



**ADHERIUM LIMITED**

ABN 24 605 352 510

ASX: ADR

**APPENDIX 4E**

**PRELIMINARY FINAL REPORT**

**FOR THE YEAR ENDED**

**30 JUNE 2022**

# Adherium Limited

ABN 24 605 352 510

Adherium Limited provides the following information under listing rule 4.3A:

## Details of the reporting period and the previous corresponding period

- Reporting period 12 months ended 30 June 2022
- Previous corresponding period 12 months ended 30 June 2021

## Results for announcement to the market

	12 months 30 June 2022 \$000	12 months 30 June 2021 \$000	Change \$000	Change %
Revenue from ordinary activities	529	401	128	31.9%
Profit (loss) from ordinary activities after tax attributable to members	(11,224)	(15,036)	3,812	25.4%
Net profit (loss) for the period attributable to members	(11,224)	(15,036)	3,812	25.4%
Dividends:				
Amount per Ordinary Share	Nil	Nil		
Franked amount per Ordinary Share	Nil	Nil		
Record date for determining entitlements to the dividends	N/A	N/A		
Net tangible asset backing per Ordinary Share	0.2 cents	0.7 cents		

## Commentary on results

During the 12 months to 30 June 2022, Adherium continued to drive a strong development program of its cutting-edge Hailie® sensors and software platform for both Asthma and chronic obstructive pulmonary disease (COPD) medication inhalers. The Company remains focused on its remote patient monitoring growth strategy following distribution agreements with world-class companies, key regulatory achievements, software platform enhancements and senior management team appointments to help build the Company's commercial expertise.

During the year, Adherium made significant progress, notably:

### US and UK Partnerships

- Most recently, the Company signed a distribution agreement for US patient monitoring with Perigon Health 360 to sell the Hailie platform, including its new, next generation sensors. Adherium's innovative Hailie product portfolio has been incorporated into Perigon's world-class proprietary platform, Medesto, enabling optimum patient management and treatment. The signing of this distribution agreement is for an initial three-year term and patient enrolment and set-up for remote patient monitoring has already commenced.
- Adherium also announced that it signed its first UK distribution agreement with Helicon Health Ltd to sell the Hailie sensor range and cloud data services. Adherium's Hailie sensor connects via the Hailie app to Helicon's comprehensive remote patient monitoring platform creating, for the first time, the most advanced care for Asthma and COPD patients that are in remote settings.
- For clinical trial services, Adherium announced in June 2022 that it has been awarded the contract for the supply of the Hailie solution to Avillion LLP, sponsor of a US-based clinical study in mild Asthma in partnership with AstraZeneca. With the contract revenue guidance of approximately US\$650,000, the

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upcoming clinical study is an expansion of the clinical co-development agreement with AstraZeneca for PT027, a potential first-in-class inhaled, fixed-dose combination rescue medication containing albuterol, a short-acting beta2-agonist (SABA), and budesonide, an inhaled corticosteroid (ICS), in the US.

These agreements mark another milestone in Adherium's journey towards improving clinical outcomes and helping respiratory patients live longer healthier lives. The execution of Adherium's commercial strategy for the Hailie platform in the US and, for the first time, in the UK expands its footprint to deliver enhanced remote patient care, accelerating momentum in the digital healthcare industry.

