InhaleRx Limited Level 9, 505 Little Collins Street Melbourne VIC 3000

ACN: 611 845 820

https://inhalerx.com.au/ info@inhalerx.com.au

# InhaleRx Limited

#### Notice of 2023 Annual General Meeting

Explanatory Statement | Proxy Form

Thursday, 30<sup>th</sup> May 2024 **3pm (AEST)** 

> This Notice of Meeting should be read in its entirety. If Shareholders are in doubt as to how they should vote, they should seek advice from their professional advisers prior to voting.

### Contents

Venue and Voting Information	2
Notice of Annual General Meeting – Agenda and Resolutions	5
Notice of Annual General Meeting – Explanatory Statement	11
Glossary	24
Annexure A – Independent Expert's Report	Attached
Annexure A – Independent Expert's Report	Attached
Annexure A – Independent Expert's Report	Attached
Proxy Form	Attached

#### Important Information for Shareholders about the Company's 2023 AGM

This Notice is given based on circumstances as of 16 April 2024. Should circumstances change, the Company will make an announcement on the ASX market announcements platform and the Company's website at <u>https://inhalerx.com.au/</u>. Shareholders are urged to monitor the ASX announcements platform and the Company's website.

### Venue and Voting Information

The Annual General Meeting of the Shareholders of InhaleRx Limited ACN 611 845 820 to which this Notice of Meeting relates will be held at 3pm (AEST) on Thursday, 30<sup>th</sup> May 2024 as a **virtual meeting** 

If you wish to virtually attend the AGM (which will be broadcast as a live webinar), please **<u>pre-</u>** <u>**register**</u> in advance for the virtual meeting here:

https://us02web.zoom.us/webinar/register/WN\_mir9uj6LTZ24MAM-aRnbAg

After registering, you will receive a confirmation containing information on how to attend the virtual meeting on the day of the AGM.

Shareholders will be able to vote (see the "Voting virtually at the Meeting" section of this Notice of Meeting below) and ask questions at the virtual meeting.

Shareholders are also encouraged to submit questions in advance of the Meeting to the Company.

Questions must be submitted by email to the Company Secretary, James Barrie, at <u>james.barrie@inhalerx.com.au</u> at least 48 hours before the AGM.

The Company will also provide Shareholders with the opportunity to ask questions during the Meeting with respect to the formal items of business as well as general questions with respect to the Company and its business.

#### Your vote is important

The business of the Annual General Meeting affects your shareholding, and your vote is important.

#### Voting virtually at the Meeting

The company is pleased to also provide shareholders with the opportunity to attend and participate in the Meeting through an online meeting platform, where shareholders will be able to watch, listen, ask questions and vote online.

To access the virtual meeting:

- 1. Open your internet browser and go to: <u>https://us02web.zoom.us/webinar/register/WN\_mir9uj6LTZ24MAM-aRnbAg</u>
- 2. Enter your registered holding name, email address, HIN/SRN and postcode and click "register".
- 3. Shareholders are encouraged to register prior to the day of the meeting to ensure there is no delay in attending the meeting.
- 4. Once your details are verified, you will receive a separate email with details of how to logon on the day of the meeting.
- 5. Click on the URL you will be sent to join the webcast where you can view and listen to the hybrid meeting, as well as ask questions in relation to the business of the meeting.
- 6. Once the Chair of the Meeting has declared the poll open for voting, select "For", "Against" or "Abstain" for each resolution.

#### Voting by proxy

To vote by proxy, please use one of the following methods:

Online	Lodge the Proxy Form online at <u>https://investor.automic.com.au/#/loginsah</u> by following the instructions: Login to the Automic website using the holding details as shown on the Proxy Form. Click on 'View Meetings' – 'Vote'. To use the online lodgement facility, Shareholders will need their holder number (Securityholder Reference Number (SRN) or Holder Identification Number (HIN)) as shown on the front of the Proxy Form. For further information on the online proxy lodgement process please see the <b>Online Proxy Lodgement Guide</b> at <u>https://www.automicgroup.com.au/virtual- agms/</u>
By post	Automic, GPO Box 5193, Sydney NSW 2001
By hand	Automic, Level 5, 126 Phillip Street, Sydney NSW 2000
By email	Completing the enclosed Proxy Form and emailing it to: <u>meetings@automicgroup.com.au</u>

Your Proxy instruction must be received no later than 48 hours before the commencement of the Meeting. **Proxy Forms received later than this time will be invalid.** 

#### Power of Attorney

If the proxy form is signed under a power of attorney on behalf of a shareholder, then the attorney must make sure that either the original power of attorney or a certified copy is sent with the proxy form, unless the power of attorney has already provided it to the Share Registry.

#### **Corporate Representatives**

If a representative of a corporate shareholder or a corporate proxy will be attending the Meeting, the representative should provide the Share Registry with adequate evidence of their appointment, unless this has previously been provided to the Share Registry.

### Notice of Annual General Meeting

Notice is hereby given that the Annual General Meeting of Shareholders of InhaleRx Limited ACN 611 845 820 will be held at 3pm (AEST) on Thursday, 30<sup>th</sup> May 2024 as a **virtual meeting** (**Meeting**).

The Explanatory Statement to this Notice of Meeting provides additional information on matters to be considered at the Annual General Meeting. The Explanatory Statement and the Proxy Form each form part of this Notice of Meeting.

The Directors have determined pursuant to Regulation 7.11.37 of the *Corporations Regulations* 2001 (Cth) that the persons eligible to vote at the Annual General Meeting are those who are registered Shareholders at 7pm (AEST) on Tuesday, 28<sup>th</sup> May 2024.

Terms and abbreviations used in this Notice of Meeting and Explanatory Statement are defined in the Glossary.

### Agenda

#### **Ordinary business**

#### Financial statements and reports

"To receive and to consider the Annual Financial Report of the Company for the financial year ended 31 December 2023 together with the declaration of the Directors, the Directors' Report, the Remuneration Report and the Auditor's Report for that financial year."

#### Note: This item of ordinary business is for discussion only and is not a resolution.

Pursuant to the Corporations Act, Shareholders will be given a reasonable opportunity at the Meeting to ask questions about, or make comments in relation to, each of the aforementioned reports during consideration of these items.

### Resolutions

#### **Remuneration Report**

#### 1. **Resolution 1** – Adoption of Remuneration Report

To consider and, if thought fit, to pass the following resolution as an **Ordinary Resolution**:

"That, for the purpose of Section 250R(2) of the Corporations Act and for all other purposes, approval is given for the adoption of the Remuneration Report as contained in the Company's Annual Financial Report for the financial year ended 31 December 2023."

**Note**: The vote on this Resolution is advisory only and does not bind the Directors or the Company. Shareholders are encouraged to read the Explanatory Memorandum for further details on the consequences of voting on this Resolution.

**Voting Exclusion Statement**: In accordance with the Corporations Act, the Company will disregard any votes cast on Resolution 1 by or on behalf of a member of the Company's key management personnel (including the Directors) (**KMP**), whose remuneration details are included in the Remuneration Report, or any of that person's Closely Related Parties (such as close family members and any controlled companies of those persons)

(collectively referred to as **Restricted Voter**). However, the Company need not disregard a vote if:

- (a) it is cast by a person as a proxy appointed in writing that specifies how the proxy is to vote on Resolution 1; and
- (b) it is not cast on behalf of a Restricted Voter.

If you appoint the person chairing the Meeting (**Chair**) and you are not a Restricted Voter, by submitting the Proxy Form you authorise the person chairing the Meeting to exercise the proxy even though Resolution 1 is connected directly or indirectly with the remuneration of a KMP, and you will be taken to have directed the Chair to vote in accordance with his or her stated intention to vote in favour of Resolution 1. If you do not want your vote exercised in favour of Resolution 1, you should direct the person chairing the Meeting to vote "against", or to abstain from voting on, this Resolution.

#### **Election of Directors**

#### 2. **Resolution 2** – Election of James Barrie as Director

To consider and, if thought fit, to pass with or without amendment, the following resolution as an **Ordinary Resolution**:

"That James Barrie, a Director appointed as an additional Director and holding office until the next general meeting of the Company after his appointment in accordance with clause 108 of the Company's Constitution and ASX Listing Rule 14.4, be elected as a Director of the Company, effective immediately."

#### 3. Resolution 3 – Re-election of Sean Williams as Director

To consider and, if thought fit, to pass with or without amendment, the following resolution as an **Ordinary Resolution** 

"That Sean Williams, a Director who retires by rotation in accordance with clause 104.2(d) of the Constitution and ASX Listing Rule 14.2, and being eligible, is elected as a Director."

#### ASX Listing Rule 7.1A (Additional 10% Capacity)

## 4. **Resolution 4** – ASX Listing Rule 7.1A Approval of Future Issue of Equity Securities

To consider and, if thought fit, to pass the following resolution as a **Special Resolution**:

"That, for the purposes of ASX Listing Rule 7.1A and for all other purposes, the Shareholders approve the issue of Equity Securities up to 10% of the issued capital of the Company (at the time of issue) calculated in accordance with the formula prescribed in ASX Listing Rule 7.1A.2 and otherwise on the terms and conditions set out in the Explanatory Statement which accompanies and forms part of this Notice of Meeting."

**Voting Exclusion Statement**: The Company will disregard any votes cast in favour of Resolution 4 by or on behalf of:

- (a) a person who is expected to participate in, or who will obtain a material benefit as a result of, the proposed issue (except a benefit solely by reason of being a holder of ordinary securities in the Company); or
- (b) an Associate of that person or those persons.

However, this does not apply to a vote cast in favour of Resolution 4 by:

- (i) a person as proxy or attorney for a person who is entitled to vote on the Resolution, in accordance with directions given to the proxy or attorney to vote on the Resolution in that way; or
- (ii) the Chair of the Meeting as proxy or attorney for a person who is entitled to vote on the Resolution, in accordance with a direction given to the Chair to vote on the Resolution as the Chair decides; or
- (iii) a holder acting solely in a nominee, trustee, custodial or other fiduciary capacity on behalf of a beneficiary provided the following conditions are met:
  - the beneficiary provides written confirmation to the holder that the beneficiary is not excluded from voting, and is not an associate of a person excluded from voting, on the Resolution; and
  - the holder votes on the Resolution in accordance with directions given by the beneficiary to the holder to vote in that way.

#### <u>Issue of Incentive Securities under the Incentive Entitlements</u> <u>Plan</u>

5. **Resolution 5** – Approval of Issue of Incentive Securities to Mr Sean Williams, Director of the Company

To consider and, if thought fit, to pass the following resolution as an **Ordinary Resolution**:

"That, for the purposes of ASX Listing Rule 10.14 and for all other purposes, the Shareholders of the Company approve the issue and allotment of 2,000,000 unlisted Options, exercisable at \$0.15 (15 cents), and expiring 3 years from the issue date, under the Incentive Entitlements Plan to Mr Sean Williams, Director of the Company, and otherwise on the terms and conditions set out in the Explanatory Statement which accompanies and forms part of this Notice of Meeting."

**Voting Exclusion Statement**: The Company will disregard any votes cast in favour of Resolution 5 by or on behalf of:

- (a) a person referred to in rule 10.14.1, 10.14.2 or 10.14.3 who is eligible to participate in the Incentive Entitlements Plan; or
- (b) an Associate of that person or those persons.

However, this does not apply to a vote cast in favour of Resolution 5 by:

- (i) a person as proxy or attorney for a person who is entitled to vote on the Resolution, in accordance with directions given to the proxy or attorney to vote on the Resolution in that way; or
- (ii) the Chair of the Meeting as proxy or attorney for a person who is entitled to vote on the Resolution, in accordance with a direction given to the Chair to vote on the

Resolution as the Chair decides; or

- (iii) a holder acting solely in a nominee, trustee, custodial or other fiduciary capacity on behalf of a beneficiary provided the following conditions are met:
  - the beneficiary provides written confirmation to the holder that the beneficiary is not excluded from voting, and is not an associate of a person excluded from voting, on the Resolution; and
  - the holder vote on the Resolution in accordance with directions given by the beneficiary to the holder to vote in that way.

