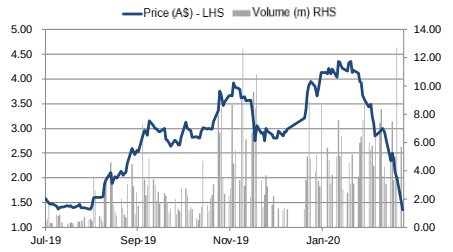
Paradigm Biopharmaceuticals

On its knees

HOLD (previously REDUCE)

Current price:	A$1.35
Target price:	A$2.16
Previous target:	A$2.16
Up/downside:	60.0%
Reuters:	PAR.AX
Bloomberg:	PAR AU
Market cap:	US$160m
	A$259m
Average daily turnover:	US$2.4m
	A$3.9m
Current shares o/s	192.2m
Free float:	72.2%



Price performance	1M	3M	12M
Absolute (%)	-63.4	-47.4	-4.2
Relative (%)	-41.4	-29.6	6.1

Iain WILKIE
T (61) 7 3334 4521
E iain.wilkie@morgans.com.au

Scott POWER
T (61) 7 3334 4884
E scott.power@morgans.com.au

Dr Derek JELLINEK
T (61) 2 9043 7904
E derek.jellinek@morgans.com.au

Analyst(s) own shares in the following stock(s) mentioned in this report:

– N/A

- PAR's share price fallen ~70% since mid February, and while we are certain the market volatility caused by COVID-19 has much to do with this, we believe that investor expectations had built up to unsustainable levels in the lead-up, resulting in a more severe market reaction.
- In this note, we re-cap on the Phase 2 results and highlight a number of concerns including the competitive landscape and the intellectual property (IP) position.
- While the share price is now trading well below our price target, we continue to retain a cautious view in the current environment. Given current market volatility we move to a Hold (from Reduce) recommendation. We make no changes to forecasts and our price target of A$2.16 remains.

Timelines stretching

Delays are not uncommon in the life sciences space although recent lags to timelines have likely added to investor concerns as to realistic regulatory and potential commercial timelines, in our view. With COVID-19 likely on the forefront of regulatory minds, we see potential for further clinical trial delays and increasing costs. PAR's pre-IND meeting minutes are due shortly and will give investors better insight into the potential size, structure and timelines heading into the Phase 3 trial which PAR anticipates commencing toward the end of CY20. Again, we have long held the assumption that based on the Phase 2 data we see a more arduous range of endpoints and likely to be tested against a standard of care rather than simple saline solution.

Data quality, IP strength and substitution risks

Reservations remain regarding PAR's Ph2 OA results which we outlined in previous reports. We continue to view the primary and secondary data as interesting but less than groundbreaking, and subsequent biomarker data inconclusive. Clinical data aside, we continue to hold a number of concerns regarding IP as well as high substitution risks with a number of alternative and novel treatments in the pipeline. We recently became aware of a new study looking at using the same drug (in tableted form) to treat the same disease via a different pathway and thereby potentially circumnavigating PAR's patents. More detail overleaf.

Investment view – still not the time to buy

We have made no changes to our forecasts although note due to heightened volatility and global concerns surrounding the COVID-19 pandemic that fundamental value doesn't appear to be a consideration at this time. While PAR is now trading at a reasonable discount to our valuation, there remains a number of critical questions that need answers. We note NTA is ~A$0.39 per share and hold the view that prices are likely to remain significantly weaker in the coming months. There is likely to be a time to buy this stock but based on the information we have on hand at present, right now is not it in our view. Due to recent share price weakness, we move our recommendation to a Hold (from Reduce) but remain on the sidelines for now. An investment in PAR is appropriate for investors with a higher risk-profile.

Financial Summary	Jun-18A	Jun-19A	Jun-20F	Jun-21F	Jun-22F
Revenue (A$m)	2.7	3.0	2.3	4.3	70.2
Operating EBITDA (A$m)	-6.2	-15.9	-17.1	-50.4	15.2
Net Profit (A$m)	-6.2	-15.6	-15.5	-49.2	10.8
Normalised EPS (A$)	-0.04	-0.09	-0.08	-0.25	0.05
Normalised EPS Growth	22660.2%	115.5%	(15.1%)	212.9%	(122.0%)
FD Normalised P/E (x)					24.69
DPS (A$)	0.000	0.000	0.000	0.000	0.000
Dividend Yield	0.00%	0.00%	0.00%	0.00%	0.00%
Franking (%)	0	0	0	0	0
EV/EBITDA (x)	-41.52	-11.78	-11.68	-4.87	16.17
P/FCFE (x)	NA	NA	NA	NA	14,361.7
Net Gearing	(18.0%)	(87.4%)	(88.8%)	(78.0%)	(48.9%)
P/BV (x)	14.09	3.13	3.97	14.76	9.24
ROE	(45.7%)	(32.4%)	(20.7%)	(115.2%)	46.0%