## Key Regulatory Achievements

- In September 2021, Adherium announced it had received U.S. Food and Drug Administration (FDA) 510(k) clearance to market its first, next generation Hailie sensor with physiological parameters for monitoring Asthma and COPD medication use. That sensor, designed for use with AstraZeneca's Symbicort® aerosol inhaler, was the first in a series of planned Hailie devices specifically designed to enable physicians and providers to enhance patient care and clinical workflow by capturing physiological parameters including inhalation flow rate, duration, volume, and peak inhalation flow. This data is especially valuable for clinicians to improve patient inhaler use technique. Clinical studies have shown that up to 92% of Asthma patients use their inhaler incorrectly. Improving technique improves patient quality of life.
- In January 2022, the Company received its Medicines and Healthcare products Regulatory Agency (MHRA) registration confirmation as a medical devices manufacturer of inhaler dose sensors in the UK. The current generation of Hailie sensor products are CE Marked and are available in the UK to patients working with National Health Service (NHS).
- Adherium announced, in March 2022, the submission to the FDA of a 510(k) clearance to market application to connect Ellipta® inhaler users with its next generation Hailie sensor, and received clearance in July 2022. Adherium's latest Hailie sensor, designed for use with the GlaxoSmithKline (GSK) Ellipta® dry powder inhaler (DPI), is the second in Adherium's series of new next-generation sensors to receive US clearance, following the Hailie for Symbicort®, designed to capture physiological parameters.
- In early August 2022, Adherium announced another submission to the FDA of a 510(k) clearance to market application, this time to connect GSK Ventolin®, Advair®, and Flovent® pressurised metered-dose inhaler (pMDI) users with its next generation Hailie sensor. Most recently, a further 510(k) clearance to market application has been submitted, this for Adherium's fourth next generation Hailie sensor, connecting users of Teva's ProAir® and Albuterol Sulphate HFA metered dose inhalers.

The strong regulatory capabilities the Company is consolidating and further developing will increase global market availability as well as create a competitive advantage in an increasingly regulated global environment. Adherium has 510(k) clearances for 91% of the US top 20 branded inhalers for adherence usage enabling the Remote Therapeutic Monitoring (RTM) reimbursement codes, and 32% coverage for physiological parameters enabling the Remote Physiological Monitoring (RPM) reimbursement codes.

## Hailie® Sensor and Platform Developments

- Adherium continues to make great progress in the development of its next generation Hailie sensors, with the first production run for the new Hailie for Symbicort® completed in February 2022.
- The Company continues to invest in development, updates and enhancements of its innovative digital platform. Especially important is offering a flexible channel platform to integrate the Hailie sensor including introducing an advanced Rest application programming interface (API) and a new, updated software development kit (SDK) to improve connection with channel partners and customer patient management systems. These releases extend Adherium's interoperability capabilities and integration of the Hailie platform with disease management and clinical trial customers.

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## Senior Management and Board Appointments

- In February 2022, Lou Panaccio was appointed as a non-executive director and subsequently, in March 2022, as Chairman of the Board. Mr Panaccio brings more than 30 years of leadership experience in healthcare services, ASX and NASDAQ listings, and has extensive global commercial experience, particularly in the US.
- Adherium welcomed in April 2022 Mr Francis White as Vice President of Global Business Development based in the UK. Previously serving as Managing Director of Olympus Medical UKIE, Mr White brings over 20 years of healthcare leadership experience, including key account management, sales and marketing expertise.
- Following Mr White's appointment, Adherium appointed Tara Creaven-Capasso as its Vice President of Quality, Regulatory and Clinical Affairs. With over two decades of experience in the medical device, pharmaceutical, bioscience, and vaccine sectors, Mrs Creaven-Capasso joins Adherium from COVID19 Vaccine Corporation Ltd. (CVC), which she co-founded in 2020.

At this pivotal time in Adherium's market expansion strategy, the Company is pleased to welcome Mr Lou Panaccio, Mr Francis White and Mrs Tara Creaven-Capasso, strengthening both the Board and leadership team, and ensuring it remains poised to capitalise on all upcoming commercial opportunities as it progresses through the development of its Hailie sensors and integrated digital platform.