**Voting Prohibition Statement**: In accordance with section 250BD of the Corporations Act, a person appointed as a proxy must not vote, on the basis of that appointment, on Resolution 5 if:

- (a) the proxy is either:
  - (i) a member of the Company's KMP; or
  - (ii) a closely related party of a member of the Company's KMP; and
- (b) the appointment does not specify the way the proxy is to vote on the Resolution.

However, the above prohibition does not apply if:

- (a) the proxy is the Chair of the Meeting; and
- (b) the appointment expressly authorises the Chair to exercise the proxy even if the Resolution is connected directly or indirectly with remuneration of a member of the Company's KMP.

#### **Appointment of Contract Research Organisation**

# 6. **Resolution 6** – Approval to Appoint Ingenu CRO Pty Ltd as the Contract Research Organization, a Related Party of the Company

To consider and, if thought fit, pass the following resolution as an **Ordinary Resolution**:

"That, for the purposes of Listing Rule 10.1, and for all other purposes, Shareholders approve the appointment of Ingenu CRO Pty Ltd, a related party of the Company as the Contract Research Organisation, on the terms and conditions set out in the Explanatory Statement."

#### See the Explanatory Statement for further information.

**Voting Exclusion Statement**: The Company will disregard votes cast in favour of this Resolution 6 by or on behalf of:

- (a) Ingenu CRO Pty Ltd ACN 656 400 056 and its Associates;
- (b) Cannvalate Pty Ltd ACN 625 982 756 and its Associates;
- (c) Mr Darryl Davies and his Associates; or
- (d) any other person who will obtain a material benefit as a result of the appointment of Ingenu CRO Pty Ltd as Contract Research Organisation for the Company (except a benefit solely by reason of being a holder of ordinary securities in the Company), or an associate of those persons.

However, this exclusion does not apply to a vote cast in favour of this Resolution if it is cast by:

(a) a person as a proxy or attorney for a person who is entitled to vote on the Resolution, in accordance with the directions given to the proxy or attorney to vote on the Resolution in that way; or

- (b) the Chair as proxy or attorney for a person who is entitled to vote on the Resolution, in accordance with a direction given to the Chair to vote on the Resolution as the Chair decides; or
- (c) a holder acting solely in a nominee, trustee, custodial or another fiduciary capacity on behalf of a beneficiary provided the following conditions are met:
  - (i) the beneficiary provides written confirmation to the holder that the beneficiary is not excluded from voting, and is not an associate of a person excluded from voting, on the Resolution; and
  - (ii) the holder votes on the Resolution in accordance with directions given by the beneficiary.

**Independent Expert's Report:** Shareholders should carefully consider the Independent Expert's Report prepared by the Independent Expert accompanying the Explanatory Statement as Annexure A. The Independent Expert's Report opines on the fairness and reasonableness of the appointment, the subject of this Resolution. The Independent Expert has determined that the appointment of the subject of this Resolution is Fair and Reasonable to the non-associated Shareholders.

#### BY ORDER OF THE BOARD

James Barrie Company Secretary

### Explanatory Statement

This Explanatory Statement has been prepared for the information of the Shareholders in connection with the business to be conducted at the Annual General Meeting to be held at 3pm (AEST) on Thursday, 30<sup>th</sup> May 2024 as a **virtual meeting**.

The purpose of this Explanatory Statement is to provide information that the Directors believe to be material to Shareholders in deciding whether or not to pass the Resolutions in the Notice of Meeting.

If you are in any doubt about what to do in relation to the Resolutions contemplated in the Notice of Meeting and this Explanatory Statement, it is recommended that you seek advice from an accountant, solicitor or another professional advisor.

Full details of the business to be considered at the Annual General Meeting are set out below.

### Agenda

#### **Ordinary business**

#### Financial statements and reports

In accordance with the Constitution and the Corporations Act, the business of the Annual General Meeting will include receipt and consideration of the Annual Financial Report of the Company for the financial year ended 31 December 2023 together with the declaration of the Directors, the Director's Report, the Remuneration Report and the Auditor's Report.

In accordance with the amendments to the Corporations Act, the Company is no longer required to provide a hard copy of the Company's Annual Financial Report to Shareholders unless a Shareholder has specifically elected to receive a printed copy.

Whilst the Company will not provide a hard copy of the Company's Annual Financial Report unless specifically requested to do so, Shareholders may view the Company Annual Financial Report on its website at <u>https://inhalerx.com.au/</u>.

No resolution is required for this item, but Shareholders will be given the opportunity to ask questions and to make comments on the management and performance of the Company.

The Company's auditor will be present at the Meeting. During the discussion of this item, the auditor will be available to answer questions on the:

- Conduct of the audit;
- Preparation and content of the Auditor's Report;
- Accounting policies adopted by the Company in relation to the preparation of the financial statements; and
- Independence of the auditor in relation to the conduct of the audit.

#### Written questions of the auditor

If you would like to submit a written question about the content of the Auditor's Report or the conduct of the audit of the Annual Financial Report of the Company's auditor, please send your question to the Company Secretary, James Barrie, at <u>james.barrie@inhalerx.com.au</u>. A list of qualifying questions will be made available at the Meeting.

Please note that all written questions must be received at least five business days before the Meeting, which is by Thursday, 23<sup>rd</sup> May 2024.

### Resolutions

#### **Remuneration Report**

#### **Resolution 1** – Adoption of Remuneration Report

The Corporations Act requires that at a listed company's annual general meeting, a resolution that the remuneration report be adopted must be put to the shareholders. However, such a resolution is advisory only and does not bind the company or the directors of the company.

The remuneration report sets out the company's remuneration arrangements for the directors and senior management of the company. The remuneration report is part of the directors' report contained in the annual financial report of the company for a financial year.

The chair of the meeting must allow a reasonable opportunity for its shareholders to ask questions about or make comments on the remuneration report at the annual general meeting.

A company is required to put to its shareholders a resolution proposing the calling of another meeting of shareholders to consider the appointment of directors of the company (Spill Resolution) if, at consecutive annual general meetings, at least 25% of the votes cast on a remuneration report resolution are voted against adoption of the remuneration report and at the first of those annual general meetings a Spill Resolution was not put to vote. If required, the Spill Resolution must be put to vote at the second of those annual general meetings.

If more than 50% of votes cast are in favour of the Spill Resolution, the company must convene a shareholder meeting (Spill Meeting) within 90 days of the second annual general meeting.

All of the directors of the company who were in office when the directors' report (as included in the company's annual financial report for the most recent financial year) was approved, other than the managing director of the company, will cease to hold office immediately before the end of the Spill Meeting but may stand for re-election at the Spill Meeting.

Following the Spill Meeting those persons whose election or re-election as directors of the company is approved will be the directors of the company.

At the Company's previous annual general meeting, the votes cast against the remuneration report considered at that annual general meeting were less than 25%. Accordingly, the Spill Resolution will not be relevant for this Annual General Meeting.

#### Voting

Note that a voting exclusion applies to Resolution 1 in the terms set out in the Notice of Meeting. In particular, the Directors and other Restricted Voters must not vote on this Resolution and must not cast a vote as proxy, unless the appointment gives a direction on how to vote, or the proxy is given to the Chair and you submit the Proxy Form, authorising the Chair to exercise the proxy <u>even</u> though Resolution 1 is connected directly or indirectly with the remuneration of a KMP and that in doing so you will be taken to have directed the Chair to vote in accordance with the Chair's stated intention to vote in favour of Resolution 1.

Shareholders are urged to read carefully the Proxy Form and to provide a direction to the proxy on how to vote on this Resolution.

#### **Election of Director**

#### Resolution 2 – Election of James Barrie as Director

Clause 108.2 of the Company's Constitution provides that any Director appointed in addition to

the existing Directors will hold office until the next following annual general meeting and is then eligible for re-election.

ASX Listing Rule 14.4 also provides that each additional director appointed during the year is to hold office until the next annual general meeting and is then eligible for election as a Director of the Company.

James Barrie was appointed as an additional Director of the Company on 1 March 2024 and has since served as a Director of the Company.

Under this Resolution, James Barrie seeks election as a Director of the Company at this AGM.

James Barrie's strength and expertise are driven by his extensive career and background across various industry sectors including various roles in pharmaceuticals, from start-ups to ASX 20.

Mr Barrie provides the Board independent advice and expertise across various governance and corporate responsibility requirements required of an ASX-listed company. Mr Barrie's skills include corporate governance, share registry, employment plans, treasury, capital management, accounting, commercial analysis, mergers and acquisitions, strategy, stakeholder relations and business development.

Mr Barrie is also the company secretary and/or a director of several other ASX, NSX and unlisted companies.

#### Directors' recommendation

The Directors (excluding James Barrie) recommend that Shareholders vote in favour of this Resolution.

#### **Re-election of Director**

#### Resolution 3 - Re-election of Sean Williams as Director

In accordance with clause 104.2(d) of the Company's Constitution Sean Williams, who was last reelected as a Director at the General Meeting held 15 September 2021 and, being eligible for reelection, offers himself for re-election as a Director of the Company at this AGM.

Sean graduated from Swinburne University with a Bachelor's Degree in Business (accounting) and was admitted to the Institute of Chartered Accountants in Australia and New Zealand in 1993.

Sean has over 30 years' experience in senior executive and finance roles across the pharmaceutical, healthcare, investment management and supply chain sectors. Having commenced his career with an international accounting firm, Sean has held a number of senior roles including General Manager, Finance for Symbion Pharmacy (Australia's largest pharmaceutical wholesaler). He also headed up Symbion's market leading hospital pharmacy and dental divisions and was responsible for Independent Pharmacy Solutions (a short-line wholesale business). Sean has worked as an investment director in private equity and as a senior executive in private equity backed ventures. He has also led management buy-outs and been involved in founding start-up businesses within the supply chain sector. Most recently, Sean was CEO of a \$500m investment management business specialising in Australian agricultural investments.

#### Directors' recommendation

The Directors (excluding Sean Williams) recommend that Shareholders vote in favour of this Resolution.

#### ASX Listing Rule 7.1A

#### Resolution 4 – ASX Listing Rule 7.1A Approval of Future Issue of

#### Securities

#### **General Information**

Broadly speaking, and subject to a number of exceptions, Listing Rule 7.1 limits the amount of Equity Securities that a listed company can issue without the approval of its shareholders over any 12-month period to 15% of the fully paid ordinary securities it had on issue at the start of that period.

Under Listing Rule 7.1A, however, an eligible entity can seek approval from its members, by way of a special resolution passed at its annual general meeting, to add an additional 10% capacity.

An eligible entity for the purposes of Listing Rule 7.1A is an entity that is not included in the S&P/ASX 300 Index and has a market capitalisation less than the amount prescribed by ASX (currently \$300 million).

As of the date of this Notice of Meeting was prepared, namely 16 April 2024, the Company has a market capitalisation of approximately \$7.6 million and therefore is an eligible entity. If at the time of the Meeting the Company is no longer an eligible entity this Resolution will be withdrawn.

This Resolution seeks Shareholder approval by way of a special resolution for the Company to have the additional 10% capacity provided for in Listing Rule 7.1A to issue Equity Securities without Shareholder approval.

If this Resolution is passed, the Company will be able to issue Equity Securities up to the combined 25% limit in Listing Rules 7.1 and 7.1A.

If this Resolution is not passed, the Company will not be able to access the additional 10% capacity to issue Equity Securities without Shareholder approval provided for in Listing Rule 7.1A and will remain subject to the 15% limit on issuing Equity Securities without Shareholder approval set out in Listing Rule 7.1.

#### Information Required by ASX Listing Rule 7.3A

The following information is provided to Shareholder for the purposes of Listing Rule 7.3A.

#### Period for which the approval will be valid

An approval under this Listing Rule 7.1A commences on the date of the annual general meeting at which the approval is obtained and expires on the first to occur of the following:

- (a) the date which is 12 months after the date of the annual general meeting at which the approval is obtained;
- (b) the time and date of the Company's next annual general meeting; and
- (c) the time and date on which Shareholders approve a transaction under Listing Rule 11.1.2 (a significant change to the nature or scale of activities) or Listing Rule 11.2 (disposal of main undertaking).