SOURCE: MORGANS, COMPANY REPORTS

Paradigm Biopharmaceuticals

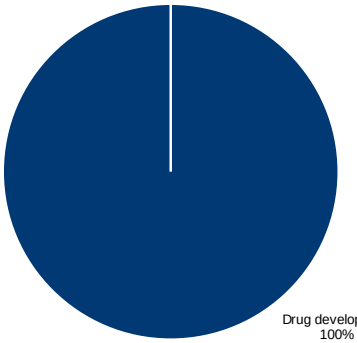
as at March 17, 2020

Market cap (A$m):	259	Rating:	HOLD
Shares outstanding (m):	192.2	Price (A$):	1.35
Free float (%):	72.2	Target price (A$):	2.16
Website:	https://paradigmbiopharma.com/	Upside/downside to target price (%):	60.0

Company description

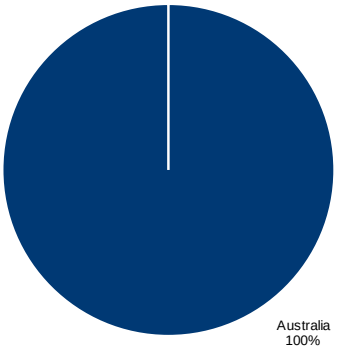
Paradigm Biopharmaceuticals Limited (PAR) is an Australian biopharmaceutical company focused on repurposing the drug 'pentosan polysulphate sodium' (PPS) for the treatment of bone marrow edema. Paradigm is targeting addressable markets with the aim to use the shortened development pathway utilising repurposed drugs.

Business segmentation by revenue FY20



SOURCE: MORGANS

Geographical segmentation by revenue FY20



SOURCE: MORGANS

PAR corporate milestones

Milestones for CY2020
Initiate Compassionate Use program with NFL 'Pro Players Elite Network'
Peer review publication of Phase 2a Viral Arthritis clinical trial.
Phase 3 OA/BMEL Clinical Trial: • Commence Phase 3 Clinical Trial in USA
Phase 2/3 MPS Clinical Trial: • Commence Phase 2/3 Clinical Trial in USA and EU
Peer reviewed publication of Phase 2b OA/BMEL Results
Progress MPS Indication
TGA Provisional Approval for iPPS to treat OA in Australia
Ongoing assessment of respiratory indication

SOURCE: PARADIGM BIOPHARMACEUTICALS

Catalyst table

Upcoming catalysts:

Peer-reviewed publication of OA/BMEL results

TGA provisional approval results

Release of Ph3 trial protocol (FDA IND)

Ex-NFL player EAP

Partnership transaction discussions

Ph3 commencement

SOURCE: MORGANS

Market assumptions

MARKET DATA	#
Population of target market	325.70
Prevalence of disease	12.1%
Post-traumatic portion	12.0%
Number of Cases Forecast for Year 1	4.7
Annual Population Growth	0.70%
Peak Market Penetration	10.0%
Revenue Per Unit ($US)	$ 1,750
Market Ramp Time to Peak Penetration (Years	5
Hold peak	5
Life cycle of drug	20

SOURCE: MORGANS

Key drivers / risks

Key Drivers

Licencing deal value for late stage assets

Potential for early commercialisation

Key risks:

