtual patient visits and remote cognitive assessments.

Management commented on the investor webinar on 24 July, that while the business development team did not see a lot of activity until mid-June, July has been a busy month. At that stage Cogstate had submitted 14 proposals for Clinical Trial services and expected to submit at total of 28 proposals by the end of the month. This is almost double the 15 proposals that were submitted in July 2019.

While the large number of proposals probably represents a catch up from the lack of activity in June quarter, it is an encouraging sign that Pharma companies are continuing with planning and contracting for new clinical trials, despite the disruptions due to the pandemic.

While new contract sales saw a dramatic decline from mid-March to mid-June, there has been much less impact on service delivery. The main impact has been to delay the initiation of new studies, with assessments of subjects already on study largely continuing according to plan. Academic hospitals have been more impacted than for-profit clinical trials centres.

Eisai collaboration shows progress for Healthcare segment partnership model

The company's decision to pursue a partnership model for the commercialisation of Cognigram began to bear fruit in FY20. In August 2019 Cogstate entered into an exclusive license agreement with Eisai (Tokyo, Japan) to market Cogstate technology as a digital cognitive assessment tool in Japanese markets. Eisai provided a US$1m upfront royalty payment and invested ~A$2.9m in Cogstate equity. Eisai funded development costs to adapt the Cogstate Brief Battery (which underlies Cognigram) for the Japanese market and is also funding launch costs. The two parties will share profits equally after taking into account Eisai's development and launch costs and the cost of sales for the product in Japan.

Eisai launched NouKNOW™, a new brain health digital self-assessment tool based on the Cogstate Brief Battery, on 31 March. NouKNOW, which is conducted via a PC or tablet device, is not considered to be a medical device, and the initial launch is targeting sales to corporations and municipalities. Eisai is also investigating the possibility of developing the Cogstate Brief Battery for medical device use in Japan.

Eisai announced on 28 July that it is working towards the launch of an app-based version of NouKNOW in Japan by the end of September, in order to expand access into the broader population. The app is being developed in conjunction with DeNA Co., Ltd and Eisai is covering the cost of development.

We view the announcement as further validation for Cogstate's strategy of out-licensing its technology for Healthcare applications. Although the contribution of the Healthcare segment to revenue is currently modest, it is making a positive contribution to earnings. Revenue in the Healthcare segment totalled US$2.4m in FY20, comprising the US$1.0m upfront payment plus reimbursement by Eisai of development costs incurred by Cogstate that relate to the joint venture.

Aducanumab filing creates a big opportunity for Healthcare business

The US Biotech Biogen (NAS.BIIB) announced on 7 August that the FDA has granted a six-month Priority Review for it's Alzheimer's drug aducanumab, with a PDUFA date of 7 March 2021. This means that the FDA decision on whether or not to approve aducanumab is due by 7 March 2021. Under a Standard Review timetable the FDA decision would not have been due until July 2021.

The announcement has positive implications for Cogstate, because Biogen now has less than seven months to prepare for a potential launch of aducanumab.

Biogen is collaborating with Eisai for the global development of aducanumab, but Biogen is responsible for marketing the drug in the US. We expect Biogen to be examining ways to increase the diagnosis rate of patients who are at the early stages of developing Alzheimer's disease. Given that its partner Eisai has already identified Cogstate's Cognigram as the best available technology for screening for cognitive impairment, we see a high probably that Cogstate will enter into a deal of some kind with Biogen to use Costate technology as a screening tool to identify patients with early signs of Alzheimer's disease, who might be candidates for treatment with aducanumab (if approved).

While the announcement of a deal with Biogen would be a positive, the real value for Cogstate depends on aducanumab gaining FDA approval. We assume a modest 30% chance that aducanumab will be granted FDA approval because only one of two Phase III studies met the primary endpoint of demonstrating a statistically significant benefit in Alzheimer's disease patients (the FDA typically requires two positive Phase III studies). However, the lobbying power of Alzheimer's disease patient advocacy groups could play a role in tipping the balance in favour of approval, particularly as the FDA plans to hold an Advisory Committee meeting of clinicians who would be asked to vote for or against recommending approval.

We see two key areas where Cogstate technology could play a role in facilitating uptake of an Alzheimer's disease therapy.

The first area could be referred to as "filling the funnel", the identification of community dwelling people who are suffering from cognitive decline, who would be encouraged to raise the issue with their doctor. Smartphone based assessments such those that Eisai is currently developing could fulfil this role.

The second application could be providing an easy to use tool to assist primary care physicians, who may not be highly trained at assessing mild cognitive impairment. A computerised Cognigram assessment would simplify testing of cognition and provide clear reporting of outcomes. This could aid primary care physicians in triaging or prioritising which patients were referred to specialists for confirmation of Alzheimer's disease and possible initiation of therapy with aducanumab or other disease modifying Alzheimer's drug.