#### Minimum price at which the Equity Securities may be issued under Listing Rule 7.1A

Any equity securities issued under Listing Rule 7.1A.2 must be an existing quoted class of the Company's <u>Equity Securities</u> and issued for cash consideration.

The issue price per equity security must not be less than 75% of the volume weighted average market price of the equity securities in that class, calculated over 15 trading days on which trades in that class were recorded immediately before:

(a) the date on which the price at the <u>Equity Securities</u> are to be issued is agreed by the Company and the recipient of the <u>Equity Securities</u>; and

(b) if the <u>Equity Securities</u> are not issued within 10 trading days of the date in paragraph (a), the date on which the <u>Equity Securities</u> are issued.

Purposes for which the funds raised by an issue of Equity Securities under Listing Rule 7.1A may be used

As noted above, any equity securities issued under Listing Rule 7.1A.2 must be issued for cash consideration. Accordingly, every issue of equity securities under Listing Rule 7.1A.2 will have an accompanying proposed use of funds at the time of issue.

As at the date of this Notice, the Company has not formed an intention to offer any <u>Equity</u> <u>Securities</u> under Listing Rule 7.1A during the Listing Rule 7.1A mandate period. However, if Shareholders approved this Resolution and the Company did raise funds from the issue of <u>Equity</u> <u>Securities</u> under Listing Rule 7.1A, based on the Company's existing plans, the Company considers that the funds may be used for the following purposes:

- (a) the current clinical development pathway;
- (b) The development of additional inhaled medicinal formulations which target the treatment of medical conditions for which there are no or limited existing effective treatments; and
- (c) Potential acquisitions and due diligence on acquisitions.

#### Risk of economic and voting dilution to existing ordinary Shareholders

If this Resolution is approved, and the Company issues <u>Equity Securities</u> under Listing Rule 7.1A, the existing Shareholders' economic and voting power in the Company will be diluted.

There is a risk that:

- (a) the market price for the Company's <u>Equity Securities</u> in that class may be significantly lower on the issue date than on the date of the approval under Listing Rule 7.1A; and
- (b) the <u>Equity Securities</u> may be issued at a price that is at a discount (as described above) to the market price for the Company's <u>Equity Securities</u> on the issue date;

which may have an effect on the amount of funds raised by the issue of <u>Equity Securities</u> under Listing Rule 7.1A.

The table below shows the potential dilution of existing Shareholders on the basis of 3 different assumed issue prices and values for the variable "A" in the formula in rule 7.1A.2:

Number of Shares on Issue (Variable A in Listing Rule 7.1A.2)		Issue Price	\$0.020	\$0.040	\$0.060
		Shares issued – 10% voting dilution (c)	50% decrease	Current Price (b)	50% increase
			Funds Raised		
Current (a)	189,766,957	18,976,696	\$379,534	\$759,068	\$1,138,602
50% increase	284,650,436	28,465,044	\$569,301	\$1,138,602	\$1,707,903
100% increase	379,533,914	37,953,391	\$759,068	\$1,518,136	\$2,277,203

#### Notes:

- (a) Based on the total number of fully paid ordinary Shares on issue as at 16 April 2024.
- (b) Based on the closing price of the Company's Shares on ASX as at 16 April 2024.
- (c) The table assumes that the Company issues the maximum number of ordinary Shares available to be issued under Listing Rule 7.1A.
- (d) The table does not show an example of dilution that may be caused to a particular Shareholder by reason of issues of Equity Securities under Listing Rule 7.1A based on that Shareholder's holding at the date of this Explanatory Statement.
- (e) The table shows the effect of an issue of Equity Securities under Listing Rule 7.1A only, not under the Company's 15% placement capacity under Listing Rule 7.1.

#### Allocation policy for issues under Listing Rule 7.1A

The Company's allocation policy and the identity of the allottees of Equity Securities under Listing Rule 7.1A will depend on a number of factors, including:

- (a) the Company's intentions in relation to the possible issue of Equity Securities (for cash consideration) during the Listing Rule 7.1A mandate period;
- (b) the structure and timeframe of the capital raising opportunities available to the Company and any alternative methods for raising funds that are available to the Company (such as a pro rata offer or an offer under a share purchase plan);
- (c) the potential effect on the control of the Company;
- (d) the Company's financial position and the likely future capital requirements; and
- (e) advice from the Company's corporate or financial advisors.

Based on the Company's historical cashflow reports and capital raising activities in the past 12 months, the Company considers that it may raise funds during the Listing Rule 7.1A mandate period, although this cannot be guaranteed. As of the date of this Notice, no specific intention to issue Equity Securities in relation to any parties, investors or existing Shareholders have been formed. In addition, no intentions have been formed in relation to the possible number of issues, or the time frame in which the issues could be made. Subject to the requirements of the Listing Rules and the Corporations Act, the Directors reserve the right to determine at the time of any issue of Equity Securities under Listing Rule 7.1A, the allocation policy that the Company will adopt for that issue.

If and when the determination is made to proceed with an issue of Equity Securities during the Listing Rule 7.1A mandate period, details regarding the allottees and purposes of issue will be disclosed pursuant to the Company's obligations under Listing Rules 3.10.3 and 7.1A.4.

Offers made under Listing Rule 7.1A may be made to parties (excluding any related parties) including professional and sophisticated investors, existing Shareholders of the Company, clients of Australian Financial Service Licence holders and/or their nominees, or any other person to whom the Company is able to make an offer of Equity Securities.

#### <u>Issue or agreement to issue Equity Securities under Listing Rule 7.1A in the 12 months prior to</u> <u>AGM</u>

The Company has not issued or agreed to issue Equity Securities under Listing Rule 7.1A.2 in the 12 months preceding the AGM.

This Resolution is a **Special Resolution**. For a Special Resolution to be passed, at least 75% of the votes validly cast on the resolution by Shareholders (by number of ordinary shares) must be in favour of this Resolution.

#### Directors' recommendation

The Board of Directors recommend that Shareholders vote in favour of this Resolution.

#### **Issue of Incentive Securities under Incentive Entitlements Plan**

**Resolution 5**– Approval of Issue of Incentive Securities to Sean Williams, a Director of the Company

#### Background

The Company's Incentive Entitlements Plan (**Incentive Plan**) was approved by Shareholders of the Company on 31 May 2022.

The Company seeks to invite Mr Sean Williams, subject to Shareholder approval that is sought under this Resolution, to participate in the Incentive Plan by subscribing for 2,000,000 unlisted

options, exercisable at \$0.15 (15 cents) per option expiring 3 years from the issue date (**Incentive Securities**).

#### **Director and Related Party Approvals**

ASX Listing Rule 10.14 provides that a listed company must not permit any of the following persons to acquire securities under an employee incentive scheme unless it obtains the approval of its shareholders:

- (a) a director of the Company;
- (b) an associate of a director of the Company; or
- (c) a person whose relationship with the Company or a person referred to in Listing Rule 10.14.1 or 10.14.2 is such that, in ASX's opinion, the acquisition should be approved by its shareholders.

As Mr Sean Williams is a Director of the Company, the proposed issue of Incentive Securities constitutes the acquisition of securities under an employee incentive scheme for the purposes of Listing Rule 10.14 and therefore requires the approval of the Company's shareholders under Listing Rule 10.14.

To this end, Resolution 5 seeks the required Shareholder approval to issue the Incentive Securities to Mr Sean Williams under and for the purposes of Listing Rule 10.14.

If approval is obtained under Listing Rule 10.14, in accordance with Listing Rule 10.12 (exception 8), separate approval is not required under Listing Rule 10.11.

If this Resolution is passed, the Company will be able to proceed with the proposed issue of Incentive Securities.

If this Resolution is not passed, the Company will not be able to proceed with the proposed issue and there is a risk that the Company will not be able to retain the services of Mr Williams. Alternatively, the Company may be forced to increase Mr William's salary and short-term cashbased incentive remuneration in order to adequately compensate and incentivise him.

#### Chapter 2E of the Corporations Act

Section 208 of the Corporations Act prohibits the Company from giving a financial benefit to a 'related party' of the Company unless either:

- (a) the giving of the financial benefit falls within one of the exceptions set out in sections 210-216 of the Corporations Act; or
- (b) Shareholder approval is obtained prior to the giving of the financial benefit.

One of the exceptions, under section 211 of the Corporations Act, includes circumstances where the financial benefit is remuneration that is reasonable given the circumstances of the public company and related party.

The proposed issue of Incentive Securities constitutes the giving of a financial benefit and Mr Sean Williams is a related party of the Company by virtue of his position as Director of the Company.

The non-conflicted Directors of the Company (being Mr James Barrie and Dr Andrew Saich) carefully considered the issue of these Incentive Securities to Mr Sean Williams, and formed the view that the giving of this financial benefit as part of his remuneration would be reasonable, given the circumstances of the Company, the quantum and terms of the Incentive Securities, and the responsibilities held by Mr Williams in his role as Director of the Company.

Accordingly, the non-conflicted Directors of the Company believe that the issue of these Incentive Securities to Mr Williams fall within the "reasonable remuneration" exception as set out in section 211 of the Corporations Act and relies on this exception for the purposes of this Resolution. Therefore, the proposed issue of Incentive Securities to Mr Williams requires Shareholder approval under and for the purposes of Listing Rule 10.14 only.

#### Information Required by ASX Listing Rule 10.15

The following information in relation to the issue of Incentive Securities to Mr Williams is provided to Shareholders for the purposes of ASX Listing Rule 10.15:

- (a) The allottee is Mr Sean Williams Non-Executive Director of the Company and therefore falls within Listing Rule 10.14.1;
- (b) The maximum number of Incentive Securities that may be acquired is 2,000,000 unlisted Options, exercisable at \$0.15 (15 cents) and expiring 3 years from the date of issue;
- (c) The current total remuneration package received by Mr Sean Williams is \$76,650 per annum plus superannuation;
- (d) Since the Incentive Plan was last approved by Shareholders on 31 May 2022, the Company has issued the following Incentive Securities to Mr Williams:

Name	Number of securities received	Acquisition price for each security
Mr Sean Williams	2,000,000 unlisted Options exercisable at \$0.15 per Option and expiring 11/07/2026	Nil
Mr Sean Williams	2,000,000 unlisted Options exercisable at \$0.20 per Option and expiring 14/12/2026	Nil

- (e) The material terms of the Incentive Securities are as follows:
  - (i) Exercise price of \$0.15 (15 cents) per Option
  - (ii) The Options vest on the date of issue
  - (iii) Expiring 3 years from the date of issue.

The Company has chosen this type of security because it provides a tax effective form of incentive which preserves the Company's short-term cash reserves.

As at 16 April 2024 a preliminary valuation of the Incentive Securities using the Black-Scholes model indicated a value of \$0.0148 per Option (based on a one day VWAP as at 16 April 2024 (\$0.04)). The value of 2 million Options was therefore \$29,634 in total.

- (f) The Incentive Securities will be issued within 3 years from the date of this Meeting, if approved by Shareholders of the Company.
- (g) The Incentive Securities are being issued for nil consideration pursuant to the terms of the Incentive Plan.
- (h) The material terms of the Incentive Plan are set out in Annexure A of this Notice of Meeting.

Details of any securities issued under the Incentive Plan will be published in each annual report of the Company relating to a period which securities have been issued, and that approval for the issue of securities was obtained under ASX Listing Rule 10.14. Any additional persons who become entitled to participate in the Incentive Plan after the resolution was approved and who were not named in the notice of meeting will not participate until approval is obtained under ASX Listing Rule 10.14. **Directors' recommendation** 

The Board of Directors (excluding Mr Williams) recommend that Shareholders vote in favour of this Resolution.