## Financial commentary

- Revenue to 30 June 2022 was \$529,000, compared with \$401,000 in the prior year, the increase due to a higher level of clinical trial activity in 2022.
- Research and development activities to 30 June 2022 amounted to \$5,877,000 compared with \$5,477,000 in the prior year, the increased expenditure resulting from progress in developing the new next generation sensors with physiological parameters, and the enhanced Hailie portal, Rest API and SDK.
- Sales and Marketing costs were \$944,000 to 30 June 2022, compared with \$845,000 in the prior year. This increase reflects recruitment and increased activity in the US and UK which has resulted in the announced commercial arrangements.
- Administrative costs decreased to \$5,263,000 for 2022, down from \$6,143,000 in the year ended 30 June 2021. Within this, payroll decreased from \$1,751,000 in the prior year to \$1,654,000 following senior management changes earlier in the year, and non-cash costs included asset depreciation and amortisation expense of \$183,000 compared to \$145,000 in the prior year. The overall decrease in administrative costs related largely to the decrease in foreign exchange losses of \$33,000 in 2022 compared to losses of \$888,000 in the prior year.
- In the year to 30 June 2022, the Company received in cash annual Australian R&D Tax Incentives of \$370,000 and \$1,627,000 for both the 2020 and 2021 financial years respectively, and the Company intends to submit an R&D Tax Incentive claim for the 2022 financial year before the end of calendar 2022.
- In addition to the changes noted above, the loss for the 2022 year of \$11,224,000 decreased from \$15,036,000 in 2021 due to finance expenses of \$2,228,000 on convertible notes. Those notes converted to ordinary shares during the 2021 financial year and so the finance expenses did not reoccur in 2022.
- Adherium ended the year to 30 June 2022 with cash of \$5,283,000.

## Dividends

The board has not declared dividends or made dividend payments in the periods ended 30 June 2021 and 2022. The Company does not have any dividend or distribution reinvestment plans in operation.

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## Details of entities over which control has been gained or lost

There have been no changes in control over entities in the year ended 30 June 2022.

## Details of associates and joint venture

Adherium does not have any associates or joint ventures.

## Audit status

This Appendix 4E and the included financial information are based on financial statements which are in the process of being audited and the audited financial statements will be published in September 2022. As in prior years, the independent auditor's report may contain an emphasis of matter reflecting a material uncertainty in respect of going concern related to the raising of additional capital or alternative funding until the group is supported by cash flows from operations. Despite this, the Directors are of the view that adoption of the going concern basis of preparation of the financial statements continues to be appropriate.

## Financial report

The following financial report included in this Appendix 4E does not include all notes of the type normally included within the annual financial report and therefore cannot be expected to provide as full an understanding of the financial performance, financial position and operating, financing and investing activities of the consolidated entity as the full financial report. The financial report should be read in conjunction with any public announcements made by Adherium Limited in accordance with the continuous disclosure obligations of the ASX Listing Rules.

The accounting policies applied are the same as those noted in the most recent interim financial report and the previous annual report.

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## Consolidated Statement of Profit or Loss and Other Comprehensive Income for the year ended 30 June 2022

		12 months June 2022 \$000	12 months June 2021 \$000
<b>Continuing Operations</b>			
Sales	1	529	401
Cost of sales		(207)	(426)
<b>Gross profit</b>		322	(25)
Other income – Covid19 payroll support		-	61
Other income – R&D tax credit		1,627	370
Manufacturing support		(1,012)	(764)
Research and development costs		(5,877)	(5,477)
Sales and marketing costs		(944)	(845)
Administrative expenses		(5,363)	(6,143)
<b>Operating loss</b>		(11,247)	(12,823)
Finance income	1	24	23
Finance expense		(1)	(2,236)
<b>Finance income (cost) - net</b>		23	(2,213)
<b>Loss before income tax</b>	1	(11,224)	(15,036)
Income tax expense		-	-
<b>Loss for the period attributable to equity holders</b>		(11,224)	(15,036)
<b>Other Comprehensive Income</b>			
Items that may be reclassified subsequently to profit or loss when certain conditions are met:			
Foreign exchange differences on translation of foreign operations		57	864
<b>Other comprehensive income for the period, net of tax</b>		57	864
<b>Total comprehensive loss for the period</b>		(11,167)	(14,172)
<b>Total comprehensive loss attributable to:</b>			
Equity holders of Adherium Limited		(11,167)	(14,172)
<b>Basic and diluted loss per share</b>	3	(0.5) cents	(1.7) cents

The accompanying notes form part of this financial report.

