



**Monday 27th February 2023**

## **ASX Announcement**

### **Preliminary Results for the year ending 31 December 2022**

InhaleRx Ltd (ASX: IRX), ("**InhaleRx**", "**IRX**" or "**the Company**") an Australian healthcare company developing unique medicinal cannabinoid drug-device products to address unmet medical needs in pain management and mental health sectors, is pleased to provide its Preliminary Financial Report for the year ending 31 December 2022.

The financial loss for the consolidated entity, after providing for income tax and non-controlling interests, amounted to \$1,896,605 up 71% compared to previous period (31 December 2021: \$1,111,129), with the Company substantially increasing its research and development activities and associated expenditure during the year.

IRX is presently a small company, both by market capitalisation and the scale of its operations. However, significant ground was covered by the small, but extremely capable IRX team over the course of 2022 calendar year, with important progress made with respect to the Company's novel treatments for Complex Regional Pain Syndrome ("**CRPS**") and Panic Disorder ("**PD**").

CRPS is a form of chronic pain that usually affects an arm or a leg. It typically develops after an injury, a surgery, a stroke or a heart attack. The pain is out of proportion to the severity of the initial injury. CRPS is a significant cause of disability globally. In addition, no drugs have been specifically approved for CRPS and patients often resort to a combination of opioids, lyrica and atypical antidepressants. There remains a significant need for additional therapies to improve the therapeutic outcome for these patients as the sudden onset of pain and time to analgesic effect from current treatments is mismatched.

PD refers to the experience of recurrent and disabling panic attacks which last up to a few minutes and are accompanied by physical symptoms such as heart palpitations, shaking, shortness of breath, and dizziness. Currently, there are no effective treatments for PD and sufferers are forced to rely on atypical antidepressants (SSRI), sedatives (benzodiazapines) and anti-convulsants (gabapentin).

The Company's overarching goal is to achieve a New Drug Approval ("**NDA**") with the FDA for both CRPS and PD. IRX is committed to driving cost efficiencies while delivering quality outcomes in the shortest time frame possible.

In the case of each treatment, IRX has now completed the following:

- Development of novel drug formulations and the completion of stability testing;
- Drafting of clinical trial Protocols and Investigator Brochures;
- Identification and procurement of the necessary Active Pharmaceutical Ingredients ("**API**") and pressurised metered dose inhaler ("**pMDI**") device componentry;
- Commissioned the manufacturing of the trial drugs; and

- Completion of an international tender for the selection of a Clinical Research Organisation (“**CRO**”) to oversee the clinical trial programmes.

In addition, the IRX team has continued to make significant progress in the Company’s journey towards opening an Investigational New Drug (“**IND**”) application with the US Food & Drug Administration (“**FDA**”) for each indication. Significantly, on 19 October 2022, IRX completed a pre-IND meeting with the FDA covering its plans for the development of its cannabidiol (“**CBD**”) drug device combination for the treatment of PD, which was a very informative and affirming meeting. IRX has also progressed an Ethics Committee submission in preparation for the planned Phase 1 clinical trial of its tetrahydrocannabinol (“**THC**”) based drug-device combination for the treatment of CRPS to be conducted in Melbourne over the coming months. A pre-IND meeting with the FDA for this treatment has also been scheduled for 30<sup>th</sup> March 2023.

On 17 February 2023, at the Extraordinary General Meeting, shareholders approved the appointment of Ingenu CRO Pty Ltd (which is a related party) as CRO for the proposed clinical trial programme for each. Ingenu CRO was selected through a competitive tender process and presented the most attractive offer received on a value for money basis.

The planned clinical trial programme will be some of the first clinical trials involving inhaled cannabinoid medications for treating pain and anxiety related conditions. Furthermore, we expect that they will also be the first clinical trials for inhaled cannabinoid treatments for CRPS and panic disorder to be completed anywhere in the world. The IRX Board and Management team are very excited about the prospect of commencing the clinical trial programmes and are very optimistic about where these programmes may lead.

