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**INHALE RX LIMITED**  
**ACN 611 845 820**  
**NOTICE OF GENERAL MEETING**

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Notice is given that the Meeting will be held at:

**TIME:** 4.00pm AEDT

**DATE:** Thursday, 6 March 2025


**PLACE:** The meeting is a virtual meeting. Please pre-register prior to the day of the meeting at:

[https://us02web.zoom.us/webinar/register/WN\\_dD6TFIAUR8G6hWtqyfq1g](https://us02web.zoom.us/webinar/register/WN_dD6TFIAUR8G6hWtqyfq1g)

***The business of the Meeting affects your shareholding and your vote is important.***

***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.***

***The Directors have determined pursuant to Regulation 7.11.37 of the Corporations Regulations 2001 (Cth) that the persons eligible to vote at the Meeting are those who are registered Shareholders at 7pm AEDT on Tuesday, 4 March 2025.***



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## **BUSINESS OF THE MEETING**

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### **AGENDA**

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**1. RESOLUTION 1 – APPROVAL TO APPOINT INGENU CRO PTY LTD AS THE CONTRACT RESEARCH ORGANISATION, 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.”*

**A voting exclusion statement applies to this Resolution. Please see below.**

**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.*

**Dated: 4 February 2025**

**By order of the Board**

**James Barrie**  
**Non-Executive Director and Company Secretary**

## Voting Exclusion Statement

In accordance with Listing Rule 14.11, the Company will disregard any votes cast in favour of the resolution by or on behalf of the following persons:

- (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;
- (d) Dr Sud Agrawal and his associates or
- (e) 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 the 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.

## Voting by proxy

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To vote by proxy, please complete and sign the enclosed Proxy Form and return by the time and in accordance with the instructions set out on the Proxy Form.

In accordance with section 249L of the Corporations Act, Shareholders are advised that:

- each Shareholder has a right to appoint a proxy;
- the proxy need not be a Shareholder of the Company; and
- a Shareholder who is entitled to cast two (2) or more votes may appoint two (2) proxies and may specify the proportion or number of votes each proxy is appointed to exercise. If the member appoints two (2) proxies and the appointment does not specify the proportion or number of the member's votes, then in accordance with section 249X(3) of the Corporations Act, each proxy may exercise one-half of the votes.

Shareholders and their proxies should be aware that:

- if proxy holders vote, they must cast all directed proxies as directed; and
  - any directed proxies which are not voted will automatically default to the Chair, who must vote the proxies as directed.
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## **Voting online at the virtual meeting**

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The company is pleased to 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.

**Shareholders are encouraged to register well prior to the day of the Meeting to ensure there is no delay in attending the Meeting.**

To access the virtual meeting:

1. If you do not have a free and secure Zoom logon, please download the Zoom Mobile App from your play store or download the Zoom Client for Meetings file from your internet browser.
2. Please pre-register by opening your internet browser and going to:  
[https://us02web.zoom.us/webinar/register/WN\\_dD6TFIAUR8G6hWtqyfq1g](https://us02web.zoom.us/webinar/register/WN_dD6TFIAUR8G6hWtqyfq1g)
3. Select the capacity in which you are attending, then enter your registered holding name, email address of your zoom account, HIN/SRN and postcode and click "register".
4. Once your details are verified, you will receive a separate personalised email with details of how to logon on the day of the Meeting.
5. Click on the personalised link you will be emailed to join the Meeting, where you can view and listen to the Meeting, vote during the poll 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.

**Should you wish to discuss the matters in this Notice please do not hesitate to contact the Company Secretary, James Barrie, at [james.barrie@inhalerx.com.au](mailto:james.barrie@inhalerx.com.au).**

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## EXPLANATORY STATEMENT

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This Explanatory Statement has been prepared to provide information which the Directors believe to be material to Shareholders in deciding whether or not to pass the Resolution.