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## Consolidated Statement of Financial Position as at 30 June 2022

<b>ASSETS</b>	<i>Notes</i>	<b>June 2022</b>	<b>June 2021</b>
		<b>\$000</b>	<b>\$000</b>
<b>Current assets</b>			
Cash and cash equivalents	4	5,283	15,178
Trade and other receivables	5	420	567
Inventories	6	1,071	962
Prepayments		272	202
<b>Total current assets</b>		<b>7,046</b>	<b>16,909</b>
<b>Non-current assets</b>			
Property, plant and equipment		227	127
Intangible assets		1	3
Right-of-use assets		86	-
<b>Total assets</b>		<b>7,360</b>	<b>17,039</b>
<b>LIABILITIES</b>			
<b>Current liabilities</b>			
Trade and other payables		1,697	2,319
Income received in advance		1,214	685
Lease liabilities		42	-
<b>Total current liabilities</b>		<b>2,953</b>	<b>3,004</b>
<b>Non-current liabilities</b>			
Lease liabilities		43	-
<b>Total liabilities</b>		<b>2,996</b>	<b>3,004</b>
<b>EQUITY</b>			
Share capital	8	110,523	110,172
Accumulated deficit		(84,609)	(73,385)
Other reserves		(21,550)	(22,752)
<b>Total equity</b>		<b>4,364</b>	<b>14,035</b>
<b>Total liabilities &amp; equity</b>		<b>7,360</b>	<b>17,039</b>

The accompanying notes form part of this financial report.

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## Consolidated Statement of Changes in Equity for the year ended 30 June 2022

	Share Capital	Accumulated Deficit	Share, Option & SARs Compensation Reserve	Foreign Currency Translation Reserve	Merger Reserve	Total Equity
	\$000	\$000	\$000	\$000	\$000	\$000
<b>Equity as at 1 July 2021</b>	110,172	(73,385)	4,170	613	(27,535)	14,035
Loss for the period	-	(11,224)	-	-	-	(11,224)
Other comprehensive income (loss)	-	-	-	57	-	57
Total comprehensive loss	-	(11,224)	-	57	-	(11,167)
<i>Transactions with owners:</i>						
Share, option and SARs grants for services	351	-	1,145	-	-	1,496
<b>Equity as at 30 June 2022</b>	<b>110,523</b>	<b>(84,609)</b>	<b>5,315</b>	<b>670</b>	<b>(27,535)</b>	<b>4,364</b>
<b>Equity as at 1 July 2020</b>	87,682	(58,349)	1,837	(251)	(27,535)	3,384
Loss for the period	-	(15,036)	-	-	-	(15,036)
Other comprehensive income (loss)	-	-	-	864	-	864
Total comprehensive loss	-	(15,036)	-	864	-	(14,172)
<i>Transactions with owners:</i>						
Shares and options issued on conversion of Convertible Notes	4,063	-	1,165	-	-	5,228
Shares and options issued in Placement	19,014	-	858	-	-	19,872
Share and option grants for services	222	-	310	-	-	532
Share issue costs	(809)	-	-	-	-	(809)
<b>Equity as at 30 June 2021</b>	<b>110,172</b>	<b>(73,385)</b>	<b>4,170</b>	<b>613</b>	<b>(27,535)</b>	<b>14,035</b>

The accompanying notes form part of this financial report.