In a scenario analysis which assumes that aducanumab is approved and Biogen adopts Cogstate technology as a screening tool, we estimate that the Alzheimer's disease screening opportunity to be worth over $1.00 per share to Cogstate.

Could an Alzheimer's blood test impact the future population screening opportunity?

The results of 2 studies presented at the Alzheimer's Association International Conference (AAIC) 2020 revealed that blood tests that measured the levels of p-tau217 protein could distinguish Alzheimer disease (AD) from other neurodegenerative disorders as accurately as other established diagnostic methods, such as a spinal tap or a brain amyloid positron emission tomography (PET) scan. Blood p-tau217 level was also closely linked to build up of amyloid plaques in the brain as measured by PET scan. The full details of the studies have not yet been published.

While the performance of this test needs to be verified and confirmed in subsequent studies, the results open up the possibility that a blood test could be developed for the early diagnosis of Alzheimer's disease. It is important to note that even if the accuracy of the blood test can be confirmed, any potential commercial launch of a blood test would be several years away.

We do not believe that there is any risk that a blood test could replace the need for cognitive tests such as Cognigram, because identifying patients who could benefit from treatment with a disease-modifying Alzheimer's disease drug would require demonstrating both cognitive impairment and the presence of AD biomarkers, as part of the diagnostic process. However, we can envisage some circumstances where a blood test could compete with Cognigram for market share.

Depending on its accuracy and cost, an Alzheimer's disease blood test could be seen as an alternative to Cognigram for initial screening by a primary care physician that was conducted either in response to patient concerns about cognition or as part of a general health check in older patients. In this setting each test would have advantages and disadvantages. The advantage of a blood test is that it can be included among the other blood tests that are performed as part of a general health check-up, so it may be more convenient for the doctor. The disadvantage is that it would take several days to get result. On the other hand, while Cognigram testing takes about 15 minutes to complete, it can be supervised by the practice nurse and the results are available immediately.

We think that it is unlikely that a blood test would compete with use of a smartphone based cognitive assessment tool in the general community for early assessment of cognitive changes (filling the funnel).

Regardless of the order in which testing is done, cognition would need to be assessed as part of the diagnostic workup of a patient with suspected Alzheimer's disease.

Our thesis that Cogstate could achieve a 10% uptake for screening patients of early signs of Alzheimer's for a modest fee would still hold even if there was an approved blood test to screen for Alzheimer's disease, in our view. While we do not believe that the progress on developing blood tests for Alzheimer's will have any impact on the near-term opportunity for Cogstate, it is an area that is worth watching as it could have implications for the screening opportunity in the Healthcare space over the long term.

In the near term a blood test for Alzheimer's could even be a positive for Cogstate, by making Alzheimer's disease clinical trials cheaper to run. By filtering out subjects who are unlikely to have brain amyloid plaques, a blood test could reduce the number of candidates undergoing expensive PET scans for amyloid plaque in the brain during the recruitment process. This would reduce the cost of recruitment and therefore may increase the number of Alzheimer's clinical trials that pharma companies choose to conduct.

Valuation

Our base case valuation of Cogstate, which is based on a discounted cash flow model, excludes the Cognigram (Healthcare) business unit, which we evaluate in a separate scenario analysis.

We have adjusted the contract book at the start of FY21 to US$39.4m in line with the reported value, and have lowered the proportion of the contract backlog that exists at the start of each half-year that is reported as revenue during that half year period from 27% to 22%, to ensure that our forecasts match the guidance for revenue run off in FY21 that was given in the quarterly report. We assume the run-off will increase to 23% per half year in subsequent years. Our assumption that 25% of the value of each contract is reported as revenue in the half year that the contract is signed is unchanged.

We continue to assume that contract sales in FY21 will be US$36m, in line with sales reported in FY18, but have increased our forecast for the rate of growth in new contracts signed for the years FY22 to FY25 from 5% to 10% to reflect the potential increase in sales through the ERT channel. We have amended our long-term exchange rate to US$0.70/A$ (from US$0.65/A$). Our other assumptions as detailed in our initiation report dated 2 April are unchanged.

Our valuation has increased to A$158m or A$0.93 per share (from A$129m or A$0.76 per share) on an undiluted basis and A$0.92/share (from (A$0.75/share) after diluting for the 8.3m options on issue.

We have based our cashflow forecasts on the earnings assumptions outlined in the table above and have extended the cashflow forecasts out to 2025. We have also included a terminal value with a 3% terminal growth rate and apply a 10% discount rate.

The table below summarises our cash flow model and DCF valuation (excluding the Healthcare/Cognigram business unit).