### 1. RESOLUTION 1 – APPROVAL TO APPOINT INGENU CRO PTY LTD AS THE CONTRACT RESEARCH ORGANISATION, A RELATED PARTY OF THE COMPANY

#### 1.1 Background

As announced in the Company's Dec24 Quarterly Activities Report on 23 January 2025, in November 2024 the Company commenced a tender process involving a number of local and international Contract Research Organisations (**CRO**) for the purpose of selecting a CRO to oversee the conduct of its planned Phase 1 IRX616a and Phase 2 IRX-211 human clinical trials.

Formal request for tender packs for each clinical trial were compiled comprising a final draft of the relevant synopsis and a proposed Transfer of Regulatory Obligations (**TORO**) document. The tender document incorporated an evaluation process and selection criteria to be applied by the tender CRO selection committee (**Committee**).

A key requirement of the tender was to maximise the eligibility of clinical trial expenditure for inclusion in the Federal Department of Industry's Research & Development Tax Incentive Scheme (**RDTI**).

A further significant consideration was the nominated completion timelines for the trials outlined in the funding agreement with Clendon Biotech Capital Pty Ltd announced on 18 October 2024 (**Clendon Facility**), namely a 2 to 3-year window for completion of the Phase 2 clinical trial for IRX-211 (and required non-clinical studies) and a 3 to 4-year window for completion of the Phase 1 & 2 clinical trials for IRX-616a (and required non-clinical studies).

A Committee was established comprising non-executive director Sean Williams, non-executive director and company secretary James Barrie and Mr Ron Budhram, a UK based clinical trial specialist with over 30-years' experience.

The Vendor Selection and Management Standard Operating Procedure (**SOP**) developed for prior tenders was adopted and applied.

Other than from Ingenu, the other CRO's invited to tender declined to submit tenders for a variety of reasons:

1. Concerns expressed by CRO tender participants regarding conflicts of interest and specifically the risk to the CRO's intellectual property which may need to be shared with IRX in the conduct of the clinical trials due to the declared involvement of IRX executives in the management of Ingenu;
2. The limited scale of the trials was regarded as too small by some of the large international CRO's to be of interest; and
3. One CRO declared a conflict of interest because the IRX-616a trial was regarded as too similar to trials it was conducting for other sponsors.

After consideration of the above and the adherence to both the Company's SOP relating to CRO selection and legal advice received on the selection process, the Committee recommended the IRX board of directors should appoint Ingenu as the CRO for the purposes of conducting the Phase 1 IRX616a and Phase 2 IRX-211 human clinical trials.

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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) is a Director of Ingenu and CVL and Dr Sud Agrawal (the Company's Medicinal Adviser) is a Director of Ingenu and CVL.

At no stage were Ingenu, CVL or its directors Messrs Agarwal or Davies involved in or present during any discussion of the tender presentation and they had no involvement in any aspect of the tender pack finalisation, selection of parties or evaluation of responses,

The only information provided to IRX management related to timeframes and high-level progress against these timeframes.

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 IRX-211 and IRX-616a clinical trials 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 IRX-211 and IRX-616a clinical trials and the Company will not be able to proceed with the trials until another tender evaluation has been completed.

#### **Advantages of the Appointment**

- a) The CRO appointment documentation has been independently prepared on arms-length commercial terms having regard to the requirements of the trials and the costings included in the Ingenu tender;
- b) The tender process was undertaken by a selected Committee independent of parties associated with any of the CRO invitees;
- c) The appointment of Ingenu as the CRO for the purposes of the conduct of the planned Further Trials was determined after confirming that their tender submission met the specific tender selection criteria and would provide the necessary outcome for IRX in the absence of any other viable tender being received;
- d) Ingenu have acted as CRO for IRX for previous trials and are familiar with IRX products, procedures and processes.
- e) The Transaction will allow IRX to complete the IRX-211 and IRX-616a clinical trials and possibly create future shareholder value through the ultimate marketing and sale of these pain relief products.

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

- a) 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 raised by the Company to the selected CRO, being a related party of the Company.
- b) Given no other tenders were received for the IRX-211 and IRX-616a clinical trials, it is difficult to compare the proposal and costings provided by Ingenu.

