



ACRUX LIMITED AND CONTROLLED ENTITIES
ABN: 72 082 001 152

FINANCIAL REPORT FOR THE HALF-YEAR ENDED 31 DECEMBER 2023

This half-year financial report is to be read in conjunction with the Annual Report 2023





FINANCIAL REPORT FOR THE HALF-YEAR ENDED 31 DECEMBER 2023

TABLE OF CONTENTS

	Page
Directors' Report	3
Auditor's Independence Declaration	7
Financial Report for the half-year ended 31 December 2023	
Condensed Consolidated Statement of Profit or Loss and Other Comprehensive Income	8
Condensed Consolidated Statement of Financial Position	9
Condensed Consolidated Statement of Changes in Equity	10
Condensed Consolidated Statement of Cash Flows	11
Notes to the Condensed Consolidated Financial Statements	12
Directors' Declaration	16
Independent Auditor's Review Report	17



DIRECTORS' REPORT FOR THE HALF-YEAR ENDED 31 DECEMBER 2023

The Directors of the consolidated entity consisting of Acrux Limited ('Acrux') and its controlled entities (collectively 'the Group') have pleasure in presenting this report for the half-year ended 31 December 2023. Complying with the provisions of the *Corporations Act 2001*, the Directors report as follows:

DIRECTORS' NAMES

The names of the Directors in office during and since the end of the half-year ended 31 December 2023 are:

Ross Dobinson	Non-executive Chairman
Michael Kotsanis	Managing Director & Chief Executive Officer
Geoffrey Brooke	Non-executive Director
Don Brumley	Non-executive Director
Timothy Oldham	Non-executive Director

All Directors have held office from the start of the financial period to the date of this report.

REVIEW OF OPERATIONS

A review of the operations of the Group during the half-year and the results of these operations are as follows:

Principal Activities

Acrux is a specialty pharmaceutical company with a successful track record of developing and commercialising its portfolio of topically applied generic pharmaceutical products utilising dermal and transdermal drug delivery technology and primarily focused on the US market.

Acrux currently has 15 products in its pipeline which are at various stages of development ranging from:

- formulation and process development
- demonstration of bioequivalence with the brand name product
- submission of the dossier to the regulator for review
- regulatory approval and
- product launch and commercialisation.

A further 2 products have been identified and which have been approved for commencement of development during 2024. Subsequently the Company plans to add 2 new projects annually.

There has been no significant change in the nature of these activities during the reporting period.

Key Events During Half Year:

Through our commercial distribution partner for Prilocaine 2.5% and Lidocaine 2.5%, Cream sales have grown through 2023. The contract manufacturer for this product has raw material supply and manufacturing capacity available to supply and support further anticipated market share growth.

Since June 2023 Acrux has made the following material announcements to the ASX:

- in June 2023 Acrux received FDA approval of Dapsone 5%, Gel and preparations are well underway to support launch of this product early in 2024. Dapsone 5%, Gel is used to treat acne vulgaris and (as measured by IQVIA in October 2023) the annual addressable market is US\$15.5 million

ACRUX LIMITED AND CONTROLLED ENTITIES
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- Nitroglycerin 0.4%, Ointment was accepted for review by the FDA in July 2023. This product treats moderate to severe pain associated with chronic anal fissure and has an annual addressable market of US\$21.6 million as measured by IQVIA in October 2023
- in September, in conjunction with our commercial partner, we concluded a review of the market for Testosterone Topical Solution. We agreed to exit this market and the distribution agreement was mutually terminated
- in November 2023, \$2.869 million was received from the Australian Taxation Office in relation to Research and Development Tax Incentive Rebates ('RDTI') including eligible overseas expenditure for the year ended 30 June 2023.

Business Strategy

Acrux's key operational strategy is to develop and expand its pipeline of topically applied generic pharmaceutical products to create a portfolio which is capable of generating a consistent stream of regulatory submissions and product approvals, market launches and ultimately a revenue stream from a diversified range of products.

Acrux currently has 6 products with regulatory approval, including 2 which are currently generating revenue, namely Prilocaine 2.5% and Lidocaine 2.5%, Cream and Evamist[®]. Dapsone 5%, Gel has been approved by the FDA and the product launch is planned for early in 2024.