#### **Appointment of Contract Research Organisation**

# **Resolution 6** – Approval to Appoint Ingenu CRO Pty Ltd as the Contract Research Organisation

#### Background

On 17 February 2023, the Company's shareholders at an Extraordinary General Meeting approved the appointment of Ingenu CRO Pty Ltd (**Ingenu**) as the Contract Research Organisations (**CRO**) for the purpose of selecting a CRO to conduct its planned Panic Disorder (**PD**) and Complex Regional Pain Syndrome (**CRPS**) clinical trials. The tender process had been overseen by a tender selection committee comprising the Company's independent non-executive directors and an independent UK-based specialist CRO consultant.

The Company through its contract with Ingenu is currently in the final stages of the Phase 1 (Study A) CRPS clinical trial for its synthetic THC dronabinol based inhaled drug, IRX211, with the Clinical Study Report (being the last milestone) expected to be made available in May 2024.

To date, Ingenu has been paid \$910,000 against a contract value of \$950,000 for this trial. There was a \$70,000 variation to the trial cost agreed by the parties which was the result of a change in scope driven the Human Research Ethics Committee (**HREC**) approval of the trial design requiring trial participants to stay one night for observation in site accommodation post dosing. The original protocol had assumed participants would be released on the day of dosing, with the change reflecting the cost of the site accommodation.

There has to date been only \$20,000 paid to Ingenu in respect of the Panic Disorder trial which is still at HREC approval stage.

In March 2023, the Company completed a pre-Investigational New Drug meeting with the US Food & Drug Administration (**FDA**) in relation to its proposed clinical program for achieving a New Drug Approval of its IRX211 drug for CRPS. Whilst supportive overall, some of the FDA feedback encouraged the Company to reconsider pain indications for which the path to registration required less exploratory work and for which the IRX211 formulation was a closer fit.

Following a detailed and careful evaluation process, the Company decided to promote Breakthrough Cancer Pain (**BTcP**) (instead of CRPS) as the primary indication of focus for the proposed Phase 2 trial of IRX211. The established path to registration for BTcP offers a significant commercial opportunity for IRX211 and is also expected to substantially reduce the overall amount of exploratory work required and better mitigate regulatory uncertainty (compared to CRPS). This change was confirmed to the market via an ASX announcement in January 2024.

The pivot to BTcP has however required an increase in the number of trial participants to 60 compared to the original tendered protocol for phase 2 (Study B) of CRPS: 25. This change in scope has resulted in a revised Phase 2 clinical trial cost quote from Ingenu of \$2,597,000 across a 20 month trial period. On a per head basis, the new pricing equates to \$43,000 per trial participant versus \$54,000 based on the scope of the original trial. This cost is also lower than the alternative quoted pricing in the 2022 tender.

Whilst not completing a formal tender process, IRX engaged with a 2<sup>nd</sup> CRO service provider, Lumina Medical Research (**Lumina**), in order to obtain feedback on its plans and to verify pricing for the revised phase 2 trial. Lumina received a copy of the up-dated IRX211 Phase 2 protocol and had several meetings with IRX management and directors as part of its discovery process. On a comparable basis, the Lumina proposal was slightly more expensive than the Ingenu offer. Ingenu's experience and capability relative to Lumina in setting up and completing clinical trials to FDA standard was also assessed as superior, with Lumina's systems, processes and reporting requiring an up-grade from Australian standards in order to comply with FDA requirements.

In view of the above, the Company's board decided to appoint Ingenu as CRO to conduct the updated phase 2 trial for IRX211, subject to satisfying the requirements of the ASX Listing Rules.

It is noted that Ingenu is a wholly owned subsidiary of the Company's substantial shareholder, Cannvalate Pty Ltd (**CVL**) and party Listing Rules 10.1 applies. Furthermore, Darryl Davies (the Company's CEO and former Director) is a Director of Ingenu and CVL.

As a result, the Company is seeking shareholder approval under Listing Rule 10.1 of the appointment of Ingenu as CRO.

If this Resolution is passed, Ingenu will be appointed as the CRO for the Phase 2 clinical trial of IRX211 for BTcP and receive fees from the Company for its services.

If this Resolution is not passed, Ingenu will not be appointed as the CRO for the Phase 2 clinical trial of IRX211 for BTcP and the Company will not be able to proceed with this clinical trial until another tender evaluation has been completed.

#### Advantages of the Appointment

The original determination to appoint Ingenu as the CRO under the proposed clinical trials for PD and CRPS (approved by shareholders on 17<sup>th</sup> February 2023) was made on an independent basis following a competitive tender process. The Ingenu tender was the cheapest received and provides the best value for money for the Company. The Independent Expert Report prepared by Hall Chadwick Corporate (NSW) Limited dated 16 December 2022 concluded that the proposed transaction with Ingenu was fair and reasonable to the non-associated shareholders.

The revised quotation from Ingenu for the Phase 2 clinical trial of IRX211 for BTcP is still better value for money than the alternative proposal received in the original tender. Furthermore, the Company has tested the revised pricing provided by Ingenu which reflects the increased scope of the BTcP phase 2 clinical trial (relative to the original Phase 2 CRPS clinical trial scope) against a proposal provided by Lumina. On the results of this evaluation, Ingenu's offer remains the best value for money.

#### **Disadvantages of the Appointment**

The Company does not consider that there are any disadvantages to the appointment of Ingenu as CRO, relative to alternatives available to the Company.

#### Independent Expert's Report

The Independent Expert, Hall Chadwick Corporate (NSW) Limited, has concluded that the proposed transaction with Ingenu is fair and reasonable to the non-associated shareholders.

The Independent Expert's Report is attached to the Notice of Meeting in Annexure A.

#### Listing Rule 10.1

Listing Rule 10.1 provides that an entity (or any of its subsidiaries) must not acquire a substantial asset from, or dispose of a substantial asset to, inter alia, a related party without the approval of the holders of the entity's ordinary shares.

An asset is substantial if its value or the value of the consideration being paid or received for it is, or in ASX's opinion is, 5% or more of the equity interests of the company as set out in the latest accounts given to ASX under the Listing Rules.

The total consideration payable to Ingenu as CRO is anticipated to be approximately \$2.7 million. 5% of the equity interests of the Company as set out in its latest accounts given to the ASX is

\$33,000, therefore the payment is a transaction to which Listing Rule 10.1 applies.

#### Specific information required for the Notice of Meeting under Listing Rule 10.5

Pursuant to and in accordance with Listing Rule 10.5, the following information is provided in relation to the appointment of Ingenu as CRO:

- (a) the Company is proposing to appoint Ingenu as CRO for the Company's Phase 2 clinical trial of IRX211 as a treatment for BTcP.
- (b) Ingenu falls under Listing Rule 10.11.1 as a related party because Daryl Davies (the current CEO and former director of the Company) is also the COO and a director of Ingenu. Ingenu is also a subsidiary company of substantial IRX shareholder, CVL, a person to whom Listing Rule 10.1.3 applies. Consequently, InhaleRX is also a person to whom Listing Rule 10.1.4 applies.
- (c) the asset is a substantial payment of funds for undertaking the work required under the CRO contract.
- (d) the consideration for the transaction is anticipated to be approximately \$2.7 million to be paid in cash, subject to variations of up to 20%.
- (e) the services are expected to commence immediately following shareholder approval and complete in February 2026.
- (f) the appointment of Ingenu as CRO is occurring pursuant to an agreement. A summary of the material terms of the agreement as set out in Annexure B.
- (g) a voting exclusion statement is set out in the Notice of Meeting.
- (h) an Independent Expert's Report is included in Annexure C. The Independent Expert has determined the transaction the subject of Resolution 6 to be fair and reasonable to nonassociated Shareholders of the Company.

#### Directors' recommendation

The Directors recommend that Shareholders vote **IN FAVOUR** of this Resolution.

### Enquiries

Shareholders are asked to contact the Company Secretary, James Barrie, at <u>james.barrie@inhalerx.com.au</u> if they have any queries in respect of the matters set out in these documents.

### Glossary

**AEST** means Australian Eastern Standard Time as observed in Melbourne, Victoria.

**Annual General Meeting** or **AGM** or **Meeting** means an Annual General Meeting of the Company and, unless otherwise indicated, means the meeting of the Company's members convened by this Notice of Meeting.

**ASIC** means Australian Securities and Investment Commission.

**Associate** has the meaning given to it by the ASX Listing Rules.

**ASX** means ASX Limited ACN 008 624 691 or the financial market operated by it, as the context requires, of 20 Bridge Street, Sydney, NSW 2000.

**ASX Listing Rules** or **Listing Rules** means the official ASX Listing Rules of the ASX and any other rules of the ASX which are applicable while the Company is admitted to the official list of the ASX, as amended or replaced from time to time, except to the extent of any express written waiver by the ASX.

**Board** means the current board of Directors of the Company.

Business Day means a day on which trading takes place on the stock market of ASX.

**Chair** means the person chairing the Meeting.

**Closely Related Party** of a member of the KMP means:

- (a) a spouse or child of the member;
- (b) a child of the member's spouse;
- (c) a dependant of the member or of the member's spouse;
- (d) anyone else who is one of the member's family and may be expected to influence the member, or be influenced by the member, in the member's dealings with the Company;
- (e) a company the member controls; or
- (f) a person prescribed by the *Corporation Regulations 2001* (Cth).

Company means InhaleRx Limited ACN 611 845 820.

**Constitution** means the Company's constitution.

**Corporations Act** means the *Corporations Act 2001* (Cth) as amended or replaced from time to time.

**Director** means a current director of the Company.

Dollar or "\$" means Australian dollars.

**Equity Security** has the meaning given to that term in ASX Listing Rule 19.12.

Explanatory Statement means the explanatory statement accompanying this Notice of Meeting.

Incentive Plan means the employee incentive scheme entitled "Incentive Entitlements Plan"

**KMP** means key management personnel (including the Directors) whose remuneration details are included in the Remuneration Report.

**Notice of Meeting** or **Notice of Annual General Meeting** means this notice of Annual general meeting including the Explanatory Statement.

**Option** means an option which, subject to its terms, could be exercised into a Share.

**Ordinary Resolution** means a resolution that can only be passed if at least 50% of the total votes cast by Shareholders entitled to vote on the resolution are voted in its favour at the meeting.

Proxy Form means the proxy form attached to this Notice of Meeting.

**Related Bodies Corporate** has the meaning given to it in the Corporations Act.

**Resolutions** means the resolutions set out in this Notice of Meeting, or any one of them, as the context requires.

**Restricted Voter** means a member of the Company's KMP and any Closely Related Parties of those members.

Securities mean Shares and/or Options (as the context requires).

**Share** means a fully paid ordinary share in the capital of the Company.

Shareholder means a holder of a Share.

Share Registry means Automic Pty Ltd ACN 152 260 814.

**Special Resolution** means a resolution that can only be passed if at least 75% of the total votes cast by Shareholders entitled to vote on the resolution are voted in its favour at the meeting.

Trading Day has the meaning given to that term in ASX Listing Rule 19.12.

**VWAP** means the volume weighted average market (closing) price, with respects to the price of Shares.

# Annexure A – Summary of the material terms of the Incentive Plan

The following terms and phrases have the meanings ascribed to them below when used in this summary of the Rules:

Blackout Period	a period when the Eligible Participant is prohibited from trading in the Company's securities by the Company's Securities Trading policy or other similar policy.		
Board	the Board of Directors of the Company or a committee appointed by the Board for the purposes of the Plan		
Change of Control	the occurrence of any of the following events (each a <b>Change of</b> <b>Control Event</b> ) that results in a person or group of persons which did not have Control of the Company immediately prior to the completion or occurrence of the relevant Change of Control Event as the case may be ( <b>Completed Transaction</b> ), having Control of the Company immediately following the Completed Transaction:		
	) a takeover bid (as that term i Act) being made for the Com	s defined in the Corporations pany;	
	a Court sanctioned comprom 5.1 of the Corporations Act;	nise or arrangement under Part	
	) a selective capital reduction the Corporations Act; or	for the purposes of Chapter 2J of	
	) any other event that the Boa result in a change of Control	rd considers has resulted or will of the Company.	
Control	e same meaning as is given to that prporations Act.	term in section 50AA of the	
Corporations Act	the Corporations Act 2001 (Cth)		
Eligible Participant	a person who:		
	÷	ant' for the purposes of the ASIC loard has otherwise determined	
	) the Board Invites to participa	te in this Plan; and	
	) where the context requires, a (a) and (b), who accepts the l	a person fitting within paragraphs nvitation.	
Exemption Conditions	the exemption conditions set out in section 83A-35 of the ITAA 1997.		
Incentive Entitlement	any form of equity based incentive that entitles the recipient to be issued a Share as determined by the Board, including:		
	) Options; and		

Invitation	an invitation issued by the Board to an Eligible Participant to apply for a specified number of Incentive Entitlements pursuant to the Plan.
ITAA 1997	the Income Tax Assessment Act 1997 (Cth) as amended from time to time.
Plan	the InhaleRx Limited Incentive Entitlements Plan
Rules	the Plan Rules.
Share	a fully paid ordinary share in the capital of the Company.
Trading Lock	a mechanism arranged or approved by the Board and administered by the Company (including through its share registry or relevant securities exchange trading systems) that prevents Shares being disposed of by an Eligible Participant during the Trading Lock Period to ensure the Exemption Conditions are satisfied.