Revenue from the sale of Medihale inhalation devices and pods was \$24,800 for the 2022 year versus \$181,700 in 2021. During the second half of FY22, the Company completed a review of its Voom based Medihale inhalation device offering and identified a C-cell inhalation device model as a superior offering in terms of design and functionality. As a result, the Company ceased sales of the Voom device and the remaining stock was written-off in October. It is expected that the new Medihale 2.0 device will be launched once a review of the Company’s inhalation device supply chain is completed over the coming months.

Approved by the Board of Directors:

**For further information:**

[www.inhalerx.com.au](http://www.inhalerx.com.au)

Nova Taylor, Company Secretary

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**About InhaleRx Limited (ASX: IRX) – [www.inhalerx.com.au](http://www.inhalerx.com.au)**

InhaleRx Limited (ASX: IRX) (“**InhaleRx**” or “**the Company**”) is an Australian healthcare company which is developing novel cannabinoid derived drug device combination medications to serve unmet needs in pain management and mental health sectors.

The overarching goal is to pursue U.S. FDA approval and registration to treat Panic Disorder and Complex Regional Pain Syndrome using rapid and cost effective regulatory pathways, such as 505(b)(2). A 505(b)(2) application is a New Drug Approval that contains full reports of investigations

InhaleRx Limited (ACN 611 845 820)  
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of safety and effectiveness, where at least some of the information required for approval comes from studies available in the public domain.

There is a significant economic opportunity for InhaleRx and the Company's shareholders as these carefully selected medical indications under investigation currently have extremely limited treatment options, whilst also offering a low side effect profile.

InhaleRx holds an innovation patent and will be developing further defensible IP as the two clinical trial programmes enter the execution phase.

**InhaleRx Limited**  
**Appendix 4E**  
**Preliminary final report**

**1. Company details**

Name of entity:	InhaleRx Limited
ACN:	611 845 820
Reporting period:	For the year ended 31 December 2022
Previous period:	For the year ended 31 December 2021

**2. Results for announcement to the market**

			\$
Revenues from ordinary activities	down	77.5% to	40,927
Loss from ordinary activities after tax attributable to the owners of InhaleRx Limited	up	70.7% to	(1,896,605)
Loss for the year attributable to the owners of InhaleRx Limited	up	70.7% to	(1,896,605)

*Dividends*

There were no dividends paid, recommended or declared during the current financial period.

*Comments*

The loss for the consolidated entity after providing for income tax amounted to \$1,896,605 (31 December 2021: \$1,111,129).

**3. Net tangible assets**

	Reporting period Cents	Previous period Cents
Net tangible assets per ordinary security	<u>1.02</u>	<u>1.58</u>

**4. Control gained over entities**

Not applicable.

**5. Loss of control over entities**

During the year the below subsidiaries were liquidated: -

- Body Tel GmbH
- Lifespot AG
- Seng-Vital GmbH

	\$
Contribution of such entities to the reporting entity's profit/(loss) from ordinary activities before income tax during the period (where material)	10,924
Profit/(loss) from ordinary activities before income tax of the controlled entity (or group of entities) whilst controlled during the whole of the previous period (where material)	(69,406)

## 6. Dividends

### *Current period*

There were no dividends paid, recommended or declared during the current financial period.

### *Previous period*

There were no dividends paid, recommended or declared during the previous financial period.

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## 7. Dividend reinvestment plans

Not applicable.

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## 8. Details of associates and joint venture entities

Not applicable.

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## 9. Foreign entities

### *Details of origin of accounting standards used in compiling the report:*

Not applicable.

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## 10. Audit qualification or review

### *Details of audit/review dispute or qualification (if any):*

The financial statements have not been audited.

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## 11. Attachments

### *Details of attachments (if any):*

The Preliminary Report of InhaleRx Limited for the year ended 31 December 2022 is attached.