3 Acrux ANDAs are currently under FDA review:

- Nitroglycerin 0.4%, Ointment, a treatment for moderate to severe pain caused by chronic anal fissure
- Acyclovir 5%, Cream, a treatment for cold sores
- Dapsone 7.5%, Gel, a treatment for acne vulgaris

The FDA administers the ANDA review process and the time to final approval is influenced by both the number and the nature of questions that may arise as each FDA review progresses.

There are additional products in our portfolio that are at different stages of development, ranging from early stage formulation development through to process development and demonstration of bioequivalence and finally to regulatory dossier preparation.

Acrux presently has a total of 15 topical generic products in our portfolio (including Testosterone Topical Solution) and a further 2 products have been identified and approved for commencement over 2024. It is our expectation that the portfolio will continue to be expanded over time through the addition of 2 new projects each year.

This portfolio strategy supports our core objective of having a number of products to launch through 2024 and beyond, which is critical to creating a sustainable revenue stream and future expansion of our product pipeline. This underpins future corporate growth and shareholder value.

In December 2022, Prilocaine 2.5% and Lidocaine, 2.5%, Cream, a topical local anesthetic, became Acrux's fourth marketed product. Early in 2023 a key market competitor, which held more than 70% of the reported market share at that time, withdrew from the market. Together with our raw material suppliers, manufacturing and commercial partners, Acrux expanded the capacity to supply this market and we are pleased to report that our distribution partner is achieving significant market share for this product. The estimated annual addressable US market for the product is US\$35.6 million, as measured by IQVIA in October 2023.

Preparations are advanced to launch Dapsone 5%, Gel early in 2024. Dapsone 5%, Gel is used to treat acne vulgaris. As measured by IQVIA in October 2023, the annual addressable US market is US\$15.5 million.

ACRUX LIMITED AND CONTROLLED ENTITIES
(ABN: 72 082 001 152)



In December 2023, Acrux also entered into an additional manufacturing contract for one of its pipeline products with a new contract manufacturer. The technical transfer process for this product has begun ahead of the planned manufacturing of exhibit batches that are required for a regulatory submission for FDA review.

Operating Results

The consolidated loss after tax was \$3.239 million (2022 loss: \$3.294 million) and this reflects both commercial revenue growth and the timing of project expenses incurred in progressing the Group's generic development pipeline towards commercialisation.

Revenue

Total reported Revenue is detailed in the table below.

	Half year ended 31 December 2023 \$'000	Half year ended 31 December 2022 \$'000
Product licensing income	481	954
Sales Revenue –API	3,928	467
R&D Incentive Rebate	1,285	1,800
Interest Received	83	28
Total Revenue	5,777	3,249

Product licensing income from commercialised products reflects the Group's transition following the buy-out of the future Lenzetto® royalty stream by our licensee, Gedeon Richter Plc. which was transacted in January 2023. Licensing income now predominantly reflects profit share income associated with Prilocaine 2.5% and Lidocaine 2.5%, Cream which is marketed by Padagis in the United States and which was launched in December 2022.

Under the terms of the commercialisation agreement with Padagis, Acrux is currently responsible for the procurement of the Active Pharmaceutical Ingredients ('API') which are used in the commercial manufacture of Prilocaine 2.5% and Lidocaine 2.5%, Cream. These API purchases are recorded as Cost of Goods Sold and are in turn invoiced to Padagis and are included as Sales Revenue. The increased value of purchases and sales of Prilocaine and Lidocaine API reflect the increase in manufacturing activity relative to the prior comparative period, when the API had been purchased for the manufacture of launch stocks.

In November, Acrux reported receipt of \$2.869 million Research and Development Tax Incentive Rebates ('RDTI') in relation to the year ended 30 June 2023. \$1.285 million RDTI Income has been reported for the period ended 31 December 2023. Of this balance, \$1.138 million is an estimate of the amount which is receivable for the reporting period ending 31 December 2023, based on eligible project development expenditure incurred plus \$0.146 million which reflects higher than estimated RDTI which was received for FY23 in November 2023.

Operating Expenses

At \$4.710 million Total Operating Expenses were \$1.129 million (19%) lower than the prior corresponding period. This reduction is principally attributable to the timing of external research and development project expenses, the costs of which vary throughout the product development cycle depending on the stage of development of the project.

