



Monday 28th February 2022

ASX Announcement

Preliminary Results for the year ending 31 December 2021

InhaleRx Limited (ASX:IRX) (InhaleRx) (“IRX or the Company”) is pleased to provide its preliminary financial report for the year ending 31 December 2021.

The financial loss for the consolidated entity after providing for income tax and non-controlling interests amounted to \$1,111,129, down 7.8% compared to the previous period (31 December 2020: \$1,205,276).

Revenue from the sale of Medihale vaping devices and pods was \$167,301 for the 2021 year versus \$12,557 in 2020. A recent renewed focus on business development has generated significant interest from potential ‘white label’ partners in Australia and New Zealand and the Company is currently considering a range of opportunities to increase the market penetration of its Medihale devices. Having also recently applied for the necessary wholesale and import/export licenses to allow it to commence sourcing and supplying medicinal cannabinoid medications, the Company will also shortly be in the position to commence marketing its own medicinal cannabinoid medications for use in its Medihale device and pods.

Aside from the continued marketing focus on the Medihale inhalation device, during the year the Company began working on developing a range of inhaled therapeutic medicinal formulations for registration domestically and internationally. IRX is currently in the process of developing formulations for the treatment of chronic regional pain syndrome (**CRPS**) and panic disorder (**PD**) and is in the process of opening Investigational New Drug applications (**IND’s**) with the US Food & Drug Administration (**FDA**) for each formulation.

CRPS is a form of chronic pain that usually affects an arm or a leg. CRPS 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. 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. There are currently no effective treatments for PD with

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sufferers forced to rely on atypical antidepressants (SSRI), sedatives (benzodiazapines) and anticonvulsants (gabapentin).

IRX is in the process of developing novel drug device combinations of THC (CRPS) and CBD (PD) in pressurised metered dose inhalers (PMDI) for rapid onset symptomatic relief.

It is intended that the novel drug device combination will be designed to treat individuals with CRPS and PD, with the following objectives:

- Faster onset pain relief and relief from panic attacks;
- Reduced concomitant opioid and anti-depressant usage; and
- More convenient alternative to inhaling heated THC or CBD.

It is envisaged that these solutions will help to improve the quality of life of CRPS and PD sufferers. Furthermore, the novel drug device combination will improve the administrative efficiency and dose metering compared to smoking, vaping or oral administration of cannabinoids.

The ultimate goal of the Company is a pursuit of approval(s) with the U.S. Food and Drug Administration (FDA) via the 505(b)(2) pathway. There are many benefits to the hybrid structure of 505(b)(2), as it can be a much less expensive and much faster route to approval when compared to the alternative FDA options.

The regulatory and clinical team assembled to support the Company have extensive experience in navigating 505(b)(2), and the Company's Board is confident that this presents a far more attractive opportunity than pursuing a registration with the Therapeutic Goods Administration (TGA). Notwithstanding the plans for FDA applications, it is worth noting that the Company will be conducting its clinical trials in Australia and a tender process is currently underway to appoint a Clinical Research Organisation (CRO) partner for clinical trial site feasibility and execution.

In addition to this pathway, the Company has recently submitted a filing in parallel for an orphan category for CRPS with the FDA. There are several benefits of this dual strategy, including the waiving of PDUFA fees (approximately USD \$2.2m), tax credits for clinical drug testing and eligibility for market exclusivity for a period of 7 years after approval is granted.

The Company has recently commenced discussions with Key Opinion Leaders (KOL's) for each of the clinical trials programmes and a Psychiatrist and Pain Specialist have been selected and briefed on the Company's objectives across each programme. We expect these engagements to be formalised in the coming weeks.

Key commercial terms with a carefully selected API manufacturer for cannabinoids have been agreed in the past week and the Company is in the final stages of negotiating a supply agreement. This appointment will enable IRX to leverage existing pre-clinical and toxicology data to expedite the timeline associated with each programme.

In addition, after extensive research, the Company has appointed a UK based formulation expert group with experience in preparing cannabinoids for inhalation. Our partner has commenced preparing the formulations with a view to assembling a drug device-formulation combination using Pressurized Metered Dose Inhaler (pMDI) devices for both indications.

While Medihale is not a pMDI device, there are significant benefits to the Company continuing to market and develop its Medihale vape offering. The Company's activities in this area continue to create important data insights which enable a greater understanding of the therapeutic application of cannabinoids across a range of indications and medical conditions. Furthermore, the Company is able to draw on trends in physician prescribing behaviour to gain real world insights into the opportunities for rapid onset medications for conditions where patient needs are not currently well met.

Approved by the Board of Directors:

For further information:

Nova Taylor
Company Secretary
(02) 8072 1400

About InhaleRx Limited (ASX: IRX) – www.inhalerx.com.au

InhaleRx Limited is an Australian healthcare and technology company which is focused on developing inhalation therapies. The Company currently markets the Medihale inhalation device and is working on developing a range of inhaled therapeutic medicinal formulations for registration domestically and internationally.