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## 12. Signed

Signed  \_\_\_\_\_

Sean Williams

Date: 27 February 2023

**InhaleRx Limited**

**ACN 611 845 820**

**Preliminary Report - 31 December 2022**

**InhaleRx Limited**  
**Statement of profit or loss and other comprehensive income**  
**For the year ended 31 December 2022**

	<b>Note</b>	<b>Consolidated 2022 \$</b>	<b>2021 \$</b>
<b>Revenue</b>	2	24,800	181,740
Other income		10,924	-
Interest revenue		16,127	334
<b>Expenses</b>			
Cost of goods sold		-	(115,232)
Directors' fees and costs		(279,467)	(188,132)
Employee benefits expense		(42,254)	(228,106)
Depreciation and amortisation expense		(521)	(1,814)
Consulting costs		(366,960)	(378,593)
Corporate expenses		(192,747)	(143,131)
Marketing expenses		(33,883)	(52,345)
Product development expenditure		(951,387)	(116,990)
Other expenses		(81,237)	(68,860)
<b>Loss before income tax expense</b>		(1,896,605)	(1,111,129)
Income tax expense		-	-
<b>Loss after income tax expense for the year attributable to the owners of InhaleRx Limited</b>		(1,896,605)	(1,111,129)
<b>Other comprehensive income</b>			
<i>Items that may be reclassified subsequently to profit or loss</i>			
Foreign currency translation		(706)	18,820
Other comprehensive income for the year, net of tax		(706)	18,820
<b>Total comprehensive loss for the year attributable to the owners of InhaleRx Limited</b>		<u>(1,897,311)</u>	<u>(1,092,309)</u>
		<b>Cents</b>	<b>Cents</b>
Basic earnings per share	9	(1.096)	(0.663)
Diluted earnings per share	9	(1.096)	(0.663)

*The above statement of profit or loss and other comprehensive income should be read in conjunction with the accompanying notes*

**InhaleRx Limited**  
**Statement of financial position**  
**As at 31 December 2022**

	<b>Note</b>	<b>Consolidated 2022 \$</b>	<b>2021 \$</b>
<b>Assets</b>			
<b>Current assets</b>			
Cash and cash equivalents	3	2,133,388	2,803,480
Trade and other receivables		31,684	19,138
Inventories		-	20,605
Other	4	79,263	64,689
Total current assets		<u>2,244,335</u>	<u>2,907,912</u>
<b>Non-current assets</b>			
Property, plant and equipment		-	9,707
Intangibles		13,745	13,570
Total non-current assets		<u>13,745</u>	<u>23,277</u>
<b>Total assets</b>		<u>2,258,080</u>	<u>2,931,189</u>
<b>Liabilities</b>			
<b>Current liabilities</b>			
Trade and other payables	5	179,913	228,545
Contract liabilities		-	24,800
Employee benefits		179	-
Other	6	150,000	-
Total current liabilities		<u>330,092</u>	<u>253,345</u>
<b>Total liabilities</b>		<u>330,092</u>	<u>253,345</u>
<b>Net assets</b>		<u>1,927,988</u>	<u>2,677,844</u>
<b>Equity</b>			
Issued capital	7	13,927,516	12,901,135
Reserves	8	(304,082)	(968,991)
Accumulated losses		<u>(11,695,446)</u>	<u>(9,254,300)</u>
<b>Total equity</b>		<u>1,927,988</u>	<u>2,677,844</u>

*The above statement of financial position should be read in conjunction with the accompanying notes*