ACRUX LIMITED AND CONTROLLED ENTITIES
(ABN: 72 082 001 152)



Dividends

No dividends have been declared or paid in the period to 31 December 2023 (2022: nil).

After balance date events

No matter or circumstance has arisen since 31 December 2023 that has significantly affected, or may significantly affect, the Group's operations, results or state of affairs, or may do so in future periods.

Auditor's independence declaration

A copy of the Auditor's Independence Declaration in relation to the review for the period is provided with this report.

Rounding of amounts

The Group is a group of the kind referred to in *ASIC Corporations (Rounding in Financial/Directors' Reports) Instrument 2016/191*, dated 24 March 2016, and in accordance with that Corporations Instrument, amounts in this Directors' Report and financial statements have been rounded to the nearest one thousand dollars, unless otherwise indicated.

Signed in accordance with a resolution of the Directors made pursuant to s306(3) of the *Corporations Act 2001*.

On behalf of the Directors

A handwritten signature in black ink, appearing to read 'Ross Dobinson', with a long horizontal flourish extending to the right.

Ross Dobinson
Non-executive Chairman
27 February 2024

**AUDITOR'S INDEPENDENCE DECLARATION
TO THE DIRECTORS OF ACRUX LIMITED AND CONTROLLED ENTITIES**

In relation to the independent auditor's review for the half-year ended 31 December 2023, to the best of my knowledge and belief there have been:

- (i) no contraventions of the auditor independence requirements of the *Corporations Act 2001*; and
- (ii) no contraventions of APES 110 *Code of Ethics for Professional Accountants (including Independence Standards)*.

This declaration is in respect of Acrux Limited and the entities it controlled during the period.



N R BULL
Partner

27 February 2024



PITCHER PARTNERS
Melbourne



**CONDENSED CONSOLIDATED STATEMENT OF PROFIT OR LOSS AND OTHER COMPREHENSIVE INCOME
FOR THE HALF-YEAR ENDED 31 DECEMBER 2023**

	Note	Consolidated Half Year Ended	
		31 December 2023 \$'000	31 December 2022 \$'000
Revenue			
Revenue from licensing agreements		4,409	1,421
Other revenue		1,368	1,828
Total Revenue	1	5,777	3,249
Less: Cost of Goods Sold		3,928	493
Less: Operating Expenses			
Employee benefits expense		2,499	2,652
Directors' fees		98	98
Securities based payment expense		182	184
Depreciation and amortisation expense		258	301
Occupancy expense		109	114
External research and development expense		1,147	1,926
Professional fees		83	116
Other expense		334	448
Total Operating Expenses		4,710	5,839
Loss Before Income Tax		(2,861)	(3,083)
Income tax expense		378	211
Net loss for the half year		(3,239)	(3,294)
Total comprehensive loss for the half year		(3,239)	(3,294)
Total Comprehensive Loss attributable to members of the parent company		(3,239)	(3,294)
Loss Per Share:			
Basic loss per share		(1.12) cents	(1.15) cents
Diluted loss per share		(1.12) cents	(1.15) cents

The accompanying notes form part of these financial statements.



**CONDENSED CONSOLIDATED STATEMENT OF FINANCIAL POSITION
AS AT 31 DECEMBER 2023**

	Note	Consolidated	
		31 December 2023 \$'000	30 June 2023 \$'000
Current Assets			
Cash and cash equivalents		4,565	6,232
Receivables		3,942	3,306
Other current assets		652	353
Total Current Assets		9,159	9,891
Non-Current Assets			
Plant and equipment		536	559
Intangible assets	3	-	-
Deferred tax asset		425	803
Lease assets	4	1,896	2,032
Total Non-Current Assets		2,857	3,394
Total Assets		12,016	13,285
Current Liabilities			
Payables		3,282	1,372
Provisions		803	826
Lease liabilities	4	305	192
Total Current Liabilities		4,390	2,390
Non-Current Liabilities			
Provisions		34	38
Lease liabilities	4	1,954	2,161
Total Non-Current Liabilities		1,988	2,199
Total Liabilities		6,378	4,589
Net Assets		5,638	8,696
Equity			
Contributed equity		114,986	114,884
Reserves		8,378	8,299
Retained earnings / (Accumulated losses)		(117,726)	(114,487)
Total Equity		5,638	8,696

The accompanying notes form part of these financial statements.