Exhibit 4: Cogstate base case NPV calculation

	Valuation	FY21F	FY22F	FY23F	FY24F	FY25F
Revenue (US$m)		25.2	33.4	37.4	41.6	46.0
EBITDA (US$m)		0.1	6.2	8.9	11.6	14.5
D&A (US$m)		-1.8	-1.9	-1.9	-1.9	-2.0
Tax (US$m)		0.0	0.0	0.0	-0.9	-3.4
Capex (US$m)		-1.2	-1.2	-1.2	-1.2	-1.2
Change in NWC (US$m)		-0.2	-0.8	-0.4	-0.4	-0.4
Free CF (US$m)		-1.2	4.2	7.3	9.1	9.4
Terminal value (US$m)		0.0	0.0	0.0	0.0	138.1
PV of CF (US$m)		-1.1	3.3	5.2	5.9	87.3
NPV (US$m)	100.5					
End FY20 cash (US$m)	10.3					
Total NPV (US$m)	111.1					
Total NPV (A$m)	158.3					
Implied DCF value per share (A$)	0.93					
DCF (fully diluted, A$)	0.92					

Source: Taylor Collison research.

Cognigram scenario analysis and valuation

The company's Cognigram system detects very subtle changes in cognition that could signify the early stages of dementia. This would allow the identification of people who may be in the early stages of developing Alzheimer's disease and who could potentially benefit from treatment with a disease modifying Alzheimer's disease (DMAD) drug.

We estimate that in a scenario where Cognigram achieves market penetration of 10% of the population aged over 65 by FY25, Cogstate's royalties and profit share would have an NPV of A$182m or A$1.07 per share. This scenario models the average royalty to Cogstate per test performed being US$2.00 in the US, US$1.50 in Europe and US$3.00 in Japan. This revenue could come from a mix of full Cognigram assessments ordered by clinicians and lower-priced app-style cognitive assessment tools targeted at the general population. Our other assumptions are listed in our initiation report dated 2 April.

While we believe that this is a plausible scenario, it is contingent upon approval of a DMAD drug and Cogstate putting in place a licensing agreement with a partner that would promote the use of Cognigram in the US and Europe, in addition to the existing agreement with Eisai in Japan.

The consensus among Biogen analysts in December 2019 was that there is a 35% chance that the FDA would approve aducanumab for Alzheimer's disease based on the existing data. If we were to apply a slightly lower 30% probability to our Cognigram scenario, the risk-adjusted NPV would be A$0.32 per share.

Exhibit 4: Cognigram scenario NPV calculation

Cognigram scenario NPV calculation	Japan	US	Europe*	Total
Population aged 65 or above (m)	36.2	56.7	73.2	
Market penetration	10%	10%	10%	
Cogstate Profit share/royalty per test (US$)	3.0	2.0	1.5	
Cognigram income in FY25 (US$m)	13.3	17.4	14.5	45.3
Upfront payment to Cogstate (US$m)	1.0	7.0	3.0	
JV partner start-up costs reimbursed (US$m)	10.0	0.0	0.0	
NPV of Cogstate's profit share/royalty (US$m)	36.4	51.6	39.3	127.3
NPV of Cogstate's profit share/royalty (A$m)	52.0	73.6	56.2	181.9
NPV per share (A$/share)				1.07

*Source: Taylor Collison research. Note: * Eurozone plus UK*

Risks

Cogstate is essentially a healthcare service provider that is generating substantial revenues to offset cash burn. Our modelling indicates that Cogstate will return to profitability in FY21 and continue to report profits in future years. However, an investment in Cogstate is not without risk. We consider key risks to be:

- Disease modifying Alzheimer's drug approval risk: The major upside opportunity for Cognigram is contingent on the approval of a disease modifying Alzheimer's disease drug to drive widespread interest in screening for cognitive decline. In the absence of an approval we expect uptake of Cognigram testing to be limited.
- Cognigram partnering risk: There is a risk that an unsuccessful partner could be chosen for Cognigram. If the partner does not succeed in getting a DMAD drug approved, they would not have a strong incentive to promote Cognigram uptake. While there are performance hurdles in the Eisai agreement that must be met in order to maintain exclusivity, which would allow Cogstate to eventually change partners, there is a risk that Cogstate could miss out on the opportunity to partner with the pharma company with the first DMAD drug to market.
- Regulatory Risk: Cognigram has been granted CE mark and FDA clearance, but it has not yet obtained regulatory clearance in Japan. While the approvals in the US and Europe are strong positive indicators, and the application in Japan will benefit from being sponsored by Eisai, the regulatory risk in Japan cannot be totally discounted.
- Payor Risk: The rollout of Cognigram screening in major markets will be much more rapid and the pricing would be more favourable if the testing is reimbursed by insurers. We do not see this as a major risk given that other screening tests are reimbursed and there is already a reimbursement code for cognitive testing in the US, but the pricing and any limitation on the eligibility for testing could have significant impact on uptake.
- Competitive Risk: There are a number of companies with similar business models to Cogstate. In this environment, Cogstate may find it difficult to expand into additional disease indications and markets.
- Covid-19 disruption: On the one hand the Covid-19 pandemic could lead to delays in clinical trial recruitment and deferral of revenue recognition, while on the other hand it could accelerate the transition from paper-based to computerised cognitive assessments, which would increase the market opportunity for Costate.

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