#### 1. Objectives

The objectives of the Plan are to:

(a) provide Incentive Entitlements to Eligible Participants who are considered to be key to the future success of the Company, in order to retain the services of those Eligible Participants in the future and incentivise their performance;

(b) provide a means by which Eligible Participants may acquire Shares in the Company in addition to their remuneration; and

(c) recognise and reward the performance of Eligible Participants and their contribution to the future success of the Company by providing Incentive Entitlements to those Eligible Participants.

#### 2. Principal Conditions

This Plan may be operated so that Incentive Entitlements issued to or acquired by Eligible Participants under the Plan satisfy the Exemption Conditions so as to permit the application of section 83A-35 of the ITAA 1997.

3. Invitation

The Board may from time to time in its absolute discretion issue Invitations to Eligible Participants.

Participation in the Plan by Eligible Participants is voluntary, and no eligible participant is required to participate in the Plan.

4. Payment for Incentive Entitlements

In determining Incentive Entitlements, the Board may from time to time:

(a) issue Incentive Entitlements to the Eligible Participants for such amount as determined by the Board in its absolute discretion, including but not limited to issuing Incentive Entitlements for nil consideration; and

(b) may require or invite an Eligible Participant to pay money on account of Incentive Entitlements to be acquired under the Plan, either by cash or salary sacrifice.

5. Disposal restrictions on rights transfer of Incentive Entitlements

(a) Incentive Entitlements issued under the Plan are not generally transferable without the prior written consent of the Board.

(b) An issue of Shares may be subject to a Trading Lock for a specified period of time. The Board can take whatever actions it deems necessary in order to enforce that Trading Lock, or to ensure that the Exemption Conditions are satisfied.

(c) The Board has a broad discretion to refuse to register the transfer of an Incentive Entitlement, or a Share issued on the exercise of an Incentive Entitlement, where that transfer would be in breach of:

- (i) the terms of this Plan;
- (ii) the terms of any restriction on dealing with that Incentive Plan (whether a Trading Lock or otherwise);
- (iii) the Corporations Act; or
- (iv) the ASX Listing Rules,

(d) A holder of the Incentive Entitlement may not grant a security interest over it unless the Board approval gives its prior written consent. Where attempts are made to do so without that consent, that Incentive Entitlement will immediately lapse.

(e) Any offer for the sale or issue of securities must be made under a disclosure document (such as a prospectus), unless an exception is expressly provided for under the Corporations Act, or by ASIC exercising its power to provide for certain amendments to the Corporations Act. ASIC has promulgated an exception to the need for a disclosure document, in respect of securities issued under an employee incentive scheme, provided that those schemes meet the criteria currently set out in ASIC Class Order 14/1000.

The Plan is designed to comply with ASIC Class Order 14/1000.

One of the requirements of ASIC Class Order 14/1000 is that the Company may not issue any Incentive Entitlements, or Shares pursuant to the exercise of such Incentive Entitlements (the **Relevant Issue**), unless the Company has reasonable grounds to believe that by doing so:

- (i) the total number of Shares that may be issued or required to be issued as a result;
- (ii) when aggregated with the total number of Shares that have been issued or may be issued as a result of offers made under previous employee incentive schemes in reliance on ASIC Class Order 14/1000 in the previous three years,

would not exceed 5% of the total number of Shares on issue at the date of the Relevant Issue.

6. Vesting of Incentive Entitlements

(a) The Board may issue Incentive Entitlements subject to any vesting conditions that it sees fit including such conditions as length of tenure, or meeting key performance indicators (Vesting Conditions).

(b) In certain circumstances the Incentive Entitlements may lapse including where the Board deems that they shall lapse as a result of the Incentive Entitlements Holder:

(i) acting fraudulently or dishonestly, being grossly negligent, demonstrating serious and wilful misconduct, or causing material damage to the reputation of the Company in any of its subsidiaries;

(ii) having his or her employment office terminated due to serious wilful misconduct or otherwise for cause without notice; or

(iii) dealing with any Incentive Entitlement contrary to the provisions of this Plan, the relevant Invitation, or applicable law.

(c) Part 2D.2 Division 2 of the Corporations Act (Part 2D.2 Division 2) prohibits the payment of termination benefits to certain senior executives unless the benefits are approved by

shareholders or specific exemptions apply. There are additional requirements imposed by the Listing Rules. The Plan allows the Board to not issue an Incentive Entitlement if it would be contrary to Part 2D.2 Division 2.

(d) All Incentive Entitlements will immediately vest if a Change of Control occurs.

7. Issue of Options

(a) One type of Incentive Entitlement that may be granted to Eligible Participants are Options.

(b) Holders of Options may exercise them by lodging a duly completed Notice of Exercise and paying the Exercise Price which has been set out in the relevant Invitation.

(c) The Eligible Participant may elect to pay the Exercise Price by setting off the total Exercise Price that it pays for exercising of its Options against the number of Shares that they would be entitled to receive on exercise of the relevant Options.

8. Exercise of Options

(a) Each Option or other type of Incentive Entitlement entitles the holder to one Share upon vesting of the Incentive Entitlement.

(b) The Company will apply for the listing on the ASX of each Share issued on the exercise of an Incentive Entitlement and each Share will rank equally in all respects with all other Shares already.

(c) There will be no transfer restrictions on Shares unless they are subject to a Trading Lock or their issue would require the preparation of a disclosure document (such as a prospectus).

(d) No Shares will be issued during a Blackout Period, or if to do so would breach the insider trading or takeover provisions of the Corporations Act.

9. Bonus Issues, Reconstruction

There may be adjustments to the number of Incentive Entitlements that an Eligible Participant is entitled to if the Company makes a bonus issue of shares, or there is a reorganisation of the Shares on issue (such as a consolidation, subdivision, reduction or return). Apart from this the holders of Incentive Entitlements are not entitled to participate in any new issue of Shares.

#### 10. Amendments

(a) The Board may make amendments to the Plan and the Rules provided that it may not do so if this would reduce the rights of the Incentive Entitlement holders in respect of their Incentive Entitlements, other than where it is necessary to do so in order to:

(i) comply with any applicable law, any practice of the ASIC, or ASX;

(ii) to correct a manifest error; or

(iii) take into account any adverse effects of tax on the plan arising from, amongst other things a change to the taxation law.

(b) Unless expressly stated in any contract of employment or service between the Company and any Eligible Participant or set out in the relevant Invitation, neither the Plan nor the Rules form part of, and are not incorporated into, any contract of employment or service. No holder of any Incentive Entitlement will have any right to compensation or damages for loss of any entitlement to Incentive Entitlements as a consequence of the termination of their office or employment.

# Annexure B – Summary of the material terms of the Ingenu appointment agreement

The material terms of Ingenu's appointment as CRO under a Master Service Agreement (**MSA**) are summarised as follows:

- The CRO is engaged to provide the services for each trial under a separate Study Order,
- Each Study Order is subject to and governed by the provisions of the MSA with the terms of the MSA to take precedent.
- The CRO and IRX, as Sponsor, are each required to take out insurance covering:
  - Clinical trial insurance of no less than \$20 million; and
  - Professional indemnity insurance of no less than \$10 million.
- The MSA outlines the standard of performance required of the CRO in providing the CRO services, with both parties required to comply with industry specific clinical trial standards and guidelines for clinical trial CRO's and Sponsors.
- The MSA specifies the reporting obligations of the parties and the terms of the indemnity provided by each party relative to its obligations and duties to the other party. Terms specifying the extent and limitation on the liability of each party are also included.
- The MSA also incorporates a number of restraint and non-circumvention provisions governing the interaction of the parties through the clinical trial process.
- The MSA makes provision for the sharing of Intellectual Property and Confidential Information belonging to each party and specifies that the ownership of the intellectual property created from clinical trial vests with IRX as Sponsor.
- The MSA incorporates with cause termination provisions either due to the default of a party or if appears that it is appropriate the study to cease (eg unacceptable or serious adverse events; the study product is proven to be ineffective etc.)
- Each Study Order specifies:
  - Name of the trial
  - Study product
  - o Services and deliverables from the CRO relevant to the clinical trial
  - $\circ$  ~ Fees to be paid to the CRO for services provided
  - Payment terms
  - Commencement and End Date of the study
  - Timeline for delivery (which is subject to IRX as Sponsor obtaining shareholder approval under ASX Listing Rules)
  - $\circ$   $\;$  Scope of work and activities to be completed in the clinical trial
  - Project deliverables
  - o Project risks
  - Project management resourcing and deliverables
  - the formal Transfer of Regulatory Obligations (TORO) between the parties for the purposes of the clinical trials.
- The Study Orders also incorporate provisions which allow IRX as Sponsor to suspend a Study Order pending capital raising or funding activities to be undertaken by IRX.
- Either party can terminate a Study Order without cause upon 30 days notice, but the CRO will only be paid for services provided or for any additional costs reasonably incurred arising directly from the Sponsor's termination of the Study Order.

### Annexure C – Independent Expert's Report



Corporate Finance & Advisory Services

23 April 2024

The Directors InhaleRx Limited Level 5 126 Phillip Street SYDNEY NSW 2000

Dear Sirs,

#### **Independent Expert's Report on related party transaction**

#### 1. INTRODUCTION

#### Background

- 1.1 InhaleRx Limited ("IRX" or "the Company") is an Australian public company listed on the Australian Securities Exchange ("ASX"). The Company focuses on developing inhalation medicinal therapies in Australia and internationally to address unmet medical needs in pain management and mental health sectors.
- 1.2 In 2022, IRX undertook a competitive global tender process to identify a Clinical Research Organisation ("CRO") which could project manage its clinical trial programs for its pain and anxiety indications.
- 1.3 Based on the tender offers received, IRX chose to partner with Ingenu CRO Pty Ltd ("Ingenu") under a Master Services Agreement ("MSA") for the supply of services under a Study Order issued pursuant to the MSA.
- 1.4 Ingenu is a wholly owned subsidiary of Cannvalate Pty Ltd ("CVL") which is a substantial shareholder of IRX. Furthermore, IRX's medical advisor, Dr Sud Agrawal and CEO (former executive director), Darryl Davies are directors of CVL such that CVL is a related party under the Corporations Act and ASX Listing Rules.
- 1.5 The nominated indication for pain was Complex Regional Pain Syndrome ("CRPS") and anxiety was Panic Disorder ("PD").
- 1.6 On 17 February 2023, the ordinary shareholders (Shareholders) of the Company approved, among other things, the appointment of Ingenu as a CRO to conduct the Company's clinical trials for mental health and pain.
- 1.7 Certain changes detailed at Section 2 of this report have been made to the Phase 2 protocols of the clinical trials for pain which requires an adjustment to costing, for which Ingenu have provided a quote to undertake.

HALL CHADWICK CORPORATE (NSW) LIMITED

ACN 080 462 488

SYDNEY

Level 40, 2 Park Street Sydney NSW 2000 Australia

GPO Box 3555 Sydney NSW 2001

Ph: (612) 9263 2600

Fx: (612) 9263 2800

E: hcsydinfo@hallchadwick.

com.au

www.hallchadwick.com.au



1.8 The renewed proposal from Ingenu to undertake the Phase 2 trials, as detailed at section 2, is referred to in this report as the "Transaction".