**CONDENSED CONSOLIDATED STATEMENT OF CHANGES IN EQUITY
FOR THE HALF-YEAR ENDED 31 DECEMBER 2023**

	Contributed equity \$'000	Reserves \$'000	Retained earnings /(losses) \$'000	Total Equity \$'000
Balance at 1 July 2023	114,884	8,299	(114,487)	8,696
Loss attributable to members of the consolidated entity	-	-	(3,239)	(3,239)
Other comprehensive income	-	-	-	-
Total comprehensive loss for the half year	-	-	(3,239)	(3,239)
Transactions with owners:				
Employee share scheme	102	79	-	181
Balance at the half year ended 31 December 2023	114,986	8,378	(117,726)	5,638
Balance at 1 July 2022	114,563	8,250	(113,723)	9,090
Loss attributable to members of the consolidated entity	-	-	(3,294)	(3,294)
Other comprehensive income	-	-	-	-
Total comprehensive loss for the half year	-	-	(3,294)	(3,294)
Transactions with owners:				
Employee share scheme	184	-	-	184
Balance at the half year ended 31 December 2022	114,747	8,250	(117,017)	5,980

The accompanying notes form part of these financial statements.



**CONDENSED CONSOLIDATED STATEMENT OF CASH FLOWS
FOR THE HALF-YEAR ENDED 31 DECEMBER 2023**

	Consolidated Half Year Ended	
	31 December 2023 \$'000	31 December 2022 \$'000
Cash flows from operating activities		
Receipts from client contracts	2,190	1,239
Payments to suppliers and employees	(6,505)	(6,298)
Interest received	122	25
Research and development tax incentive rebate received	2,869	3,732
Net cash used in operating activities	(1,324)	(1,302)
Cash flows from investing activities		
Payment for property, plant and equipment	(156)	(3)
Net cash used in investing activities	(156)	(3)
Cash flows from financing activities		
Lease liability principal repayments	(94)	(93)
Finance costs	(93)	(83)
Proceeds from capital raising	-	-
Net cash used in financing activities	(187)	(176)
Net (decrease) / increase in cash and cash equivalents	(1,667)	(1,481)
Cash and cash equivalents at beginning of half year	6,232	5,831
Cash at the end of the period	4,565	4,350

The accompanying notes form part of these financial statements



NOTES TO THE CONDENSED CONSOLIDATED FINANCIAL STATEMENTS FOR THE HALF-YEAR ENDED 31 DECEMBER 2023

General information

Statement of compliance

This half-year financial report is a general purpose financial report prepared in accordance with the *Corporations Act 2001* and AASB 134 Interim Financial Reporting. Compliance with AASB 134 ensures compliance with International Financial Reporting Accounting Standard IAS 34 Interim Financial Reporting. The half-year financial report does not include notes of the type normally included in an annual financial report and should be read in conjunction with the most recent annual financial report.

Basis of preparation

The condensed consolidated financial statements for the half-year ended 31 December 2023 have been prepared on the basis of historical cost. Cost is based on the fair values of the consideration given in exchange for assets.

All amounts are presented in Australian dollars unless otherwise noted.

The Group is a group of the kind referred to in *ASIC Corporations (Rounding in Financial/Directors' Reports) Instrument 2016/191*, dated 24 March 2016, and in accordance with that Corporations Instrument, amounts in the half-year financial report are rounded to the nearest thousand dollars, unless otherwise indicated.

The accounting policies and methods of computation adopted in the preparation of the half-year financial report are consistent with those adopted and disclosed in the Group's Annual Report for the financial year ended 30 June 2023. The accounting policies are consistent with Australian Accounting Standards and with International Financial Reporting Standards.

The Group has applied all new and revised Australian Accounting Standards and Interpretations that are applicable to reporting periods beginning on or after 1 July 2023. Application of new and revised Australian Accounting Standards did not materially impact on this half year financial report.

Going concern basis of preparation

This financial report has been prepared on a going concern basis contemplating continuity of normal business activities and realisation of assets and settlement of liabilities in the ordinary course of business.