Timing / execution risks

Trial risks

Value of intellectual property

API supply

Alternative therapies

Quality of trial data to date

SOURCE: MORGANS

Figure 1: Financial summary

Income statement	2018A	2019A	2020F	2021F	2022F
Divisional sales	0.0	0.0	0.0	0.0	0.0
Total revenue	2.7	3.0	2.3	4.3	70.2
EBITDA	**-6.2**	**-15.9**	**-17.1**	**-50.4**	**15.2**
Associate income	0.0	0.0	0.0	0.0	0.0
Depreciation	0.0	0.0	0.0	0.0	0.0
EBITA	-6.2	-15.9	-17.1	-50.4	15.2
Amortisation/impairment	0.0	0.0	0.0	0.0	0.0
EBIT	**-6.2**	**-15.9**	**-17.1**	**-50.4**	**15.2**
EBIT(incl associate profit)	-6.2	-15.9	-17.1	-50.4	15.2
Net interest expense/FX	0.0	0.0	0.3	1.6	1.2
Pre-tax profit	**-6.3**	**-15.6**	**-15.5**	**-49.2**	**15.5**
Income tax expense	0.0	0.0	0.0	0.0	4.6
After-tax profit	-6.3	-15.6	-15.5	-49.2	10.8
Minority interests	0.0	0.0	0.0	0.0	0.0
NPAT	**-6.3**	**-15.6**	**-15.5**	**-49.2**	**10.8**
Significant items	0.0	0.0	0.0	0.0	0.0
NPAT post abnormals	-6.3	-15.6	-15.5	-49.2	10.8

Cash flow statement	2018A	2019A	2020F	2021F	2022F
EBITDA	-6.2	-15.9	-17.1	-50.4	15.2
Other cash items	0.0	0.0	0.0	0.0	0.0
Net interest (pd)/rec	-0.1	-0.3	-1.6	-1.2	-0.3
Taxes paid	0.0	0.0	0.0	0.0	-4.6
Change in working capital	0.1	9.8	3.0	3.5	-10.8
Cash flow from ops (1)	**-6.1**	**-6.4**	**-15.7**	**-48.1**	**-0.5**
Capex (2)	0.0	0.0	0.0	0.0	0.0
Disposals/(acquisitions)	0.0	0.0	0.0	0.0	0.0
Other investing cash flow	0.0	-6.5	0.0	0.0	0.0
Cash flow from invest (3)	**0.0**	**-6.5**	**0.0**	**0.0**	**0.0**
Incr/(decr) in equity	5.9	82.8	0.0	0.0	0.0
Incr/(decr) in debt	0.0	0.0	0.0	0.0	0.0
Ordinary dividend paid	0.0	0.0	0.0	0.0	0.0
Preferred dividends (4)	0.0	0.0	0.0	0.0	0.0
Other financing cash flow	0.0	0.0	0.0	0.0	0.0
Cash flow from fin (5)	**5.9**	**82.8**	**0.0**	**0.0**	**0.0**
Forex and disc ops (6)	0.0	0.0	0.0	0.0	0.0
Inc/(decr) cash (1+3+5+6)	-0.3	69.9	-15.7	-48.1	-0.5
Equity FCF (1+2+4)	-6.2	-6.4	-15.7	-48.1	-0.5

Balance sheet	2018A	2019A	2020F	2021F	2022F
Cash & deposits	2.4	72.3	59.8	14.1	14.1
Trade debtors	2.7	3.5	0.4	0.7	11.5
Inventory	0.0	0.0	0.0	0.0	0.0
Investments	0.0	0.0	0.0	0.0	0.0
Goodwill	0.0	0.0	0.0	0.0	0.0
Other intangible assets	9.9	3.0	3.0	3.0	3.0
Fixed assets	0.0	0.0	0.0	0.0	0.0
Other assets	0.0	0.0	0.0	0.0	0.0
Total assets	**15.2**	**85.5**	**69.8**	**24.5**	**35.3**
Short-term borrowings	0.0	0.0	0.0	0.0	0.0
Trade payables	1.1	2.3	2.1	6.0	6.0
Long-term borrowings	0.0	0.0	0.0	0.0	0.0
Provisions	0.3	0.4	0.4	0.4	0.4
Other liabilities	0.3	0.0	0.0	0.0	0.0
Total liabilities	**1.6**	**2.7**	**2.5**	**6.4**	**6.4**
Share capital	26.6	109.5	109.5	109.5	109.5
Other reserves	2.0	4.1	4.1	4.1	4.1
Retained earnings	-15.1	-30.7	-46.2	-95.4	-84.6
Other equity	0.0	0.0	0.0	0.0	0.0
Total equity	**13.6**	**82.8**	**67.3**	**18.1**	**28.9**
Minority interest	0.0	0.0	0.0	0.0	0.0
Total shareholders' equity	13.6	82.8	67.3	18.1	28.9
Total liabilities & SE	15.2	85.5	69.8	24.5	35.3