#### **Opinion**

- 1.9 In our opinion, the Transaction is *fair and reasonable* to the Non-Associated Shareholders of IRX.
- 1.10 The ultimate decision however on whether to accept the Transaction should be based on shareholders own assessment of their circumstances.

#### **Purpose of Report**

- 1.11 You have requested Hall Chadwick Corporate (NSW) Limited ("HCC") to prepare an Independent Expert's Report to advise the shareholders of IRX not associated with the Transaction ("Non-Associated Shareholders"), in considering a resolution to approve the Transaction under ASX listing rule 10.1, whether the Transaction is fair and reasonable when considered in the context of the interests of Non-Associated Shareholders and to set out the reasons for our conclusions.
- 1.12 HCC understands and has agreed that this report is required by ASX listing rule 10.5 to accompany the notice to convene a meeting of IRX shareholders, to assist the Non-Associated Shareholders in their consideration of the Transaction.

#### 2. OUTLINE OF THE PROPOSED TRANSACTION

- 2.1 On 17 February 2023, IRX Shareholders approved, among other things, the appointment of Ingenu as a CRO to conduct the Company's clinical trials for anxiety and pain.
- 2.2 Ingenu is a wholly owned subsidiary of CVL which is a substantial shareholder of IRX. Furthermore, IRX's medical advisor, Dr Sud Agrawal and CEO (former executive director), Darryl Davies are directors of CVL such that CVL is a related party under the Corporations Act and ASX Listing Rules.
- 2.3 The appointment of Ingenu followed a process undertaken by the Company's CRO tender selection committee ("Committee") comprising non-executive directors Sean Williams and Andrew Saich. Mr Ron Budhram, a UK based clinical trial specialist with over 30 years experience, was also invited to join the Committee as a subject matter expert.
- 2.4 After adherence to both the Company's Vendor Selection and Management Standard Operating Procedure ("SOP") relating to CRO selection and legal advice and based upon its evaluation of the tender responses, the Committee recommended that the IRX board of directors should appoint lnGenu as the CRO for the purposes of the conduct of the planned anxiety and pain clinical trials.
- 2.5 IRX through its contract with Ingenu is currently in the final stages of the Phase 1 (Study A) clinical trial for its synthetic THC dronabinol based inhaled drug, IRX211 as a treatment for pain, with the Clinical Study Report ("CSR") (being the last milestone) expected to be made available in May 2024.
- 2.6 In March 2023, IRX completed a pre-Investigational New Drug ("pre-IND") meeting with the US Food & Drug Administration ("FDA") in relation to its proposed clinical program for achieving a New Drug Approval ("NDA") of its IRX211 drug for the treatment of CRPS as the primary indication of focus for pain. Whilst supportive overall, some of the FDA feedback encouraged the Company to reconsider pain indications for which the path to registration required less exploratory work and for which the IRX211 formulation was a closer fit, based on the recent Phase 1 pharmacokinetic results.
- 2.7 Following a detailed and careful evaluation process, the Company decided to promote Breakthrough Cancer Pain ("BTcP") (instead of CRPS) as the primary indication of focus for the proposed Phase 2 trial of IRX211. The established path to registration for BTcP offers a significant commercial opportunity for IRX211 and is also expected to substantially reduce the overall amount of exploratory work required and better mitigate regulatory uncertainty (compared to CRPS). This change was confirmed to the market via an ASX announcement in January 2024.
- 2.8 The pivot to BTcP has however required an increase in the number of trial participants to 60 compared to the original tendered protocol for phase 2 (Study B) of CRPS: 25. This change in scope has resulted in a revised Phase 2 clinical trial cost quote from Ingenu of \$2,656,351 across a 20-month trial period. On a per head basis, the new pricing equates to \$44,000 per trial participant versus \$54,000 based on the scope of the original trial ("Ingenu Proposal").
- 2.9 Whilst not completing a formal tender process, IRX engaged with a 2<sup>nd</sup> CRO service provider, Lumina Medical Research, in order to obtain feedback on its plans and to verify

pricing for the revised phase 2 trial. Lumina received a copy of the up-dated IRX211 Phase 2 protocol and had several meetings with IRX management and directors as part of its discovery process.

- 2.10 Lumina's quote was \$2,442,200 across a similar 20 month trial period, but excluded HREC approval which was separately quoted at \$100,000 and the Clinical Study Report (which we estimate would cost c\$100,000-150,000 to complete) ("Lumina Proposal"). So on a comparable basis, the Lumina Proposal is slightly more expensive than the Ingenu Proposal.
- 2.11 In view of the above and other details included at section 6, the IRX board has decided its strong preference is accept the Ingenu Proposal and to appoint Ingenu as CRO to conduct the up-dated phase 2 trial for IRX211, subject to satisfying the requirements of the ASX Listing Rules.

#### **STRUCTURE OF REPORT**

Our report is set out under the following headings:

- 3 PURPOSE OF REPORT
- 4 BASIS OF EVALUATION
- 5 OVERVIEW OF IRX
- 6 ASSESSMENT OF TRANSACTION TERMS
- 7 ADVANTAGES AND DISADVANTAGES OF THE TRANSACTION
- 8 CONCLUSION AS TO FAIRNESS AND REASONABLENESS

#### APPENDICES

- I SOURCES OF INFORMATION
- II STATEMENT OF DECLARATION & QUALIFICATIONS
- III FINANCIAL SERVICES GUIDE

#### **3. PURPOSE OF REPORT**

- 3.1 The purpose of this report is to advise the Non-Associated Shareholders of IRX of the fairness and reasonableness of the Transaction. This report provides an opinion on whether or not the terms and conditions in relation to the transaction are fair and reasonable to the IRX shareholders whose votes are not to be disregarded in respect of the transaction (that is, the Non-Associated Shareholders).
- 3.2 The ultimate decision whether to accept the terms of the Transaction should be based on each shareholders' assessment of their own circumstances, including their risk profile, liquidity preference, tax position and expectations as to value and future market conditions. If in doubt about the Transaction or matters dealt with in this report, shareholders should seek independent professional advice.
- 3.3 For the Transaction to be fair, the terms of the Ingenu Proposal need to be on market-based arms-length terms. To be reasonable the Non-Associated Shareholders must obtain an overall benefit if the Transaction proceeds.
- 3.4 This report has been prepared to satisfy the requirements of the ASX Listing Rules.
- 3.5 ASX Listing Rule 10.1 requires that a listed company must obtain shareholder approval before it acquires or disposes of a substantial asset. This applies where the vendor of the relevant asset is a related party of the listed company and when the assets value or the value of the consideration for it, constitutes more than 5% of the equity interest of that company at the date of the last audited accounts. The Ingenu Proposal and the value of the services to be provided for the phase 2 trial for IRX211 constitutes a substantial asset and is being entered into with a Company, Ingenu, a subsidiary of CVL which is a substantial shareholder of IRX. Furthermore, IRX's medical advisor, Dr Sud Agrawal and CEO (former executive director), Darryl Davies are directors of CVL such that CVL is a related party under the Corporations Act and ASX Listing Rules.
- 3.6 ASX Listing Rule 10.5 therefore requires a report on the transaction from an independent expert stating whether the transaction is fair and reasonable to non-associated shareholders. This report provides such an opinion.

#### 4. BASIS OF EVALUATION

- 4.1 In our assessment of whether the Transaction is fair and reasonable to IRX Non-Associated Shareholders, we have given due consideration to the Regulatory Guides issued by ASIC, in particular, Regulatory Guide 74 "Transactions Agreed to by Shareholders", Regulatory Guide 111 "Content of Experts Reports" and Regulatory Guide 112 "Independence of Experts Reports".
- 4.2 ASIC Regulatory Guide 74 requires, amongst other things, that shareholders are provided with sufficient information to make an effective, informed decision on whether the proposed Transaction is fair and reasonable. In this case, the Transaction is "fair" if the Ingenu Proposal is based on arms-length market rates. Additionally, under Regulatory Guide 111 a transaction is "reasonable" if it is fair or, if despite being unfair, based on non-financial factors, the shareholders should still approve the Transaction.
- 4.3 Our report has compared the likely advantages and disadvantages to Non-Associated shareholders if the Transaction is agreed to, with the advantages and disadvantages to those shareholders if it is not.
- 4.4 In our assessment of the Transaction we have considered, in particular the following:
  - The operational and financial position of IRX;
  - The process undertaken by IRX to CRO proposals for the phase 2 trial for IRX211;
  - The terms of the Ingenu Proposal and Lumina Proposal;
  - The advantages and disadvantages associated with approving the Transaction;
  - Other qualitative and strategic issues associated with the Transaction.
- 4.5 The documents and information relied on for the purpose of this report are set out in Appendix I. We have considered and relied upon this information and believe that the information provided is reliable, complete and not misleading and we have no reason to believe that material facts have been withheld. The information provided was evaluated through analysis, enquiry and review for the purpose of forming an opinion as to whether the Transaction is fair and reasonable. However, in assignments such as this, time is limited and we do not warrant that our enquiries have identified or verified all of the matters which an audit or more extensive examination might disclose. None of these additional tasks have been undertaken.
- 4.6 An important part of the information used in forming an opinion of the kind expressed in this report is the opinions and judgement of management. This type of information has also been evaluated through analysis, enquiry and review to the extent practical. However, it must be recognised that such information is not always capable of external verification or validation.
- 4.7 HCC are not the auditors of IRX or Ingenu. We have analysed and reviewed information provided by the Directors and management of IRX and made further enquiries where appropriate.
- 4.8 This report has been prepared after taking into consideration the current economic and market climate. We take no responsibility for events occurring after the date of this report which may impact upon this report or which may impact upon the assumptions referred to in this report.

#### 5 OVERVIEW OF IRX

#### 5.1 Corporate Overview

- 5.1.1 IRX was officially listed on the ASX on 11 January 2017 and focuses on developing inhalation medicinal therapies in Australia and internationally. The company was formerly known as Lifespot Health Ltd and changed its name to InhaleRx Limited in October 2021.
- 5.1.2 The Company is working on developing a range of inhaled therapeutic medicinal formulations for registration domestically and internationally to address unmet medical needs in pain management and mental health sectors.
- 5.1.3 IRX is currently undertaking clinical trials associated with the application of inhaled therapeutic medicinal formulations for the treatment of pain and anxiety. The initial primary indication of focus for pain was CRPS, while the initial primary indication of focus for anxiety is PD.
- 5.1.4 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, pregabalin and atypical antidepressants.
- 5.1.5 IRX211 is a THC based synthetic cannabinoid derived drug (dronabinol) delivered via a pressurised metered dose inhaler ("pMDI') in a fixed dose designed to provide rapid onset analgesia for patients suffering with acute episodic bursts of breakthrough pain. These are generally of short duration, typically lasting minutes to hours.
- 5.1.6 It is envisaged that this solution will help to improve the quality of life for sufferers of breakthrough pain. Furthermore, the novel drug device combination will improve administrative efficiency and dose metering compared to smoking, vaping or oral administration of cannabinoids.

#### 5.2 Rationale for the Transaction and overview of Ingenu

- 5.2.1 IRX sought responses from CRO's to the invitation for the provision of clinical research services as described in section 2. Following the offers received from various CRO's, IRX chose to partner with Ingenu under the MSA for the supply of services under a Study Order issued pursuant to the MSA.
- 5.2.2 Ingenu is an Australian based full-service CRO specialising in clinical trials for entheogens, cannabinoid and psychedelic pharmaceuticals. Their vision is to become a centre of excellence for drug development in this niche clinical area to accelerate positive patient outcomes.
- 5.2.3 The initial Study Order was to involve the following work with regards to the use of a novel cannabinoid derived drug that the Company had developed (IRX211):
  - (a) Pain trials valued \$880,000 for phase 1 and \$1,361,000 for phase 2. The cost of phase 1 was subsequently increased to \$950,000; and
  - (b) PD trial valued at \$2,700,000.

