Inhale Rx

GENERAL MEETING

4.00pm AEDT, Thursday 28 November 2024

WELCOME AND AGENDA

Online attendees

- If you have an IT-related issue, please click on the “Raise Hand” button
- If there is a question relating to a resolution, shareholders can ask questions by clicking on the Q&A button and typing in your question
- General questions (or not relating to the resolutions being put) will be answered during general Q&A’s

Agenda

- Resolutions 1 to 7
- Poll on those resolutions
- Formal Meeting Close
- Business update
- General Q&A’s

RESOLUTION 1

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

"That, for the purposes of Listing Rule 10.11 and for all other purposes, approval is given for the Company to issue up to the equivalent of $24,815.45 of Shares in lieu of Directors' Fees for the period 1 January 2024 to 31 December 2024 to Sean Williams, Non-Executive Director of the Company (or his nominee) on the terms and conditions set out in the Explanatory Statement."

VALID PROXIES RECEIVED	Votes	% Votes
For	19,026,119	83.81%
Open	0	0%
Against	3,675,541	16.19%
Abstain	3,282,013	
Excluded	49,612,979	

RESOLUTION 2

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

"That, for the purposes of Listing Rule 10.11 and for all other purposes, approval is given for the Company to issue up to the equivalent of $26,250 of Shares in lieu of Directors' Fees for the period 1 January 2024 to 31 December 2024 to Andrew Saich, Non-Executive Director of the Company (or his nominee) on the terms and conditions set out in the Explanatory Statement."

VALID PROXIES RECEIVED	Votes	% Votes
For	19,026,119	83.81%
Open	0	0%
Against	3,675,541	16.19%
Abstain	3,282,013	
Excluded	49,612,979	

RESOLUTION 3

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

"That, for the purposes of Listing Rule 10.11 and for all other purposes, approval is given for the Company to issue up to the equivalent of $16,500 of Shares in lieu of Directors' Fees for the period 1 January 2024 to 31 December 2024 to James Barrie, Non-Executive Director and Company Secretary of the Company (or his nominee) on the terms and conditions set out in the Explanatory Statement."

VALID PROXIES RECEIVED	Votes	% Votes
For	19,310,118	85.06%
Open	0	0%
Against	3,391,542	14.94%
Abstain	3,282,013	
Excluded	49,612,979	

RESOLUTION 4

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

"That, for the purposes of Listing Rule 10.11 and for all other purposes, approval is given for the Company to issue up to the equivalent of $8,325 of Shares in lieu of Directors' Fees for the period 1 January 2024 to 1 April 2024 to John Crock, a former Non-Executive Director of the Company (or his nominee) on the terms and conditions set out in the Explanatory Statement."

VALID PROXIES RECEIVED	Votes	% Votes
For	19,026,119	83.81%
Open	0	0%
Against	3,675,541	16.19%
Abstain	3,282,013	
Excluded	49,612,979	

RESOLUTION 5

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

"That, for the purposes of ASX Listing Rule 7.4 and for all other purposes, Shareholders ratify the issue of 3,444,828 Shares at $0.029 per Share on the terms and conditions set out in the Explanatory Statement."

VALID PROXIES RECEIVED	Votes	% Votes
For	22,572,131	86.87%
Open	0	0%
Against	3,411,542	13.13%
Abstain	0	
Excluded	49,612,979	

RESOLUTION 6

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

"That, for the purposes of ASX Listing Rule 7.4 and for all other purposes, Shareholders ratify the issue of 17,969,880 Shares at a deemed price of $0.023 per Share on the terms and conditions set out in the Explanatory Statement."

VALID PROXIES RECEIVED	Votes	% Votes
For	25,113,673	99.13%
Open	200,000	0.79%
Against	20,000	0.08%
Abstain	650,000	
Excluded		

RESOLUTION 7

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

*"That, for the purposes of Listing Rule 7.1 and all other purposes, approval is given for the Company to issue 38,449,145 Options to Clendon Biotech Capital Pty Ltd (**Clendon**) under the Facility Agreement entered into between the Company and Clendon, on the terms set out in the Explanatory Statement."*

VALID PROXIES RECEIVED	Votes	% Votes
For	25,963,673	99.92%
Open	0	0%
Against	20,000	0.08%
Abstain	0	
Excluded	49,612,979	