Closing price (A$)	1.35	Price target (A$)	2.16
Valuation metrics			
Methodology -DCF-PER Comp		Target Price	$2.16
DCF valuation inputs			
Rf	3.50%	10-year rate	5.25%
Rm-Rf	5.50%	Margin	2.0%
Beta	1.70	Kd	5.00%
CAPM (Rf+Beta(Rm-Rf))	12.9%	Ke	14.9%
E/EV*Ke+D/EV*Kd(1-t)		NPV cash flow (A$m)	470.9
Equity (E/EV)	96.2%	Minority interest (A$m)	0.0
Debt (D/EV)	3.9%	Net debt (A$m)	0.0
Interest rate	5.00%	Investments (A$m)	0.0
Tax rate (t)	30.0%	Equity market value (A$m)	470.9
WACC	12.9%	Diluted no. of shares (m)	197.8
		DCF valuation	$2.38

Multiples	2018A	2019A	2020F	2021F	2022F
Enterprise value (A$m)	264.6	194.7	207.3	252.9	252.9
EV/Sales (x)	n.a.	n.a.	n.a.	n.a.	n.a.
EV/EBITDA (x)	-42.7	-12.3	-12.1	-5.0	16.7
EV/EBIT (x)	-42.7	-12.3	-12.1	-5.0	16.7
PE (pre-goodwill) (x)	-31.1	-16.6	-17.2	-5.4	24.7
PEG (pre-goodwill) (x)	-0.2	0.0	0.1	-6.8	-0.1

At target price	2018A	2019A	2020F	2021F	2022F
EV/EBITDA (x)	-42.7	-12.3	-12.1	-5.0	16.7
PE (pre-goodwill) (x)	-49.7	-26.6	-27.5	-8.7	39.5

Per share data	2018A	2019A	2020F	2021F	2022F
No. shares	141.5	192.2	197.8	197.8	197.8
EPS (cps)	-4.3	-8.1	-7.8	-24.9	5.5
EPS (normalised) (c)	-4.3	-8.1	-7.8	-24.9	5.5
Dividend per share (c)	0.0	0.0	0.0	0.0	0.0
Dividend payout ratio (%)	0.0%	0.0%	0.0%	0.0%	0.0%
Dividend yield (%)	0.0%	0.0%	0.0%	0.0%	0.0%

Growth ratios	2018A	2019A	2020F	2021F	2022F
Sales growth	n.a.	n.a.	n.a.	n.a.	n.a.
Operating cost growth	n.a.	156.7%	7.6%	194.7%	-130.1%
EBITDA growth	n.a.	-156.6%	-7.6%	-194.7%	130.1%
EBITA growth	n.a.	n.a.	n.a.	n.a.	n.a.
EBIT growth	n.a.	n.a.	n.a.	n.a.	n.a.
NPAT growth	n.a.	n.a.	n.a.	n.a.	n.a.
Pre-goodwill NPAT growth	n.a.	n.a.	n.a.	n.a.	n.a.
Pre-goodwill EPS growth	n.a.	n.a.	n.a.	n.a.	n.a.
Normalised EPS growth	n.a.	n.a.	n.a.	n.a.	n.a.

Operating performance	2018A	2019A	2020F	2021F	2022F
Asset turnover (%)	0.0	0.0	0.0	0.0	0.0
EBITDA margin (%)	n.a.	n.a.	n.a.	n.a.	n.a.
EBIT margin (%)	n.a.	n.a.	n.a.	n.a.	n.a.
Net profit margin (%)	n.a.	n.a.	n.a.	n.a.	n.a.
Return on net assets (%)	-45.7	-19.2	-25.4	-278.6	52.5
Net debt (A$m)	-2.4	-72.3	-59.8	-14.1	-14.1
Net debt/equity (%)	-18.0	-87.4	-88.8	-78.0	-48.9
Net interest/EBIT cover (x)	n.a.	389.4	65.3	31.6	-12.7

Internal liquidity	2018A	2019A	2020F	2021F	2022F
Current ratio (x)	1.5	26.7	23.8	2.2	2.2
Receivables turnover (x)	0.0	0.0	0.0	0.0	0.0
Payables turnover (x)	6.6	9.4	7.7	12.4	-2.5

SOURCE: MORGANS RESEARCH, COMPANY

Re-cap on key points as we see it

Phase 2 study: Trendlines of efficacy measures were pointing in the right direction but statistical significance only first evident across all measures on day 39 (of a 42 day treatment regimen) and then trending back toward baseline and non-statistical significant thereafter = **slow-on / fast-off dynamics**. Data shows a sustained drop-off in efficacy after final dosing which raises questions whether the dosing regimen is required to be on a longer-term weekly basis and if so, is that viable for patients versus non-drug alternatives which include losing weight (less pressure on joints) or surgery for a permanent fix.