- 5.2.4 IRX through its contract with Ingenu is currently in the final stages of the Phase 1 (Study A) clinical trial for pain of its synthetic THC dronabinol based inhaled drug, IRX211. To date, Ingenu has been paid \$910,000 against a contract value of \$950k for this trial and \$20,000 in respect of the PD trial which is still at HREC approval stage.
- 5.2.5 As described at section 2, IRX has decided to promote BTcP instead of CRPS as the primary pain indication of focus for the proposed Phase 2 trial of IRX211. According to the 11<sup>th</sup> revision of the International Classification of Diseases, chronic cancer pain is defined as pain caused by primary cancer itself, metastases or its treatment. BTcP is described as a temporary intensification of such pain that arises either spontaneously or in connection with a particular predictable or unpredictable trigger, even when the background pain is relatively stable and well-controlled.
- 5.2.6 After considering the costings received from Ingenu and Lumina, and other factors associated with the experience of these CRO's, the Ingenu Proposal is considered the better option for the Company and therefore the IRX board has decided its strong preference is accept the Ingenu Proposal and to appoint Ingenu as CRO to conduct the up-dated phase 2 trial for IRX211, subject to satisfying the requirements of the ASX Listing Rules.

### 5.3 Public Company Information

5.3.1 IRX currently has a market capitalisation of approximately \$9.48 million.

DATE	TYPE
28 Mar 2024	• Appendix 3B (Proposed issue of securities)
28 Mar 2024	• Appendix 4G
28 Mar 2024	Corporate Governance Statement and Appendix 4G
28 Mar 2024	Annual Report to shareholders
28 Mar 2024	• Issued Capital – \$500,000 Convertible Loan Facility
20 Mar 2024	Company Presentation
13 Mar 2024	• Web Cast
6 Mar 2024	• Progress Report - Milestone achieved - Database Lock Phase 1 IRX211
1 Mar 2024	Initial Director's Interest Notice

5.3.2 IRX has released the following public company announcements in the last six months:

DATE	ΤΥΡΕ
14 Feb 2024	Preliminary Final Report
16 Jan 2024	Commitments Test Entity - Fourth Quarter Cashflow Report
16 Jan 2024	Commitments Test Entity - Fourth Quarter Activity Report
10 Jan 2024	• Progress Report - IRX211 - Targeted Pain Indication Nomination - BTcP
21 Dec 2023	Periodic Reports - Other
4 Dec 2023	<ul> <li>Progress Report - Significant Milestone - Completion of IRX211 Phase 1 Trial</li> </ul>
22 Nov 2023	Company Presentation
20 Nov 2023	• Web Cast
9 Nov 2023	• Company Administration - Clarification of claim against significant IRX shareholder
31 Oct 2023	Commitments Test Entity - Third Quarter Cashflow Report
31 Oct 2023	Commitments Test Entity - Third Quarter Activity Report
30 Oct 2023	• Company Presentation - IRX presents at AusBioInvest 2023
18 Oct 2023	<ul> <li>Progress Report - Ethics Application Submitted IRX616a Phase 2, Panic Disorder</li> </ul>

# 5.4 Financial Information

5.4.1 Set out below is the reviewed consolidated Balance Sheet of IRX as at 31 December 2023:

INHALERX LIMITED				
CONSOLIDATED BALANCI	E SHEET			
	31 December 2023			
CURRENT ASSETS				
Cash and cash equivalents	715,819			
Trade and other receivables	802,362			
Prepayments and deposits	58,703			
	1,576,884			
NON-CURRENT ASSETS				
Intangibles				
	-			
TOTAL ASSETS	1,576,884			
CURRENT LIABILITIES				
Trade and other payables	350,668			
Borrowings	560,275			
Employee benefits	179			
	911,122			
NON-CURRENT LIABILITIES	201			
Employee benefits	291			
	291			
TOTAL LIABILITIES	911,413			
IUIAL LIADILITIES	911,415			
NET ASSETS	665,471			
THE ADDE TO	003,471			
EQUITY				
Issued capital	14,075,978			
Reserves	(241,346)			
Accumulated losses	(13,169,161)			
TOTAL EQUITY	665,471			

5.4.2 Set out below is the Consolidated Profit and Loss Statements of IRX for the financial years ended 31 December 2022 ("2022") and 31 December 2023 ("2023") (audited):

INHALERX LIMIT	ED	
CONSOLIDATED PROFIT AND L	OSS STATEM	ENT
	<u>2022</u>	<u>2023</u>
Revenue	24,800	-
Gain on liquidation of German subsidiaries	10,924	-
Interest revenue	16,127	2,029
R&D tax rebate	-	1,204,046
Directors fees and costs	(252,439)	(181,659)
Employee benefits expense	(42,254)	(223,425)
Depreciation and amortisation expense	(521)	-
Write off of intangible assets	-	(13,745)
Share based payment expense	(32,245)	(57,519)
Consulting costs	(366,960)	(436,351)
Corporate expenses	(192,747)	(210,094)
Marketing expenses	(33,883)	(33,300)
Product development expenditure	(977,137)	(1,448,185)
Other expenses	(80,714)	(36,963)
Finance costs		(8,105)
Loss before tax	(1,927,049)	(1,443,271)

# 6 ASSESSMENT OF THE TRANSACTION

## 6.1 Overview of Tender Review and Selection Process

- 6.1.1 It is the policy of IRX to contract many activities relating to the development of any clinical compound. IRX have in place Standard Operating Procedures ("SOPs") that are intended to represent management processes and activities that are necessary to control and manage such outsourcing.
- 6.1.2 In 2022, IRX undertook a competitive global tender process to identify a CRO which could project manage its clinical trial programs for its pain and anxiety indications. Based on the tender offers received, IRX chose to partner with Ingenu for the supply of services under a Study Order issued pursuant to a MSA.
- 6.1.3 On 17 February 2023, the ordinary shareholders (Shareholders) of the Company approved, among other things, the appointment of Ingenu as a CRO to conduct the Company's clinical trials for PD and pain.
- 6.1.4 In January 2024, the Company released an ASX announcement confirming that it had decided to nominate Breakthrough Cancer Pain (BTcP), instead of CRPS, as the primary pain indication of focus for the proposed IRX211 phase 2 trial. The announcement also noted that the change was initially expected to result in a change in scope for the proposed IRX211 phase 2 trial (Revised Phase 2 Trial) which in turn was expected to increase its cost and duration, when compared to what was expected under the initial transaction, although the total cost and time to market would be cheaper and shorter in respect of BTcP.
- 6.1.5 The pivot to nominate BTcP as the primary pain indication for the clinical trial requires the recruitment of 60 patients for the Revised Phase 2 Trial to meet the US FDA requirements, rather than the initial 25. The Company requested price quotes concerning the Revised Phase 2 Trial from Ingenu and a third-party provider, Lumina Medical Research.
- 6.1.6 Considerations for the selection of an appropriate CRO include the following:
  - 1. IRX's requirements for a time efficient and cost effective clinical trial process;
  - 2. IRX's desire that the clinical trials be conducted within Australia to access the Australian 43% R&D tax rebates;
  - 3. The specialised nature of the trials involving inhaled cannabinoids;
  - 4. The size of the trials (required number of participants) and relatively short timeframes.

### 6.2 **Proposals and Recommendation**

- 6.2.1 The Ingenu Proposal for the phase 2 clinical trials and the recruitment of 60 patients was a quoted cost of \$2,656,351 across a 20-month trial period. On a per head basis, the new pricing equates to \$44,000 per trial participant versus \$54,000 based on the scope of the original trial.
- 6.2.2 The table below has been extracted from the Ingenu Proposal and shows the cost breakdown for the 60 patient trial.

Line Items	Cost (AUD)	Line Items	
CRO CLINICAL TRIAL ACTIVITY COSTS		3RD PARTY PASSTHROUGH COSTS	
Medical Writing	\$57,250	Import/Central Pharmacy	
Project Management	\$295,173	Safety Laboratory	
Clinical Data Management	\$217,163	Patient Fees (n=60)	
Biostatistics	\$327,979	Site Fees	
Trial Monitoring	\$182,849	Total	
Medical Monitoring	\$105,688		
Pharmacovigilance	\$85,400	GRAND TOTAL	
Sub-total	\$1,271,501		
CRO PASSTHROUGH COSTS			
Rating Scales	\$20,000		
/ieDoc (EDC)	\$94,046		
/eeva (CTMS/eTMF Hosting/Licensing)	\$7,800		
lights (Blinded & Unblinded CRA)	\$17,600		
Accommodation (Blinded & Unblinded CRA)	\$6,600		
Meal Allowance (Blinded & Unblinded CRA)	\$2,684		
Sub-total	\$148,730		
Total	\$1,420,231		

- 6.2.3 Whilst not completing a formal tender process, IRX engaged with a 2<sup>nd</sup> CRO service provider, Lumina Medical Research, in order to obtain feedback on its plans and to verify pricing for the revised phase 2 trial. Lumina received a copy of the up-dated IRX211 Phase 2 protocol and had several meetings with IRX management and directors as part of its discovery process.
- 6.2.4 The Lumina Proposal quoted \$2,442,200 across a similar 20 month trial period, but excluded HREC (Human Research Ethics Committee) approval which was separately quoted at \$100,000 and the Clinical Study Report (which IRX management estimate would cost c\$100,000-150,000 to complete).
- 6.2.5 On a comparable basis, the Lumina Proposal is slightly more expensive than the Ingenu Proposal at the high end of the range. However there were other factors IRX management considered. Lumina's clinical operations team, though comprising highly experienced and well credentialled, senior practicing medical clinicians with significant medical research experience, lacked any experience in setting up and completing clinical trials to the FDA standards. Similarly, all of Lumina's systems, processes and reporting was based on Australian standards and did not comply with FDA requirements.
- 6.2.6 While Lumina's proposal incorporated a promise to up-grade all of its trial elements to meet the required FDA standards, considerable risk was identified due to the complexity of the required amendments and a lack of experience in working with and understanding the FDA standards. This led to concerns that the trial timing and integrity could be compromised should the up-grade not be executed to plan. It also emerged during the final Lumina presentation that it did not have any demonstrated capability in trial recruitment and that any delay in recruitment was likely to result in additional costs being passed through to IRX.
- 6.2.7 In view of the above, the IRX board decided its strong preference was to accept the Ingenu Proposal and to appoint Ingenu as CRO to conduct the up-dated phase 2 trial for IRX211, subject to satisfying the requirements of the ASX Listing Rules.

# 7 ADVANTAGES & DISADVANTAGES OF THE TRANSACTION

### 7.1 Approach to assessing Fairness and Reasonableness

HCC has followed the guidelines of ASIC Regulatory Guide 111 in assessing the fairness and reasonableness of the Transaction. In forming our conclusions in this report, HCC compared the advantages and disadvantages for Non-Associated Shareholders if the Transaction proceeds.

#### 7.2 Advantages of the Transaction

- 7.2.1 The Ingenu Proposal has been independently prepared on arms-length commercial terms having regard to the requirements of the phase 2 trial for IRX211 and the costings included in the Ingenu Proposal;
- 7.2.2 The appointment of Ingenu was considered by a selected Committee independent of parties associated with any of the CRO invitees, including Ingenu;
- 7.2.3 The Vendor Selection and Management SOP has been reviewed and the terms and procedures appear appropriate and reasonable;
- 7.2.4 Nothing has come to our attention which causes us to believe that the requirements of the SOP have not been followed in the selection of the CRO;
- 7.2.5 The initial appointment of lnGenu as CRO was determined based on specific tender selection criteria which identified Ingenu's tender as the one with an overall higher evaluation score and pricing assessment outcome, providing the best value for money outcome for IRX. The decision to continue with Ingenu as CRO for the phase 2 trials was based on Ingenu still being the most cost effective and qualified CRO to undertake these trials;
- 7.2.6 The Transaction is viewed as the best alternative to allow IRX to complete the clinical trials necessary to advance the development of their PMDI and create future shareholder value.