POLL

Poll opened by the Chair

- Click on “For”, “Against” or “Abstain”, then click “Next” to move to the next resolution
- Shareholders and visitors who are not voting, click “Skip Poll”

Poll closed by the Chair

Results will be released on ASX shortly after conclusion of the AGM

MEETING FORMALLY CLOSED

BUSINESS UPDATE

General Meeting – 28 November 2024

GENERAL Q&A

General Meeting – 28 November 2024

InhaleRx

Extraordinary General Meeting
28th November 2024

DEVELOPING TOMORROW'S INHALED THERAPIES

DISCLAIMER

This presentation contains summary information about InhaleRx Limited ("InhaleRx" or "IRX" or "Company") and its activities current as at the date of this presentation. It should be read in conjunction with InhaleRx' other periodic and continuous disclosure announcements filed with the Australian Securities Exchange, available at www.asx.com.au

This presentation is for information purposes only and is not a prospectus or product disclosure statement, financial product or investment advice or a recommendation to acquire InhaleRx shares or other securities. It has been prepared without taking into account the objectives, financial situation or needs of individuals.

Before making an investment decision, prospective investors should consider the appropriateness of the information having regard to their own objectives, financial situation and needs and seek legal and taxation advice appropriate to their jurisdiction. Past performance is no guarantee of future performance.

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Forward looking statements involve known and unknown risks, uncertainties and assumptions and other important factors that could cause the actual results, performances or achievements of InhaleRx to be materially different from future results, performances or achievements expressed or implied by such statements. Readers are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date thereof.

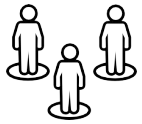
ABOUT INHALERX

InhaleRx Limited (ASX: IRX) is a clinical stage biotechnology development company focused on **developing innovative inhaled therapeutics to address unmet medical needs in pain management and mental health treatment**.

Two drug/device candidates in development

Provisional patents lodged

Rapid Onset Drug Devices



Innovation patent for inhalation of synthetic cannabinoids approved

Multiple Phase I/II and Phase II/III Clinical Trials

Supportive Safety Data from the Ph1 trial.

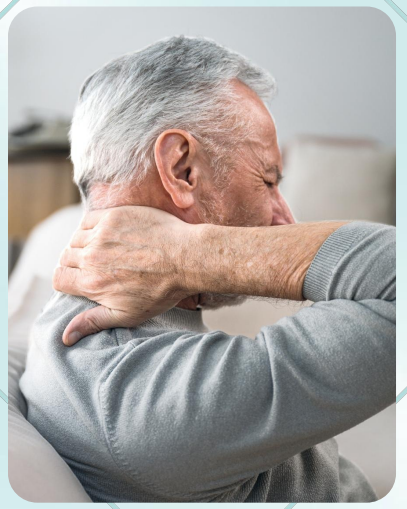
DEVELOPING **IRX-211** AS A THERAPEUTIC AGENT

IRX-211 will be a registered prescription-only medication to treat **Breakthrough Cancer Pain (BTcP)**.

Ph1 1 clinical trial complete, very promising insights and no SAE's. **Ph2 approved by HREC** to demonstrate safety and efficacy in the BTcP patient population.

Targeting the FDA, Regulatory approval(s) will allow InhaleRx to make a marketing claim. PIND complete with very supportive narrative from the FDA.
An FDA approval will open up the door to approvals with the EMA and TGA.

Access to government reimbursements + regulatory levers creates a **strong commercial and competitive position.**



PLANNING TO COMMENCE IRX-211

MILESTONE	COMPLETE	EXPECTED (QUARTER)
Funding Secured	✅	
Recut of trial design	✅	
Tender Commenced	✅	
Spec Work Commenced	✅	
Component Sourcing	✅	
HREC Approval for Ph2 trial	✅	
Protocol Amendment with HREC		**Q1**
Batch Manufacturing Complete		**Q1**
First Patient Screened		**Q2**
First Patient Dosed		**Q2**

$9b
Total Addressable Market (TAM) for the Cancer Pain Market by 2028.