## 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 \$8.9 million. of the equity interests of the Company as set out in its latest accounts given to the ASX is (\$51,986), 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 IRX-211 and IRX-616a clinical trials.
- (b) Ingenu falls under Listing Rule 10.1.1 as a related party because Daryl Davies (CEO 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, the Company 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 \$8.9 million to be paid in cash, subject to variations of up to 20%.
- (e) the services are expected to commence in May 2025 and complete in May 2028.
- (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 A. The Independent Expert has determined the transaction the subject of Resolution 1 to be fair and reasonable to non-associated Shareholders of the Company.

### Directors' recommendation

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

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## GLOSSARY

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

**ASIC** means the Australian Securities & Investments 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 ASX Limited, as the context requires.

**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.

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

**General Meeting** or **Meeting** means the meeting convened by the Notice.

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



**Notice** or **Notice of Meeting** means this notice of meeting including the Explanatory Statement and the Proxy Form.

**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.

**Resolution** means the resolution set out in this Notice of Meeting.

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

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

**Shareholder** means a registered holder of a Share.

**Share Registry** means Automic Pty Ltd ACN 152 260 814.

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

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22 January 2025

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 is focused on developing inhalation medicinal therapies in Australia and internationally, offering medical inhalation devices for the delivery of prescribed medicines.
- 1.2 IRX is currently trialling inhaled therapeutic medicinal formulations for the treatment of breakthrough cancer pain and panic disorder. In 2022 IRX invited Clinical Research Organisations (“CRO”) to tender for the provision of clinical research services for further clinical studies into these treatments. 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.
- 1.3 In 2024 IRX issued further tenders for the appointment of a CRO to oversee the following proposed further trials:
  - a) Phase 2 clinical trial of IRX-211 for the treatment of Breakthrough Cancer Pain; and
  - b) Phase 1 clinical trial of IRX-616a for the treatment of Panic Disorder.
- 1.4 The process and selection of InGenu as the continuing CRO for these trials are detailed at section 2 and are referred to in this report as the “Transaction”.

#### *Opinion*

- 1.5 In our opinion, the Transaction is *fair and reasonable* to the Non-Associated Shareholders of IRX.

HALL CHADWICK  
CORPORATE (NSW) LIMITED

ACN 080 462 488

SYDNEY

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- 1.6 The ultimate decision however on whether to accept the Transaction should be based on shareholders own assessment of their circumstances.

***Purpose of Report***

- 1.7 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.
- 1.8 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, to determine if 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.
- 1.9 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 In late 2021 a draft synopsis for two planned clinical trials for cannabinoid based drug-device combinations for the treatment of Complex Regional Pain Syndrome ('CRPS') and Panic Disorder ('PD') were developed and the IRX board began to focus on the process for appointing a CRO(s) which would oversee the clinical trials for the CRPS and PD studies
- 2.2 In May 2022, the IRX board (in the absence of Darryl Davies) formed a 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.
- 2.3 The Committee's first task was to draft and adopt a suitable Vendor Selection and Management Standard Operating Procedure ("SOP"), which was finalised on 22 July 2022. The Committee then proceeded to finalise a formal request for tender requirements for each clinical trial, including a final draft of the relevant synopsis, a proposed Transfer of Regulatory Obligations ("TORO") document and draft Master Services Agreement ("MSA"). The tender document incorporated an evaluation process and selection criteria to be applied by the Committee.
- 2.4 After adherence to both the Company's SOP relating to CRO selection and legal advice, and based upon its evaluation of the tender responses the Committee recommended the IRX board of directors should appoint InGenu as the CRO for the purposes of the conduct of the planned PD and CRPS clinical trials.
- 2.5 In 2024 IRX sought responses from CRO's to the Invitation for the provision of clinical research services to oversee the following proposed Further Trials:
- a) Phase 2 clinical trial of IRX-211 for the treatment of Breakthrough Cancer Pain; and
  - b) Phase 1 clinical trial of IRX-616a for the treatment of Panic Disorder.
- 2.6 An Invitation to Supply through a tender process was issued to various CRO's for these further IRX-211 and IRX-616a trials ("Further Trials").
- 2.7 The IRX-211 trial has been covered by two previous tenders which were approved by shareholders in 2022. The current tender is driven by the need for a substantial increase in the scope and expected cost of the IRX-211 trial, from 60 to 156 participants.
- 2.8 The IRX-616a trial is a new trial which was not previously put to tender on the assumption that the regulatory authorities (Ethics Committee) would approve the commencement of a Phase 2 trial for this treatment without the need for Phase 1 data. Further detail on this requirement is included at section 6.1.
- 2.9 In selecting the CRO to undertaken the Further Trials, the same Tender Selection Committee process and SOP was followed, with the exception that James Barrie replaced Dr Andrew Saich on the Committee.
- 2.10 For reasons set out in section 6 of this report, InGenu has been appointed as the CRO to conduct the Further Trials and intends to enter into a new MSA and Study Orders for these Further Trials.