The topline study release had to focus in on the medium pain cohort (NRS 4-6) even though the higher pain cohort (NRS 7-8) performed far better. Why? Because the patients treated with placebo in this mid-range pain cohort performed worse. In fact, **back-solving the results to strip out the NRS 4-6 patients actually shows placebo was a far better drug than iPPS for higher pain patients** across both the pain and Activity of Daily Living (ADL) measurements.

Even if we look at the objective tests performed, the BML Area and also BML Volume within the knee, the reports suggest significant improvements (~30% reduction in BML volume compared to placebo and >35% improvement in BML area) – but this time there is no mention of any statistical significant and instead the language turns to “strong trend of efficacy” which means that while the data is pointing in the right direction, it **cannot be relied upon as clinical evidence**. Looking deeper, it’s easy to understand why significance wasn’t achieved – the range of results for both iPPS patients and placebo was large. Using the BML volume data set as an example, the iPPS group results ranged from a 65% improvement to a 56% worsening of condition versus placebo group having a broadly similar result with a large range of 41% decrease to a 91% increase in BML volumes. While the averages of the groups showed the treatment group ended better off, more data is required to fully see where the potential application of the treatment may lie. Weight and age of trial arm cohorts is likely to be a significant swing factor which we currently have no information on.

More information (longer, more participants, higher bar for comparable arm) is required in order to not only convince us, but potential partners that there is a commercial opportunity, in our view.

Follow up studies: PAR reported a “breakthrough” from new data from the Phase 2 OA trial showing a reduction in cartilage degradation as measured by two biomarkers back in August 2019. The results showed a mean cartilage degradation reduction from baseline at day 1 to day 53 of 11.9% as measured by the Cartilage Oligomeric Matrix Protein (COMP) biomarker versus an increase of 2.1% in the control group. Likewise, the ADAMTS-5 protein showed a reduction of 5.1% versus increase of 10% in the control group.

We see no evidence which was presented to prove that the short term decreases in the two biomarkers tested supports what is claimed. iPPS as a "cartilage-protective and potentially blocks the progression of knee osteoarthritis". In fact, while the reference cited showed "a single measurement of increased COMP predicted subsequent cartilage loss on MRI" is correct, the referenced paper noted the increase in COMP to predict subsequent MRI cartilage loss as "modest", was based on 160 pts (but used 137 pts with complete data) from an observational study after a 30 month follow-up and noted further limitations of using biomarkers in this study (e.g. age-related increases are common and may produce variation; insufficient power; and limitations with cartilage loss on MRI as it is measured "semi-quantitatively with inherent potential observer bias and possible measurement error").

Once again, we view the data produced as interesting but inconclusive and would require longer term results to show if the lowering of these biomarkers has been sustained along with evidence of structural modification on MRI to support the biomarker data.

Intellectual property: PAR does not own / license / produce its core technology. The underlying drug is called pentosan polyphosphate saccharides (PPS) and is a generic used widely as a treatment for painful bladder syndrome for >50 years. PAR uses an injectable form of this generic with its central protection being an exclusive long-term supply agreement of the injectable form with the only FDA approved PPS manufacturer. Significant risk is an alternative manufacturer moving into the space - we note there are a number of other companies actively trying to replicate the process. While PAR also has a number of patents covering the use of the drug in the treatment of BMELs, the patents aren't likely to halt similar claims including the use of PPS for the treatment of OA via variant pathways.

We note a new study currently being undertaken out of the University of Sydney using the same active pharmaceutical ingredient (API) for a similar outcome – i.e. reduction in pain and functional improvement for OA patients. "This study aims to determine whether oral delivery of PPS drug will lower lipid levels in patients with knee OA. We are also interested to investigate if the improvement in dyslipidaemia might lead to improving OA symptoms and slowing disease progression, as measured by function, pain and MRI, in patients with mild to moderate knee osteoarthritis." We will monitor the outcomes of this trial as more information comes to pass.

Substitution/black market risk: The injectable form of the drug has been used in the veterinary arena for a number of years – predominately on dogs and horses. While PAR's drug would have to be standardised to a high quality to be fit for human consumption (GMP certified) – we speculate a solution designed for race horses is unlikely to be significantly inferior either (albeit unapproved for human use). The difference between expected treatment price is substantially higher than existing veterinary applications. PAR has indicated early expectations for pricing of the treatment in the range of US$1.5k to US$2.5k for a 12 course treatment. At the lower end of this range it calculated at A$2,200 per 2ml treatment for a 100kg person versus an indicative veterinary equivalent at $5.66 (petchemist.com.au).