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## Consolidated Statement of Cash Flows for the year ended 30 June 2022

	<i>Notes</i>	<b>12 months June 2022 \$000</b>	<b>12 months June 2021 \$000</b>
<b>Cash flows from operating activities:</b>			
Receipts from customers		809	782
Research and development tax incentive receipts		1,997	-
Interest received		24	23
Interest paid		(1)	(8)
Payments to employees		(5,918)	(4,536)
Payments to suppliers		(6,521)	(7,534)
Net cash used in operating activities		(9,610)	(11,273)
<b>Cash flows from investing activities:</b>			
Purchase of property, plant and equipment		(279)	(29)
Net cash used in investing activities		(279)	(29)
<b>Cash flows from financing activities:</b>			
Proceeds from the issues of shares	8	-	19,872
Proceeds from the issue of Convertible Notes	7	-	3,000
Payment of capital raising costs		-	(968)
Net cash provided from financing activities		-	21,904
Net increase (decrease) in cash		(9,889)	10,602
Cash at the beginning of the period		15,178	4,584
Effect of exchange rate changes on cash balances		(6)	(8)
<b>Cash at the end of the period</b>	4	<b>5,283</b>	<b>15,178</b>
<b>Reconciliation with loss after income tax:</b>			
Loss after income tax		(11,224)	(15,036)
<i>Non-cash items requiring adjustment:</i>			
Depreciation of property, plant and equipment		181	142
Amortisation of intangible assets		2	3
Fixed assets (gain)/loss on disposal		(1)	(5)
Convertible notes finance cost		-	2,228
Convertible notes issue cost		-	94
Share, option and SARs compensation expense		1,145	310
Shares granted for services		351	222
Foreign exchange loss (gain)		33	888
<i>Changes in working capital:</i>			
Trade and other receivables		(5)	(1)
Inventories		(144)	150
Trade and other payables		(525)	(268)
Income received in advance		577	-
Net cash provided from (used in) operating activities		(9,610)	(11,273)

The accompanying notes form part of this financial report.

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## Notes to the condensed consolidated financial statements for the year ended 30 June 2022

	12 months June 2022 \$000	12 months June 2021 \$000
<b>1. Revenues and expenses</b>		
<b>(a) Income from continuing operations</b>		
Sensor sales and monitoring services	294	264
New product design, engineering and other services	235	137
Total income from continuing operations	529	401
<b>(b) Loss before income tax includes the following specific expenses:</b>		
Depreciation of property, plant and equipment	181	142
Amortisation of intangible assets	2	3
Operating lease costs	140	89
Employee benefits expense		
- Wages and salaries	5,943	4,661
- Share, option and SARs compensation	1,102	189
Total employee benefits expense	7,045	4,850

## 2. Segment Information

The chief operating decision maker is the Chief Executive Officer, who reviews financial information for the Group as a whole. The information reviewed is prepared in the same format as included in the financial statements. The Company has therefore determined that one reportable segment exists for the Company's Hailie® business.

## 3. Earnings per share

Basic loss per share is based upon the weighted average number of outstanding ordinary shares. For all periods presented, the Company's potentially dilutive ordinary share equivalents (being the Convertible Notes and Options over ordinary shares) have an anti-dilutive effect on loss per share and, therefore, have not been included in determining the total weighted average number of ordinary shares outstanding for the purpose of calculating diluted loss per share.

	12 months June 2022 \$000	12 months June 2021 \$000
Profit (loss) after income tax attributable to equity holders	(11,224)	(15,036)
Weighted average shares outstanding (basic and diluted)	2,173,918,843	900,972,255
Basic and diluted loss per share	(0.5) cents	(1.7) cents

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## 4. Cash and cash equivalents and short-term investments

	June 2022 \$000	June 2021 \$000
Cash at bank and on hand	315	162
Deposits at call	4,968	15,016
	<u>5,283</u>	<u>15,178</u>

## 5. Trade and other receivables

	June 2022 \$000	June 2021 \$000
Trade receivables and accruals	302	100
R&D tax credit accrued	-	370
GST and other taxes receivable	62	77
Security deposit	56	20
	<u>420</u>	<u>567</u>