## **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

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### 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. 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 MSA 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 MSA and the value of the services to be provided pursuant to the underlying Study Order 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 MSA 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 tender process undertaken by IRX to invite and review offers from potential CRO’s;
  - The terms of the MSA and underlying Supply Order for the Further Trials;
  - 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's current focus is on developing a range of inhaled therapeutic medicinal formulations for registration domestically and internationally.
- 5.1.3 IRX has commenced trials for the application of inhaled therapeutic medicinal formulations for the treatment of breakthrough cancer pain ("BTcP") and panic disorder ("PD").
- 5.1.4 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.
- 5.1.5 IRX-211 is a novel drug device combination of THC (dronabinol) in a pressurised metered dose inhaler ("PMDI") for rapid onset symptomatic relief. While the current (mainly opioid-based e.g. fentanyl) therapeutic options play a crucial role in managing pain, their prescription and use requires careful monitoring and adherence to established guidelines to mitigate the significant risks of tolerance, dependence, and opioid-related adverse events. As a result, there is a significant unmet need in the BTcP space for a non-opioid-based rapid-onset analgesic
- 5.1.6 PD refers to the experience of recurrent and disabling panic attacks which last up to a few minutes and are accompanied by physical symptoms such as heart palpitations, shaking, shortness of breath, and dizziness.
- 5.1.7 IRX-616a is a novel drug device combination of CBD (cannabidiol) in a PMDI for rapid onset symptomatic relief. The novel drug device combination is designed to treat individuals with PD to provide faster onset relief from panic attacks and reduce concomitant anti-depressant usage.
- 5.1.8 It is envisaged that these solutions will help to improve the quality of life for BTcP and PD sufferers. 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 for
- a. Phase 2, Double-blind, Placebo-controlled, Multicenter, Cross-over Study with Titration Period to evaluate the efficacy and safety of IRX211a for the treatment of breakthrough cancer pain in opioid tolerant patients; and

- b. Phase 1, Randomized, Double-Blind, Placebo Controlled Single Ascending Dose Study to assess the pharmacokinetics, safety and tolerability of IRX-616a in healthy adult volunteers.
- 5.2.2 The invitation included a Study Order which specified, amongst other things, the scope of work and activities, project deliverables, project management and service charges/pricing submission.
- 5.2.3 For various reasons outlined in section 6, IRX was unable to obtain responses to the tenders from any CRO's other than InGenu. Therefore, following the formal tender process, IRX has chosen to partner again with InGenu for the Further Trials.
- 5.2.4 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.
- 5.2.5 The various documents we have reviewed in assessing the process undertaken by IRX to seek and review offers to determine to partner with InGenu are listed at Appendix I.