The Group incurred a loss after tax from ordinary activities of \$3.239 million for the half-year ended 31 December 2023 (31 December 2022: \$3.294 million). The Group reports total Cash and cash equivalents of \$4.565 million which is a reduction of \$1.667 million from 30 June 2023 and is similar to the reduction of \$1.481 million to \$4.350 million which was reported for the prior corresponding period to 31 December 2022. The ability of the Group to continue as a going concern is dependent on the generation of future revenues to support cashflows from operating activities.



**NOTES TO THE CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
FOR THE HALF-YEAR ENDED 31 DECEMBER 2023 (continued)**

1. SEGMENT REPORTING

The Group operates as a single operating segment. Internal management reporting systems present financial information as a single segment which derives its revenue from developing and commercialising topically applied prescription pharmaceutical products.

	31 December 2023 \$'000	31 December 2022 \$'000
Geographical segment information		
Australia	1,368	1,828
Europe and other countries	-	946
United States	4,409	475
	5,777	3,249
Revenue by product group and services provided		
Income received from licensing agreements	4,409	1,421
R&D Tax Incentive Rebate	1,285	1,800
Interest received	83	28
	5,777	3,249

2. KEY MANAGEMENT PERSONNEL

Remuneration arrangements of Key Management Personnel are disclosed in the Annual Report.

Following approval at the Annual General Meeting held on 29 November 2023, 4,864,243 rights were issued to Non-executive Directors to the approximate value of half of their annual remuneration. These rights vest on a quarterly basis over a period of one year, subject only to continuity of service.

Director Name	Number of Rights Issued
Geoff Brooke	1,062,946
Don Brumley	1,062,946
Ross Dobinson	1,675,405
Tim Oldham	1,062,946

3. INTANGIBLE ASSETS

	31 December 2023 \$'000	30 June 2023 \$'000
External development expenditure capitalised	1,071	1,071
Accumulated amortisation	(1,071)	(1,071)
Total intangible assets	-	-



**NOTES TO THE CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
FOR THE HALF-YEAR ENDED 31 DECEMBER 2023 (continued)**

3. INTANGIBLE ASSETS, continued

Reconciliation of the carrying value of capitalised development at the beginning and end of the current reporting period:

	31 December 2023 \$'000	30 June 2023 \$'000
Carrying value of Estradiol spray at the start of the period	-	375
Impairment	-	(321)
Amortisation	-	(54)
Carrying value of Estradiol spray at the end of the period	<u>-</u>	<u>-</u>

Estradiol spray was fully impaired during the year ended 30 June 2023 following the sale of future Lenzetto® royalties in relation to European and other territories. Estradiol spray is still marketed as Evamist® in the US market on behalf of Acrux by Padagis generating nominal quarterly revenue.

4. LEASING

The Group leases its office, laboratory and warehouse facilities. This lease has been extended for the first of the 3 options of 3 years each. This first 3 year lease extension period commenced on 1 June 2022 and the 2 additional options to extend for 3 year periods commence on 1 June 2025 and 1 June 2028. There is no option to purchase the leased asset at the expiry of the lease period.

	31 December 2023 000's	30 June 2023 000's
Lease liabilities are presented in the consolidated statement of financial position as follows:		
Lease liabilities (current)	305	192
Lease liabilities (non-current)	1,954	2,161
Total carrying amount of lease liabilities	<u>2,259</u>	<u>2,353</u>
Carrying amount of lease assets, by class of underlying asset:		
Buildings under lease arrangements		
At cost	2,867	2,867
Accumulated depreciation	(980)	(854)
Total carrying value of buildings under lease arrangements	<u>1,887</u>	<u>2,013</u>
Plant and equipment under lease arrangements		
At cost	89	89
Accumulated depreciation	(80)	(70)
Total carrying value of plant and equipment under lease arrangements	<u>9</u>	<u>19</u>
Total carrying value of leased assets	<u>1,896</u>	<u>2,032</u>

ACRUX LIMITED AND CONTROLLED ENTITIES (ABN: 72 082 001 152)



**NOTES TO THE CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
FOR THE HALF-YEAR ENDED 31 DECEMBER 2023 (continued)**

5. CONTINGENCIES

There were no contingencies as at 31 December 2023.

6. AFTER BALANCE DATE EVENTS

No matter or circumstance has arisen since 31 December 2023 that has significantly affected, or may significantly affect, the Group's operations, results or state of affairs, or may do so in future periods.