**InhaleRx Limited**  
**Statement of changes in equity**  
**For the year ended 31 December 2022**

<b>Consolidated</b>	<b>Issued capital \$</b>	<b>Reserves \$</b>	<b>Accumulated losses \$</b>	<b>Total equity \$</b>
Balance at 1 January 2021	10,454,902	(987,811)	(8,143,171)	1,323,920
Loss after income tax expense for the year	-	-	(1,111,129)	(1,111,129)
Other comprehensive income for the year, net of tax	-	18,820	-	18,820
Total comprehensive income for the year	-	18,820	(1,111,129)	(1,092,309)
<i>Transactions with owners in their capacity as owners:</i>				
Contributions of equity, net of transaction costs (note 7)	2,446,233	-	-	2,446,233
Balance at 31 December 2021	<u>12,901,135</u>	<u>(968,991)</u>	<u>(9,254,300)</u>	<u>2,677,844</u>
<b>Consolidated</b>	<b>Issued capital \$</b>	<b>Reserves \$</b>	<b>Accumulated losses \$</b>	<b>Total equity \$</b>
Balance at 1 January 2022	12,901,135	(968,991)	(9,254,300)	2,677,844
Loss after income tax expense for the year	-	-	(1,896,605)	(1,896,605)
Other comprehensive loss for the year, net of tax	-	(706)	-	(706)
Total comprehensive loss for the year	-	(706)	(1,896,605)	(1,897,311)
Transfer relating to expired options	-	(32,227)	32,227	-
Transfer relating to liquidated subsidiaries	-	576,768	(576,768)	-
<i>Transactions with owners in their capacity as owners:</i>				
Contributions of equity, net of transaction costs (note 7)	1,026,381	-	-	1,026,381
Share-based payments	-	27,028	-	27,028
Transfer to profit and loss on derecognition of FX subsidiaries	-	94,046	-	94,046
Balance at 31 December 2022	<u>13,927,516</u>	<u>(304,082)</u>	<u>(11,695,446)</u>	<u>1,927,988</u>

*The above statement of changes in equity should be read in conjunction with the accompanying notes*

**InhaleRx Limited**  
**Statement of cash flows**  
**For the year ended 31 December 2022**

	<b>Note</b>	<b>Consolidated</b>	
		<b>2022</b>	<b>2021</b>
		<b>\$</b>	<b>\$</b>
<b>Cash flows from operating activities</b>			
Receipts from customers		-	117,879
Payments to suppliers and employees		(1,862,293)	(1,281,220)
		(1,862,293)	(1,163,341)
Interest received		15,995	334
Other revenue		-	14,439
		(1,846,298)	(1,148,568)
<b>Cash flows from investing activities</b>			
Payments for property, plant and equipment		-	(11,521)
Payments for intangibles		(175)	(13,570)
		(175)	(25,091)
<b>Cash flows from financing activities</b>			
Proceeds from issue of shares		1,200,000	2,271,042
Share issue transaction costs		(23,619)	(13,139)
		1,176,381	2,257,903
Net increase/(decrease) in cash and cash equivalents		(670,092)	1,084,244
Cash and cash equivalents at the beginning of the financial year		2,803,480	1,719,479
Effects of exchange rate changes on cash and cash equivalents		-	(243)
Cash and cash equivalents at the end of the financial year	3	<u>2,133,388</u>	<u>2,803,480</u>

*The above statement of cash flows should be read in conjunction with the accompanying notes*

**InhaleRx Limited**  
**Notes to the financial statements**  
**31 December 2022**

**Note 1. Operating segments**

*Identification of reportable operating segments*

The consolidated entity is organised into one operating segments: being development of various medical technologies. This operating segment is based on the internal reports that are reviewed and used by the Board of Directors (who are identified as the Chief Operating Decision Makers ('CODM')) in assessing performance and in determining the allocation of resources.