### 5.3 Public Company Information

- 5.3.1 IRX currently has a market capitalisation of approximately \$7 million.
- 5.3.2 IRX has released the following public company announcements in the last six months:

DATE	TYPE
19 Dec 2024	Progress Report
17 Dec 2024	Cleansing Notice
17 Dec 2024	Change of Director's Interest Notice
17 Dec 2024	Change of Director's Interest Notice
17 Dec 2024	Appendix 2A
17 Dec 2024	Appendix 3H (Notification of cessation of securities)
16 Dec 2024	Appendix 3B (Proposed issue of securities)
16 Dec 2024	Appendix 3G
16 Dec 2024	Issued Capital - Other

<b>DATE</b>	<b>TYPE</b>
29 Nov 2024	Results of Meeting
28 Nov 2024	Company Presentation EGM Slides
28 Nov 2024	Director appointment, resignation and Initial Director's Interest Notice
15 Nov 2024	Progress Report – Ethics Approval for Phase 2 Clinical Trial of IRX-211 opens
14 Nov 2024	Change in substantial holding
31 Oct 2024	Commitments Test Entity - Third Quarter Cashflow Report
31 Oct 2024	Commitments Test Entity - Third Quarter Activity Report
29 Oct 2024	Web Cast – General Meeting
29 Oct 2024	Notice of General Meeting
29 Oct 2024	Proxy Form
28 Oct 2024	Change in substantial holding
24 Oct 2024	Appendix 2A
23 Oct 2024	Cleansing Notice
23 Oct 2024	Issued Capital - Other
23 Oct 2024	Appendix 3B (Proposed issue of securities)
18 Oct 2024	Appendix 3B (Proposed issue of securities)
18 Oct 2024	Debt Facility - \$38.5m to fully fund clinical development plans
3 Oct 2024	Appendix 2A
2 Oct 2024	Appendix 3B (Proposed issue of securities)
2 Oct 2024	Issued Capital - Other

<b>DATE</b>	<b>TYPE</b>
30 Aug 2024	Half Yearly Report
31 Jul 2024	Commitments Test Entity - Second Quarter Activity Report
31 Jul 2024	Commitments Test Entity - Second Quarter Cashflow Report
25 Jul 2024	Company Presentation
5 Jul 2024	Progress Report – IRX-616a Application Outcome
3 Jul 2024	Progress Report – Final clinical study report received, Phase 1 IRX-211 opens

## 5.4 Financial Information

5.4.1 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) and for the half year ended 30 June 2024 (“HY2024”) (reviewed):

<b>INHALERX LIMITED</b>			
<b>CONSOLIDATED PROFIT AND LOSS STATEMENT</b>			
	<b>2022</b>	<b>2023</b>	<b>HY2024</b>
Revenue	24,800	-	-
Gain on liquidation of subsidiary	10,924	-	-
Interest revenue	16,127	2,029	3,636
R&D tax rebate	-	1,204,046	121,395
Directors fees and costs	(252,439)	(181,659)	(97,647)
Employee benefits expense	(42,254)	(223,425)	(100,689)
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)	(244,229)
Corporate expenses	(192,747)	(210,094)	-
Marketing expenses	(33,883)	(33,300)	-
Product development expenditure	(977,137)	(1,448,185)	(186,363)
Other expenses	(80,714)	(36,963)	(178,311)
Finance costs	-	(8,105)	(55,368)
<b>Loss before tax</b>	<b>(1,927,049)</b>	<b>(1,443,271)</b>	<b>(737,576)</b>

5.4.2 Set out below is the reviewed consolidated Balance Sheet of IRX as at 30 June 2024:

<b>INHALERX LIMITED</b>	
<b>CONSOLIDATED BALANCE SHEET</b>	
	<b>30 June 2024</b>
<b><u>CURRENT ASSETS</u></b>	
Cash and cash equivalents	332,631
Trade and other receivables	142,100
Prepayments and deposits	107,028
	581,759
<b>TOTAL ASSETS</b>	<b>581,759</b>
<b><u>CURRENT LIABILITIES</u></b>	
Trade and other payables	314,743
Borrowings	318,616
	633,359
<b><u>NON-CURRENT LIABILITIES</u></b>	
Employee benefits	386
	386
<b>TOTAL LIABILITIES</b>	<b>386</b>
<b>NET ASSETS</b>	<b>(51,986)</b>
<b><u>EQUITY</u></b>	
Issued capital	14,075,978
Reserves	(221,227)
Accumulated losses	(13,906,737)
<b>TOTAL EQUITY</b>	<b>(51,986)</b>