DIRECTORS' DECLARATION

The Directors declare that:

(a) in the Directors' opinion, the attached financial statements and notes thereto are in accordance with the *Corporations Act 2001*, including compliance with accounting standards and giving a true and fair view of the financial position and performance of the consolidated entity.

(b) in the Directors' opinion, there are reasonable grounds to believe that the Group will be able to pay its debts as and when they become due and payable; and

Signed in accordance with a resolution of the Directors made pursuant to s.303(5) of the *Corporations Act 2001*.

On behalf of the Directors

A handwritten signature in black ink, appearing to read "Ross Dobinson", with a long horizontal flourish extending to the right.

Ross Dobinson
Non-executive Chairman
Melbourne
27 February 2024

**INDEPENDENT AUDITOR'S REVIEW REPORT
TO THE MEMBERS OF ACRUX LIMITED AND CONTROLLED ENTITIES**

Report on the Half-Year Financial Report

Conclusion

We have reviewed the half-year financial report of Acrux Limited, "the Company" and its controlled entities "the Group", which comprises the condensed consolidated statement of financial position as at 31 December 2023, the condensed consolidated statement of comprehensive income, condensed consolidated statement of changes in equity and condensed consolidated statement of cash flows for the half-year ended on that date, a summary of significant accounting policies and other explanatory information, and the directors' declaration.

Based on our review, which is not an audit, we have not become aware of any matter that makes us believe that the accompanying half-year financial report of the Group does not comply with the *Corporations Act 2001* including:

- (a) giving a true and fair view of the Group's financial position as at 31 December 2023 and of its performance for the half-year ended on that date; and
- (b) complying with Accounting Standard AASB 134 *Interim Financial Reporting* and the *Corporations Regulations 2001*.

Basis for Conclusion

We conducted our review in accordance with ASRE 2410 *Review of a Financial Report Performed by the Independent Auditor of the Entity*. Our responsibilities are further described in the *Auditor's Responsibilities for the Review of the Financial Report* section of our report. We are independent of the Company in accordance with the auditor independence requirements of the *Corporations Act 2001* and the ethical requirements of the Accounting Professional and Ethical Standards Board's APES 110 *Code of Ethics for Professional Accountants (including Independence Standards)* (the Code) that are relevant to our audit of the annual financial report in Australia. We have also fulfilled our other ethical responsibilities in accordance with the Code.

We confirm that the independence declaration required by the *Corporations Act 2001* which has been given to the directors of the Company, would be in the same terms if given to the directors as at the time of this auditor's review report.

Responsibility of the Directors for the Financial Report

The directors of Acrux Limited are responsible for the preparation of the half-year financial report that gives a true and fair view in accordance with Australian Accounting Standards and the *Corporations Act 2001* and for such internal control as the directors determine is necessary to enable the preparation of the half-year financial report that gives a true and fair view and is free from material misstatement, whether due to fraud or error.

Auditor's Responsibility for the Review of the Financial Report

Our responsibility is to express a conclusion on the half-year financial report based on our review. ASRE 2410 requires us to conclude whether we have become aware of any matter that makes us believe that the half-year financial report is not in accordance with the *Corporations Act 2001* including giving a true and fair view of the Group's financial position as at 31 December 2023 and its performance for the half-year ended on that date, and complying with Accounting Standard AASB 134 *Interim Financial Reporting* and the *Corporations Regulations 2001*.

ACRUX LIMITED AND CONTROLLED ENTITIES

ABN 72 082 001 152



**INDEPENDENT AUDITOR'S REVIEW REPORT
TO THE MEMBERS OF ACRUX LIMITED AND CONTROLLED ENTITIES**

A review of a half-year financial report consists of making enquiries, primarily of persons responsible for financial and accounting matters, and applying analytical and other review procedures. A review is substantially less in scope than an audit conducted in accordance with Australian Auditing Standards and consequently does not enable us to obtain assurance that we would become aware of all significant matters that might be identified in an audit. Accordingly, we do not express an audit opinion.

A handwritten signature in black ink, appearing to be "N R Bull".

N R BULL

Partner

27 February 2024

A handwritten signature in black ink, appearing to be "Pitcher Partners".

PITCHER PARTNERS

Melbourne