**Note 2. Revenue**

	<b>Consolidated</b>	
	<b>2022</b>	<b>2021</b>
	<b>\$</b>	<b>\$</b>
<i>Revenue from contract with customers</i>		
Sales of services	-	19,829
Sales of goods	24,800	147,472
	<u>24,800</u>	<u>167,301</u>
<i>Other revenue</i>		
Other revenue	-	14,439
	<u>-</u>	<u>14,439</u>
Revenue	<u>24,800</u>	<u>181,740</u>

**Note 3. Current assets - cash and cash equivalents**

	<b>Consolidated</b>	
	<b>2022</b>	<b>2021</b>
	<b>\$</b>	<b>\$</b>
Cash at bank	122,326	2,803,480
Cash on deposit	2,011,062	-
	<u>2,133,388</u>	<u>2,803,480</u>

**Note 4. Current assets - other**

	<b>Consolidated</b>	
	<b>2022</b>	<b>2021</b>
	<b>\$</b>	<b>\$</b>
Prepayments	79,263	63,611
Other current assets	-	1,078
	<u>79,263</u>	<u>64,689</u>

**Note 5. Current liabilities - trade and other payables**

	<b>Consolidated</b>	
	<b>2022</b>	<b>2021</b>
	<b>\$</b>	<b>\$</b>
Trade payables *	97,435	73,355
Other payables *	82,478	155,190
	<u>179,913</u>	<u>228,545</u>

\* all trade and other payables are unsecured

**InhaleRx Limited**  
**Notes to the financial statements**  
**31 December 2022**

**Note 6. Current liabilities - other**

	<b>Consolidated</b>	
	<b>2022</b>	<b>2021</b>
	<b>\$</b>	<b>\$</b>
Funds received ahead of the issue of shares	150,000	-

**Note 7. Equity - issued capital**

	<b>2022</b>	<b>2021</b>	<b>2022</b>	<b>2021</b>
	<b>Shares</b>	<b>Shares</b>	<b>\$</b>	<b>\$</b>
Ordinary shares - fully paid	187,266,957	168,466,957	13,927,516	12,901,135

*Movements in ordinary share capital*

<b>Details</b>	<b>Date</b>	<b>Shares</b>	<b>Issue price</b>	<b>\$</b>
Balance	1 January 2021	134,773,493		10,454,902
Issue of shares	5 January 2021	22,363,891	\$0.0700	1,565,472
Issue of shares	19 January 2021	11,329,573	\$0.0700	793,070
Reversal of prior year accrual in relation to cost of capital raised		-	\$0.0000	100,830
Less cost of capital raised		-	\$0.0000	(13,139)
Balance	31 December 2021	168,466,957		12,901,135
Issue of shares	3 October 2022	17,500,000	\$0.0600	1,050,000
Issue of shares to lead manager	3 October 2022	1,300,000	\$0.0600	78,000
Less cost of capital raised		-	\$0.0000	(101,619)
	31 December 2022	187,266,957		13,927,516

**Note 8. Equity - reserves**

	<b>Consolidated</b>	
	<b>2022</b>	<b>2021</b>
	<b>\$</b>	<b>\$</b>
Foreign currency reserve	-	(93,340)
Share-based payments reserve	27,028	32,227
Other reserves	-	(576,768)
Non-controlling interest derecognised	(331,110)	(331,110)
	(304,082)	(968,991)

**InhaleRx Limited**  
**Notes to the financial statements**  
**31 December 2022**

**Note 9. Earnings per share**

	<b>Consolidated</b>	
	<b>2022</b>	<b>2021</b>
	<b>\$</b>	<b>\$</b>
Loss after income tax attributable to the owners of InhaleRx Limited	<u>(1,896,605)</u>	<u>(1,111,129)</u>
	<b>Number</b>	<b>Number</b>
Weighted average number of ordinary shares used in calculating basic earnings per share	<u>173,051,066</u>	<u>167,570,844</u>
Weighted average number of ordinary shares used in calculating diluted earnings per share	<u>173,051,066</u>	<u>167,570,844</u>
	<b>Cents</b>	<b>Cents</b>
Basic earnings per share	(1.096)	(0.663)
Diluted earnings per share	(1.096)	(0.663)