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## 6 ASSESSMENT OF THE TRANSACTION

### 6.1 Overview of Tender and Selection Process

- 6.1.1 It is the policy of IRX to contract many activities relating to the development of its clinical compounds. 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 May 2022, the IRX board (in the absence of Darryl Davies) formed a 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 year experience, was also invited to join the Committee as a subject matter expert.
- 6.1.3 The Committee's first task was to draft and adopt a suitable Vendor Selection and Management SOP, which was finalised on 22 July 2022. The Committee then proceeded to finalise a formal request for tender pack for each clinical trial, including a final draft of the relevant synopsis, a proposed Transfer of Regulatory Obligations (“TORO”) document and draft MSA. The tender document incorporated an evaluation process and selection criteria to be applied by the Committee.
- 6.1.4 The Vendor Selection and Management SOP was followed to select CRO’s to undertake relevant studies and trials. The SOP describes processes for the following activities relevant to the appointment of a CRO:
- Identification, evaluation, selection and approval
  - Contract preparation and transfer of responsibilities
  - Management
  - Completion of service
- 6.1.5 In November 2024 IRX sought responses from CRO’s to the Invitation for the provision of clinical research services to oversee the following proposed Further Trials:
- a) Phase 2 clinical trial of IRX-211 for the treatment of Breakthrough Cancer Pain; and
  - b) Phase 1 clinical trial of IRX-616a for the treatment of Panic Disorder.
- 6.1.6 IRX has secured a funding agreement with Clendon Biotech Capital (“Clendon”) which would provide funding for the cost of development of both IRX-211 and IRX-616a through to Phase 3. The Clendon funding agreement provides for a 2-3 year window for completion of the Phase 2 clinical trial for IRX-211 (and required non-clinical studies) and a 3-4 year window for completion of the Phase 1 & 2 clinical trials for IRX-616a (and required non-clinical studies).
- 6.1.7 An Invitation to Supply through a tender process was issued to various CRO’s for these further IRX-211 and IRX-616a trials (“Further Trials”).
- 6.1.8 The IRX-211 trial has been covered by two previous tenders which were approved by shareholders in 2022. The current tender is driven by the need for a substantial increase in the scope and expected cost of the IRX-211 trial, from 60 to 156 participants.
- 6.1.9 The IRX-616a trial is a new trial which was not previously put to tender on the assumption that the regulatory authorities (Ethics Committee) would approve the commencement of a Phase 2 trial for this treatment without the need for Phase 1 data.

6.1.10 In December 2023, IRX applied to the Bellberry Human Research Ethics Committee (“Bellberry HREC”) for approval to proceed with its planned phase 2 trial for IRX-616a. Unfortunately, this application was declined with the Bellberry HREC seeking phase 1 data (safety & pharmacokinetics) before approving the commencement of the phase 2 trial which was to involve dosing of IRX-616a to patients suffering from PD. This was an unexpected requirement given that IRX-616a is a cannabidiol (“CBD”) based formulation and CBD is broadly accepted as safe in low doses and presently is sold in some overseas jurisdictions (eg the UK) under very low levels of regulation.

6.1.11 The availability of funding via the Clendon facility has now unlocked the IRX-616a phase 1 clinical trial – which had been delayed due to uncertainty regarding how it would be funded. Given this trial was not included in the 2022 Tender, there was a need to formally issue a tender process covering IRX’s requirements for a CRO to oversee the phase 1 clinical trial.

6.1.12 In selecting the CRO to undertake the Further Trials, the same Tender Selection Committee process and SOP was followed, with the exception that James Barrie replaced Dr Andrew Saich on the Committee.