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 2021
Previous period: For the year ended 31 December 2020

2. Results for announcement to the market

			\$
Revenues from ordinary activities	up	712.1% to	182,074
Loss from ordinary activities after tax attributable to the owners of InhaleRx Limited	down	7.8% to	(1,111,129)
Loss for the year attributable to the owners of InhaleRx Limited	down	7.8% to	(1,111,129)

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 \$1,111,129 (31 December 2020: \$1,205,276).

3. Net tangible assets

	Reporting period Cents	Previous period Cents
Net tangible assets per ordinary security	<u>1.58</u>	<u>0.98</u>

4. Control gained over entities

Not applicable.

5. Loss of control over entities

Not applicable.

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.

7. Dividend reinvestment plans

Not applicable.

8. Details of associates and joint venture entities

Not applicable.

9. Foreign entities

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

Not applicable.

10. Audit qualification or review

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

The attached financial information is being audited.

11. Attachments

Details of attachments (if any):

The Preliminary Report of InhaleRx Limited for the year ended 31 December 2021 is attached.

12. Signed

Signed  _____

Sean Williams

Date: 28 February 2022

For persons only

InhaleRx Limited

ACN 611 845 820

Preliminary Report - 31 December 2021

InhaleRx Limited
Statement of profit or loss and other comprehensive income
For the year ended 31 December 2021

	Note	Consolidated 2021 \$	2020 \$
Revenue	1	181,740	22,127
Interest revenue		334	292
Expenses			
Cost of goods sold		(115,232)	(168,794)
Direct project costs		-	(177)
Directors' fees and costs		(188,132)	(159,695)
Travel expenses		-	(1,068)
Employee benefits expense		(228,106)	(71,225)
Entertainment expenses		(351)	(988)
Depreciation and amortisation expense		(1,814)	-
Consulting costs		(378,593)	(400,350)
Corporate expenses		(143,131)	(91,370)
Marketing expenses		(52,345)	(41,472)
Product development expenditure		(116,990)	(201,159)
Other expenses		(68,509)	(91,397)
Loss before income tax expense		(1,111,129)	(1,205,276)
Income tax expense		-	-
Loss after income tax expense for the year attributable to the owners of InhaleRx Limited		(1,111,129)	(1,205,276)
Other comprehensive income			
<i>Items that may be reclassified subsequently to profit or loss</i>			
Foreign currency translation		18,820	(22,600)
Other comprehensive income for the year, net of tax		18,820	(22,600)
Total comprehensive loss for the year attributable to the owners of InhaleRx Limited		(1,092,309)	(1,227,876)
		Cents	Cents
Basic earnings per share	9	(0.663)	(1.215)
Diluted earnings per share	9	(0.663)	(1.215)

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 2021

	Note	Consolidated 2021 \$	2020 \$
Assets			
Current assets			
Cash and cash equivalents	2	2,803,480	1,719,479
Trade and other receivables	3	19,138	74,400
Inventories		20,605	-
Other	4	64,689	105,840
Total current assets		<u>2,907,912</u>	<u>1,899,719</u>
Non-current assets			
Property, plant and equipment		9,707	-
Intangibles		13,570	4,302
Total non-current assets		<u>23,277</u>	<u>4,302</u>
Total assets		<u>2,931,189</u>	<u>1,904,021</u>
Liabilities			
Current liabilities			
Trade and other payables	5	228,545	404,340
Contract liabilities		24,800	84,938
Employee benefits		-	3,323
Other	6	-	87,500
Total current liabilities		<u>253,345</u>	<u>580,101</u>
Total liabilities		<u>253,345</u>	<u>580,101</u>
Net assets		<u>2,677,844</u>	<u>1,323,920</u>
Equity			
Issued capital	7	12,901,135	10,454,902
Reserves	8	(968,991)	(987,811)
Accumulated losses		(9,254,300)	(8,143,171)
Total equity		<u>2,677,844</u>	<u>1,323,920</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 2021

Consolidated	Issued capital \$	Reserves \$	Accumulated losses \$	Total equity \$
Balance at 1 January 2020	8,243,190	(965,211)	(6,937,895)	340,084
Loss after income tax expense for the year	-	-	(1,205,276)	(1,205,276)
Other comprehensive loss for the year, net of tax	-	(22,600)	-	(22,600)
Total comprehensive loss for the year	-	(22,600)	(1,205,276)	(1,227,876)
<i>Transactions with owners in their capacity as owners:</i>				
Contributions of equity, net of transaction costs (note 7)	2,211,712	-	-	2,211,712
Balance at 31 December 2020	<u>10,454,902</u>	<u>(987,811)</u>	<u>(8,143,171)</u>	<u>1,323,920</u>
Consolidated	Issued capital \$	Reserves \$	Accumulated losses \$	Total equity \$
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>