Similarly, if the trial out of University of Sydney shows comparable efficacy in the tableted form (noting higher potential impacts of first-pass metabolism via oral delivery) - we view it likely that it would be significantly more appealing method for both the patient and prescriber than via intravenous delivery. Using the same example as above (100kg person), the trial participant would require 10 tablets per 4 days over 180 days (45 dosage days) – which based on standard Elmiron 100mg 100 capsule packets (4.5 packets needed) available via Chemist Warehouse, would cost $550 per treatment after PBS or based on prices obtained from pharmacychecker.com, can be obtained for about US$1.33 per pill (US$600).

Conclusion

Although we have a cautious view, we still believe long-term value exists in PAR's assets. The data shown to date, while interesting and showing positive initial trends of efficacy is by no means conclusive and given the company specific significant risks ahead (trials/approvals/costs/marketing/time-value), we failed to see the value considering the risks at the levels experienced well above our price target. While now we view the stock is potentially undervalued with its ~60% upside to our fundamental price target, we continue to caution investors that a significant component of our valuation comprises of medium-term milestone payments which we assessed at US$600m (albeit heavily back-end loaded) based on the most recent biotech deal metrics. In the current risk-off market, the appetite from big-pharma for these/similar assets will have likely slowed, dragging down achievable headline metrics. We note based on our current modelling, our DCF valuation declines A$0.27 per share for each US$100m in total deal value lost from our headline assumption of US$600m and visa-versa. At this stage, we see no evidence of this but continue to monitor the latest industry reports for any structural adjustments as a result of recent global issues.

Queensland

Brisbane	+61 7 3334 4888
Stockbroking, Corporate Advice, Wealth Management	
Brisbane: Edward St	+61 7 3121 5677
Brisbane: Tynan Partners	+61 7 3152 0600
Brisbane: North Quay	+61 7 3245 5466
Bundaberg	+61 7 4153 1050
Cairns	+61 7 4222 0555
Caloundra	+61 7 5491 5422
Gladstone	+61 7 4972 8000
Gold Coast	+61 7 5581 5777
Holland Park	+61 7 3151 8300
Ipswich/Springfield	+61 7 3202 3995
Kedron	+61 7 3350 9000
Mackay	+61 7 4957 3033
Milton	+61 7 3114 8600
Newstead	+61 7 3151 4151
Noosa	+61 7 5449 9511
Redcliffe	+61 7 3897 3999
Rockhampton	+61 7 4922 5855
Spring Hill	+61 7 3833 9333
Sunshine Coast	+61 7 5479 2757
Toowoomba	+61 7 4639 1277
Townsville	+61 7 4725 5787

New South Wales

Sydney	+61 2 9043 7900
Stockbroking, Corporate Advice, Wealth Management	
Sydney: Grosvenor Place	+61 2 8215 5000
Sydney: Reynolds Securities	+61 2 9373 4452
Sydney: Currency House	+61 2 8216 5111
Armidale	+61 2 6770 3300
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Bowral	+61 2 4851 5555
Chatswood	+61 2 8116 1700
Coffs Harbour	+61 2 6651 5700
Gosford	+61 2 4325 0884
Hurstville	+61 2 8215 5079
Merimbula	+61 2 6495 2869
Mona Vale	+61 2 9998 4200
Neutral Bay	+61 2 8969 7500
Newcastle	+61 2 4926 4044
Orange	+61 2 6361 9166
Port Macquarie	+61 2 6583 1735
Scone	+61 2 6544 3144
Wollongong	+61 2 4227 3022

Victoria

Melbourne	+61 3 9947 4111
Stockbroking, Corporate Advice, Wealth Management	
Brighton	+61 3 9519 3555
Camberwell	+61 3 9813 2945
Domain	+61 3 9066 3200
Geelong	+61 3 5222 5128
Richmond	+61 3 9916 4000
South Yarra	+61 3 8762 1400
Southbank	+61 3 9037 9444
Traralgon	+61 3 5176 6055
Warrnambool	+61 3 5559 1500

Australian Capital Territory

Canberra	+61 2 6232 4999

Northern Territory

Darwin	+61 8 8981 9555

Tasmania

Hobart	+61 3 6236 9000

Western Australia

West Perth	+61 8 6160 8700
Stockbroking, Corporate Advice, Wealth Management	
Perth	+61 8 6462 1999

South Australia

Adelaide	+61 8 8464 5000
Exchange Place	+61 8 7325 9200
Norwood	+61 8 8461 2800
Unley	+61 8 8155 4300