6.1.13 At no stage were Messrs Agarwal or Davies involved in (or present during any discussion of) the tender process and there was no involvement of either in any aspect of the tender pack finalisation, selection of parties or evaluation of responses. Nor was there any sharing of sensitive information relative to the tender or the tender responses.

## **6.2 Selection of Tender Participants and Committee Recommendation**

6.2.1 The IRX-616a tender pack protocol proposed a Phase 1, randomized, double-blind, placebo controlled single ascending dose study to assess the pharmacokinetics, safety and tolerability of CBD Inhalation aerosol in 24 healthy adult volunteers.

6.2.2 The IRX-211 tender pack protocol for the Phase 2 clinical trial proposed a Phase 2, double-blind, placebo-controlled, multicenter, cross-over study with titration period to evaluate the efficacy and safety of IRX211a for the treatment of BTcP in opioid tolerant patients. The trial design required 156 patients to be enrolled in the first stage, involving titration to evaluate and identify effective dosing. It was anticipated that 60% of these patients would advance to the 2<sup>nd</sup> stage where the trial would involve 78 patients for the conduct of the double-blind, randomized, placebo-controlled phase of the trial.

6.2.3 A list of CRO's to be invited to participate in the tender process was formed after considering 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 relatively small size of the trials (required number of participants) and relatively short timeframes.

6.2.4 An initial list of seven CRO's was developed through on-line research and considered by the Committee. In developing this short-list of potential tender participants contacted, the Committee's focus was on identifying CRO's with an operational presence in Australia who

also had experience in trials involving one or more of the following:

1. Inhaled medicines;
2. Cannabinoids; and
3. Pain or anxiety

6.2.5 With the exception of InGenu, the remaining six CRO's declined to submit tenders for the following reasons:

1. Concerns expressed by CRO tender participants regarding conflicts of interest and specifically the risk to the CRO's intellectual property which may need to be shared with IRX in the conduct of the clinical trials due to the declared involvement of IRX executives in the management of InGenu;
2. The limited scale of the trials was regarded as too small by some of the large international CRO's to be of interest; and
3. One CRO declared a conflict of interest because the IRX-616a trial was regarded as too similar to trials it was conducting for other sponsors.

6.2.6 After consideration of the above and the adherence to both the Company's SOP relating to CRO selection and legal advice received on the selection process, the Committee recommended that the IRX board of directors should appoint InGenu as the CRO for the purposes of conducting the Further Trials.

### **6.3 InGenu Proposals**

6.3.1 InGenu submitted two options for the IRX-616a Phase 1 trial:

- a. Completion of the trial using the Cmax phase 1 facility in Adelaide (one of two highly credentialed Phase 1 sites in Australia) at a cost of \$1.592m (\$66k per participant); and
- b. Completion of the trial at a small recently established Melbourne site (Vitalis Clinical Research) ('Vitalis') at a cost of \$0.98m (\$41k per participant).

6.3.2 A site inspection of the Vitalis facility was completed in December 2024 by members of the Committee. This inspection involved the site's director, Dr Arul Sivanesan, an experienced anaesthetist, pain management specialist and medical researcher. The inspection confirmed that the site appeared to be set-up in a functional and compliant manner, but was yet to become operational with the first clinical trial activity expected to commence in January 2025.

6.3.3 While the site inspection confirmed that the Vitalis site appeared to meet the functional requirements of the trial, there are significant risks associated with the site not yet being operational. Accordingly, it is recommended that the trial be conducted at the well established CMax site in Adelaide, notwithstanding that this results in an additional \$612k in cost.

6.3.4 InGenu submitted the following options for the IRX-211 Phase 2 trial after consultation regarding keeping the trial duration to within the 2-3 year window stipulated in the Clendon Funding Facility:

- a. Completion of the trial using four Australian sites across a 50 month period at a cost of \$6.0m for 156 patients (cost per patient: \$43k); and



- b. Completion of the trial using four Australian and up to ten Malaysian sites across a 34.5 month period at a cost of \$7.3m for 156 patients (cost per patient: \$43k). The cost of the Malaysian components of the trial is estimated at \$940k.