## 6. Inventories

	June 2022 \$000	June 2021 \$000
Raw materials and components	960	868
Finished goods	111	94
	<u>1,071</u>	<u>962</u>

## 7. Convertible Notes

### June 2021

During the year to 30 June 2021 the Company issued Secured Convertible Notes ("2020 Notes") with a face value of \$3 million, an interest rate of 9% per annum, and maturity date of 25 October 2022. The terms of the 2020 Notes included conversion features, which allowed the noteholder to convert the principal and accrued interest to shares in the Company at 3 cents per share after the occurrence of certain events, including partnering and funding milestones.

The 2020 Notes were accounted for as two separate liability components from their issue date – the debt portion recorded at amortised cost and the embedded derivative conversion option recorded at fair value. In accounting for the debt portion of the 2020 Notes, settlement was assumed to take place on 25 October 2022 with interest accruing at 9% per annum to that date. The calculation of the fair value of the embedded derivative conversion option took into account the probability of the noteholder converting and the market price of the ordinary shares.

On 18 March 2021 the Company and noteholder agreed to modify the 2020 Notes' terms to:

- automatically convert the 2020 Notes principal plus interest to ordinary shares at the same time and price as under a capital raise for at least \$15 million; and
- in consideration of the variation of the 2020 Notes to provide for the automatic conversion mechanism referred to above; at closing of the capital raising to issue to the noteholder various options over ordinary shares.

On 30 April 2021, the Company received shareholder approval to amend the 2020 Notes and proceed with the capital raise. This was completed on 7 May 2021 for a total of \$18 million, and accordingly the 2020 Notes automatically converted to 238,989,991 ordinary shares in addition to the grant to the noteholder of:

- 25,000,000 options with an exercise price of \$0.02 and an expiry date of 7 May 2023;
- 25,000,000 options with an exercise price of \$0.03 and an expiry date of 7 May 2023;
- 25,000,000 options with an exercise price of \$0.04 and an expiry date of 7 May 2023; and

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- 104,855,877 options with an exercise price of \$0.03 and an expiry date of 25 October 2022.

The fair value of the modification of the 2020 Notes terms was assessed at \$1,344,000, and the fair value of the options granted \$1,165,000, with both recorded as a finance cost.

Convertible Notes	June 2021		
	Debt component at amortised cost	Embedded derivative conversion option at fair value	Total
	\$000	\$000	\$000
Recognition at Note issue	1,622	1,378	3,000
Financing cost:			
- Amortised cost	519	-	519
- Fair value change		(800)	(800)
- Modification	1,444	(100)	1,344
<b>Total financing cost</b>	<b>1,963</b>	<b>(900)</b>	<b>1,063</b>
<b>Carrying value at conversion</b>	<b>3,585</b>	<b>478</b>	<b>4,063</b>
Conversion:			
- Shares issued			4,063
			<b>4,063</b>

## 8. Share capital

	Ordinary Shares	\$000
<b>Share capital as at 1 July 2020</b>	601,906,334	87,682
Shares issued in employee share plans	13,250,000	-
Shares issued in placements	1,262,405,631	19,014
Shares issued on conversion of Convertible Notes	238,989,991	4,063
Shares issued for services	9,181,155	222
Shares issue costs	-	(809)
<b>Share capital as at 30 June 2021</b>	<b>2,125,733,111</b>	<b>110,172</b>
Shares issued in employee share plans	68,490,750	-
Cancellation of shares issued in employee share plans	(7,399,372)	-
Shares issued for services	21,426,603	351
Shares issue costs	-	-
<b>Share capital as at 30 June 2022</b>	<b>2,208,251,092</b>	<b>110,523</b>

## 9. Events occurring after the balance sheet date

There are no events occurring after the balance sheet date which require disclosure or adjustment in the financial statements.