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 2021

	Note	Consolidated 2021 \$	2020 \$
Cash flows from operating activities			
Receipts from customers		117,879	77,666
Payments to suppliers and employees		<u>(1,266,781)</u>	<u>(1,136,944)</u>
		(1,148,902)	(1,059,278)
Interest received		334	292
Other revenue		<u>-</u>	<u>9,750</u>
Net cash (used in) operating activities		<u>(1,148,568)</u>	<u>(1,049,236)</u>
Cash flows from investing activities			
Payments for property, plant and equipment		(11,521)	-
Payments for intangibles		<u>(13,570)</u>	<u>(4,302)</u>
Net cash (used in) investing activities		<u>(25,091)</u>	<u>(4,302)</u>
Cash flows from financing activities			
Proceeds from issue of shares		2,271,672	2,407,228
Share issue transaction costs		<u>(13,769)</u>	<u>(36,533)</u>
Net cash from financing activities		<u>2,257,903</u>	<u>2,370,695</u>
Net increase in cash and cash equivalents		1,084,244	1,317,157
Cash and cash equivalents at the beginning of the financial year		1,719,479	424,922
Effects of exchange rate changes on cash and cash equivalents		<u>(243)</u>	<u>(22,600)</u>
Cash and cash equivalents at the end of the financial year	2	<u><u>2,803,480</u></u>	<u><u>1,719,479</u></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 2021

Note 1. Revenue

	Consolidated	Consolidated
	2021	2020
	\$	\$
<i>Sales revenue</i>		
Sales of goods and services	167,301	12,557
<i>Other revenue</i>		
Other revenue	14,439	9,570
Revenue	<u>181,740</u>	<u>22,127</u>

Note 2. Current assets - cash and cash equivalents

	Consolidated	Consolidated
	2021	2020
	\$	\$
Cash at bank	<u>2,803,480</u>	<u>1,719,479</u>

Note 3. Current assets - trade and other receivables

	Consolidated	Consolidated
	2021	2020
	\$	\$
Other receivables	61,714	140,016
Less: Allowance for expected credit losses	(54,201)	(83,760)
	<u>7,513</u>	<u>56,256</u>
GST receivable	11,625	18,144
	<u>19,138</u>	<u>74,400</u>

Note 4. Current assets - other

	Consolidated	Consolidated
	2021	2020
	\$	\$
Prepayments	63,611	103,436
Other current assets	1,078	2,404
	<u>64,689</u>	<u>105,840</u>

InhaleRx Limited
Notes to the financial statements
31 December 2021

Note 5. Current liabilities - trade and other payables

	Consolidated	
	2021	2020
	\$	\$
Trade payables *	73,355	124,740
Other payables *	155,190	279,600
	<u>228,545</u>	<u>404,340</u>

* all trade and other payables are unsecured

Note 6. Current liabilities - other

	Consolidated	
	2021	2020
	\$	\$
Funds received ahead of the issue of shares	-	87,500
	<u>-</u>	<u>87,500</u>

Note 7. Equity - issued capital

	2021	Consolidated		2020
	Shares	2020	2021	2020
		Shares	\$	\$
Ordinary shares - fully paid	168,466,957	134,773,493	12,901,135	10,454,902
	<u>168,466,957</u>	<u>134,773,493</u>	<u>12,901,135</u>	<u>10,454,902</u>

Movements in ordinary share capital

Details	Date	Shares	Issue price	\$
Balance	1 January 2020	77,568,678		8,243,190
Issue of shares	2 March 2020	10,128,635	\$0.0330	334,244
Issue of shares	23 June 2020	9,090,990	\$0.0330	300,002
Issue of shares	24 July 2020	151,515	\$0.0330	5,000
Shares issued to settle trade payables	24 July 2020	733,675	\$0.0400	29,347
Issue of shares	25 September 2020	24,000,000	\$0.0400	960,000
Issue of shares	13 November 2020	13,100,000	\$0.0550	720,500
Less cost of capital raised		-	\$0.0000	(137,381)
Balance	31 December 2020	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	793,700
Reversal of prior year accrual in relation to cost of capital raised		-	\$0.0000	100,830
Less cost of capital raised		-	\$0.0000	(13,769)
	31 December 2021	<u>168,466,957</u>		<u>12,901,135</u>

InhaleRx Limited
Notes to the financial statements
31 December 2021

Note 8. Equity - reserves

	Consolidated	
	2021	2020
	\$	\$
Foreign currency reserve	(93,340)	(112,160)
Share-based payments reserve	32,227	32,227
Other reserves	(576,768)	(576,768)
Non-controlling interest derecognised	(331,110)	(331,110)
	<u>(968,991)</u>	<u>(987,811)</u>

Note 9. Earnings per share

	Consolidated	
	2021	2020
	\$	\$
Loss after income tax attributable to the owners of InhaleRx Limited	<u>(1,111,129)</u>	<u>(1,205,276)</u>
	Number	Number
Weighted average number of ordinary shares used in calculating basic earnings per share	<u>167,570,844</u>	<u>99,191,395</u>
Weighted average number of ordinary shares used in calculating diluted earnings per share	<u>167,570,844</u>	<u>99,191,395</u>
	Cents	Cents
Basic earnings per share	(0.663)	(1.215)
Diluted earnings per share	(0.663)	(1.215)