6.3.5 Given the need to reduce the trial duration in line with the requirements of the Clendon Funding Agreement and in view of the potential recruitment challenges relevant to BTcP patients in Australia, it is recommended that the trial design allow for the use of Malaysian sites. This would be subject to the primary objective being that the key non-dosing trial processes be conducted in Australia and that the majority of dosed patients are in Australia in order to maximise the RDTI (research and development tax incentive) eligibility of the trial expenditure.

6.3.6 The Clendon Funding Agreement will cover the funding of the costs of the proposed IRX-616a Phase 1 and IRX-211 Phase 2 trials. IRX shareholders are only required to fund the working capital and operational costs of the Company for the duration of these trials.

## **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 MSA has been independently prepared on arms-length commercial terms having regard to the requirements of the trials and the costings included in the InGenu tender;
- 7.2.2 The tender process was undertaken by a selected Committee independent of parties associated with any of the CRO invitees;
- 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 appointment of InGenu as the CRO for the purposes of the conduct of the planned Further Trials was determined after confirming that their tender submission met the specific tender selection criteria and would provide the necessary outcome for IRX in the absence of any other viable tender being received;
- 7.2.6 InGenu have acted as CRO for IRX for previous trials and are familiar with IRX products, procedures and processes.
- 7.2.7 The Transaction will allow IRX to complete the Further Trials and possibly create future shareholder value through the ultimate marketing and sale of these pain relief products.

### **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 raised by the Company to the selected CRO, being a related party of the Company.
- 7.3.2 Given no other tenders were received for the Further Trials, it is difficult to compare the proposal and costings provided by InGenu.

## 8 CONCLUSION AS TO FAIRNESS AND REASONABLENESS

### 8.1 Fairness

8.1.1 For the Transaction to be fair, the terms of the MSA need to be at market based arms-length terms.

8.1.2 We have considered, amongst other things, the information available on the Company, its current operations, the terms of the MSA and the process in which a CRO was selected.

8.1.3 In our opinion the Transaction is **fair** as:

- a) The MSA has been independently prepared on arms-length commercial terms having regard to the requirements of the trials and the costings included in the InGenu tender;
- b) The tender process was undertaken by a selected Committee independent of parties associated with any of the CRO invitees;
- 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 appointment of InGenu as the CRO for the purposes of the conduct of the planned Further Trials was determined after confirming that their tender submission met the specific tender selection criteria and would provide the necessary outcome for IRX in the absence of any other viable tender being received.

### 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 terms of the arrangement in the absence of a better alternative.

8.2.2 We have concluded that the Transaction is fair and therefore also reasonable. In forming our opinion we have also considered the fact that the Transaction will allow IRX to complete the Further Trials and possibly create future shareholder value through the ultimate marketing and sale of these pain relief and anxiety management products.

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 Consolidated Profit and Loss Statements of IRX for the financial years ended 31 December 2022 (“2022”) and 31 December 2023 (“2023”) (audited) and for the half year ended 30 June 2024 (“HY2024”) (reviewed);
- InhaleRx Shareholders Register;
- 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;
- InGenu Tender responses and accompanying capabilities and costings annexures;
- CRO Tender Offer Evaluation Scorecard;
- 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’.

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## **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.

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## 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](http://www.afca.org.au) or by contacting them directly at:

Australian Financial Complaints Authority  
717 Bourke Street, Docklands, Victoria 3008  
Telephone: 1800 931 678  
Website: [www.afca.org.au](http://www.afca.org.au)  
Email: [info@afca.org.au](mailto: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.



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## APPENDIX B – SUMMARY OF MATERIAL TERMS OF THE INGENU APPOINTMENT AGREEMENT

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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
  - Services and deliverables from the CRO relevant to the clinical trial
  - 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)
  - Scope of work and activities to be completed in the clinical trial
  - Project deliverables
  - 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.