# 7.3 Disadvantages of the Transaction

7.3.1 There are risks associated with clinical trials not resulting in the commercialisation of products that shareholders are accepting if they approve the Transaction and agree to release the funds to the selected CRO, being a related party of the Company.

# 8 CONCLUSION AS TO FAIRNESS AND REASONABLENESS

#### 8.1 Fairness

- 8.1.1 For the Transaction to be fair, the terms of the Ingenu Proposal need to be at market-based arms-length terms.
- 8.1.2 We have considered, amongst other things, the information available on the Company, the terms of the Ingenu Proposal and the process through which a CRO was selected.
- 8.1.3 In our opinion the Transaction is **fair** as:
  - a) The Ingenu Proposal has been independently prepared on arms-length commercial terms having regard to the requirements of the trials and the costings included in the proposal;
  - b) The appointment of Ingenu was considered by a selected Committee independent of parties associated with any of the CRO invitees, including Ingenu;
  - c) The Vendor Selection and Management SOP has been reviewed and the terms and procedures appear appropriate and reasonable;
  - d) Nothing has come to our attention which causes us to believe that the requirements of the SOP have not been followed in the selection of the CRO;
  - e) The initial appointment of lnGenu as CRO was determined based on specific tender selection criteria which identified Ingenu's tender as the one with an overall higher evaluation score and pricing assessment outcome, providing the best value for money outcome for IRX. The decision to continue with Ingenu as CRO for the phase 2 trials was based on Ingenu still being the most cost effective and qualified CRO to undertake these trials.

## 8.2 Reasonableness

- 8.2.1 ASIC Regulatory Guide 111 states that a transaction is reasonable if:
  - The Transaction is fair; or
  - Despite not being fair the expert believes that there are sufficient reasons for security holders to accept the offer in the absence of any higher bid before the close of the offer.
- 8.2.2 We have concluded that the Transaction is fair and also reasonable. In forming our opinion we have also considered the fact that the Transaction is viewed as the best alternative to allow IRX to complete the clinical trials necessary to advance the development of their PMDI and create future shareholder value.
- 8.2.3 Having considered that the Transaction is fair, the potential advantages and disadvantages of the Transaction, in our opinion the Non-Associated Shareholders of IRX should benefit if the Transaction proceeds and therefore, in our opinion the Transaction is fair and reasonable.

Yours faithfully Hall Chadwick Corporate (NSW) Limited

DREW TOWNSEND

# **APPENDIX I - SOURCES OF INFORMATION**

- InhaleRx Limited Audited Financial Reports for the financial years ended 31 December 2022 and 31 December 2023;
- Ingenu CRO Pricing Proposal for IRX211a phase 2 trial;
- Lumina Medical Research Pricing Proposal for IRX211a phase 2 trial;
- Invitation to Supply: Contract Research Organisation (CRO) Invitation to Supply and tender process;
- CRPS and PD Synopses;
- InhaleRx Vendor Selection and Management Standard Operating Procedure;
- Avance and Ingenu Tender responses and accompanying capabilities and costings annexures;
- InhaleRx Limited Contract Research Organisation ('CRO') Tender Recommendation dated 10 October 2022;
- CRO Tender Offer Evaluation Scorecard;
- Contract Research Services (CRO) Master Services Agreement (MSA) and Study Order issued pursuant to the MSA;
- IRX Notice of General Meeting and Explanatory Memorandum;
- IRX Company registry details;
- Publicly available information on IRX and Ingenu;
- Regulatory Guide 111 'Content of Expert Reports'; and
- Regulatory Guide 112 'Independence of Expert's Reports'.

# **APPENDIX II - STATEMENT OF DECLARATION & QUALIFICATIONS**

#### **Confirmation of Independence**

Prior to accepting this engagement HCC determined its independence with respect to IRX and Ingenu with reference to ASIC Regulatory Guide 112 (RG 112) titled "Independence of Expert's Reports". HCC considers that it meets the requirements of RG 112 and that it is independent of IRX and Ingenu.

Also, in accordance with s648 (2) of the Corporations Act we confirm we are not aware of any business relationship or financial interest of a material nature with IRX, its related parties or associates that would compromise our impartiality.

Mr Drew Townsend, director of Hall Chadwick Corporate (NSW) Limited, has prepared this report. Neither he nor any related entities of Hall Chadwick Corporate (NSW) Limited have any interest in the promotion of the Transaction nor will Hall Chadwick Corporate (NSW) Limited receive any benefits, other than normal professional fees, directly or indirectly, for or in connection with the preparation of this report. Our fee is not contingent upon the success or failure of the proposed transaction, and has been calculated with reference to time spent on the engagement at normal professional fee rates for work of this type. Accordingly, HCC does not have any pecuniary interests that could reasonably be regarded as being capable of affecting our ability to give an unbiased opinion under this engagement.

HCC provided a draft copy of this report to the Directors and management of IRX for their comment as to factual accuracy, as opposed to opinions, which are the responsibility of HCC alone. Changes made to this report, as a result of the review by the Directors and management of IRX have not changed the methodology or conclusions reached by HCC.

### **Reliance on Information**

The statements and opinions given in this report are given in good faith and in the belief that such statements and opinions are not false or misleading. In the preparation of this report HCC has relied upon information provided on the basis it was reliable and accurate. HCC has no reason to believe that any information supplied to it was false or that any material information (that a reasonable person would expect to be disclosed) has been withheld from it. HCC evaluated the information provided to it by IRX as well as other parties, through enquiry, analysis and review, and nothing has come to its attention to indicate the information provided was materially mis-stated. We believe the information relied upon provides reasonable grounds upon which to base this report.

Our procedures and enquiries do not include verification work, nor constitute an audit or review in accordance with Australian Auditing Standards (AUS). HCC does not imply and it should not be construed that it has audited or in anyway verified any of the information provided to it, or that its enquiries could have verified any matter which a more extensive examination might disclose.

The sources of information that we relied upon are outlined in Appendix I of this report.

IRX has provided an indemnity to HCC for any claims arising out of any mis-statement or omission in any material or information provided by IRX to HCC in preparation of this report.

# Qualifications

Hall Chadwick Corporate (NSW) Limited ("HCC") carries on business at Level 40, 2 Park Street, Sydney NSW 2000. HCC holds Australian Financial Services Licence No. 227902 authorising it to provide financial product advice on securities to retail clients. HCC's representatives are therefore qualified to provide this report.

## **Consent and Disclaimers**

The preparation of this report has been undertaken at the request of the Directors of IRX. It also has regard to relevant ASIC Regulatory Guides. It is not intended that the report should be used for any other purpose than to accompany the Notice of General Meeting to be sent to IRX shareholders. In particular, it is not intended that this report should be used for any purpose other than as an expression of HCC's opinion as to whether or not the proposed Transaction is fair and reasonable to Non-Associated shareholders of IRX.

HCC consent to the issue of this report in the form and context in which it is included in the Notice of General Meeting to be sent to IRX shareholders. Shareholders should read all documents issued by IRX that consider the proposed Transaction in its entirety, prior to proceeding with a decision. HCC had no involvement in the preparation of these additional documents.

This report has been prepared specifically for the Non-Associated shareholders of IRX. Neither HCC, nor any member or employee thereof undertakes responsibility to any person, other than a Non-Associated shareholder of IRX, in respect of this report, including any errors or omissions howsoever caused. This report is "General Advice" and does not take into account any person's particular investment objectives, financial situation and particular needs. Before making an investment decision based on this advice, you should consider, with or without the assistance of a securities advisor, whether it is appropriate to your particular investment needs, objectives and financial circumstances.

Our procedures and enquiries do not include verification work, nor constitute an audit or review in accordance with Australian Auditing Standards (AUS).

Our opinions are based on economic, market and other conditions prevailing at the date of this report. Such conditions can change significantly over relatively short periods of time. Furthermore, financial markets have been particularly volatile in recent times. Accordingly, if circumstances change significantly, subsequent to the issue of the report, our conclusions and opinions may differ from those stated herein. There is no requirement for HCC to update this report for information that may become available subsequent to this date.

# **APPENDIX III - FINANCIAL SERVICES GUIDE**

Hall Chadwick Corporate (NSW) Limited ("HCC") carries on business at Level 40, 2 Park Street, Sydney NSW 2000. HCC holds Australian Financial Services Licence No. 227902 authorising it to provide financial product advice on securities to retail clients.

The Corporations Act 2001 requires HCC to provide this Financial Services Guide ("FSG") in connection with its provision of an independent expert's report ("Report") which is included in a Notice of Meeting ("Notice") provided to members by the company or other entity for which HCC prepares the Report.

HCC does not accept instructions from retail clients. HCC provides no financial services directly to retail clients and receives no remuneration from retail clients for financial services. HCC does not provide any personal retail financial product advice to retail investors nor does it provide market-related advice to retail investors.

When providing Reports, HCC's client is the Entity to which it provides the Report. HCC receives its remuneration from the Entity. In respect of this Report for InhaleRx Limited ("IRX"), HCC will receive a fee for its services on a time cost basis estimated to be \$15,000, excluding GST.

No related body corporate of HCC, or any of the directors or employees of HCC or of any of those related bodies or any associate receives any remuneration or other benefit attributable to the preparation and provision of the Report.

HCC is required to be independent of the Entity in order to provide a Report. The guidelines for independence in the preparation of Reports are set out in Regulatory Guide 112 issued by the Australian Securities & Investments Commission. The following information in relation to the independence of HCC is stated in Appendix II of this Report:

"Hall Chadwick Corporate (NSW) Limited ("HCC") has a license to prepare reports under the Corporations Act and its representatives are qualified to provide this report. Prior to accepting this engagement HCC determined its independence with respect to IRX and Ingenu with reference to ASIC Regulatory Guide 112(RG 112) titled "Independence of Expert's Reports". HCC considers that it meets the requirements of RG 112 and that it is independent of IRX and Ingenu.

Also, in accordance with s648 (2) of the Corporations Act we confirm we are not aware of any business relationship or financial interest of a material nature with IRX or Ingenu, or their related parties or associates that would compromise our impartiality.

Mr Drew Townsend, director of Hall Chadwick Corporate (NSW) Limited, has prepared this report. Neither he nor any related entities of Hall Chadwick Corporate (NSW) Limited have any interest in the promotion of the Transaction nor will Hall Chadwick Corporate (NSW) Limited receive any benefits, other than normal professional fees, directly or indirectly, for or in connection with the preparation of this report. Our fee is not contingent upon the success or failure of the proposed transaction, and has been calculated with reference to time spent on the engagement at normal professional fee rates for work of this type. Accordingly, HCC does not have any pecuniary interests that could reasonably be regarded as being capable of affecting our ability to give an unbiased opinion under this engagement."

### **Complaints resolution**

If you have a complaint, please let HCC know. Formal complaints should be sent in writing to: The Complaints Officer Hall Chadwick Corporate (NSW) Limited GPO Box 3555 Sydney NSW 2001

If you have difficulty in putting your complaint in writing, please telephone the Complaints Officer on 02 9263 2600 and they will assist you in documenting your complaint.

Written complaints are recorded, acknowledged within 5 days and investigated. As soon as practical, and not more than 45 days after receiving the written complaint, the response to your complaint will be advised in writing.

### **External complaints resolution process**

If HCC cannot resolve your complaint to your satisfaction within 45 days, you can refer the matter to the Australian Financial Complaints Authority (AFCA). AFCA is an independent authority that has been established to provide advice and assistance to consumers to help in resolving complaints relating to the financial services industry.

Further details about AFCA are available at the AFCA website www.afca.org.au or by contacting them directly at:

Australian Financial Complaints Authority717 Bourke Street, Docklands, Victoria 3008Telephone:1800 931 678Website:www.afca.org.auEmail:info@afca.org.au

The Australian Securities and Investments Commission also has a free call infoline on 1300 300 630 which you may use to obtain information about your rights.

HCC is only responsible for the Report and this FSG. Complaints or questions about the Notice should not be directed to HCC who is not responsible for that document. HCC will not respond in any way that might involve any provision of financial product advice to any retail investor.