IRX-211 COMMERCIAL OPPORTUNITY

1. By 2040, the global cancer burden is projected to reach approximately 29.5 million new cases annually.
2. 20%-40% U.S. cancer patients reporting cannabis use to help treat their condition
3. Growing demand / widening gap in the market for a non-opioid therapeutic options.
4. Regulatory pathway well defined vai PIND and 6 medications having achieved NDA for BTcP.

https://www.mordorintelligence.com/industry-reports/pain-management-market
https://epi.grants.cancer.gov/
https://www.who.int/news/item/01-02-2024-global-cancer-burden-growing--amidst-mounting-need-for-services

DEVELOPING **IRX-616a** AS A THERAPEUTIC AGENT

- IRX-616a will be a registered prescription-only medication to treat **Panic Disorder**.
- **Preparing for a Ph1 HREC submission**, this trial will be followed by a Ph2 to demonstrate safety and efficacy in the Panic Disorder patient population.
- Regulatory approval(s) with the FDA will allow InhaleRx to make a marketing claim. P**IND complete, IND already submitted.**
- An **FDA approval** will open up the door to approvals with the EMA and TGA.
- **No competition in terms of inhaled FDA approved medications** to treat PD.
- Access to government reimbursements + regulatory levers creates a **strong commercial and competitive position**.

PLANNING TO COMMENCE IRX-616a

MILESTONE	COMPLETE	EXPECTED (QUARTER)
Funding Secured	✅	
Medical writing complete	✅	
Tender Commenced	✅	
Spec Work Commenced	✅	
Component Sourcing	✅	
Tender complete		Q1
HREC Application		Q1
HREC Approval		Q1
Batch Manufacturing Complete		Q2
First Patient Screened		Q2
First Patient Dosed		Q2

$13.3b
USD
Total Addressable Market (TAM) for anxiety disorders and depression treatments by 2027.

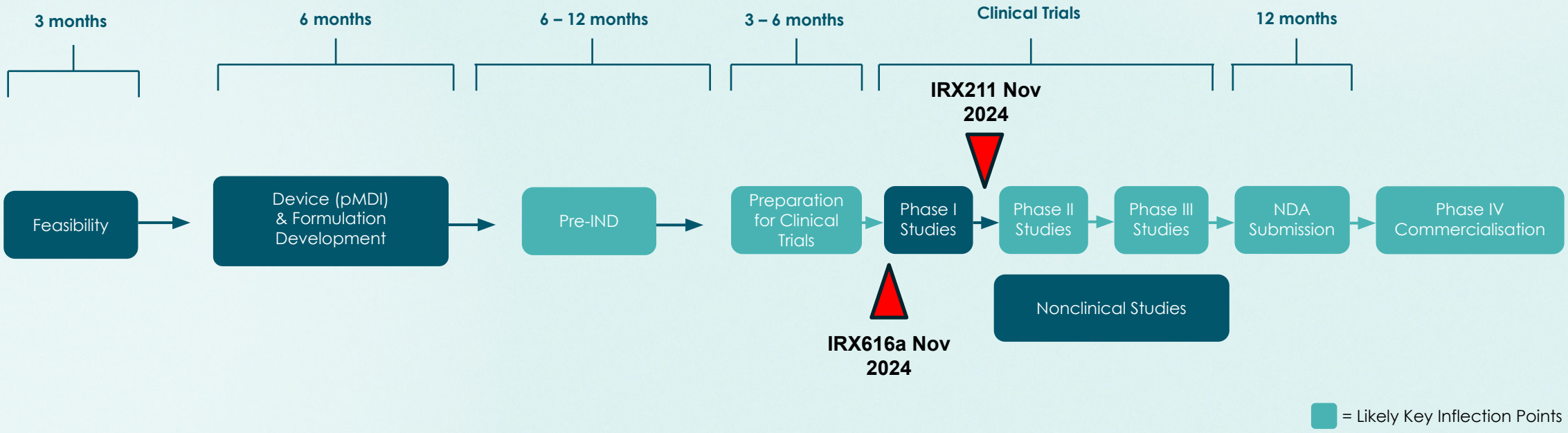
IRX-616a COMMERCIAL OPPORTUNITY

1. There are currently no FDA approved drugs for treating Panic Disorder via inhalation.
2. Covid-19 triggered a 25% increase in prevalence, median onset age of 24.
3. Existing drugs like SSRI's can affect sleep, sexual function, carry drug interactions and in some cases, suicidality risk.
4. Regulatory pathway well defined with a number of on-label oral drugs FDA approved.

Anxiety Disorders and Depression Treatment Market - Share, Size, Growth & Analysis (mordorintelligence.com)
https://pubmed.ncbi.nlm.nih.gov/15297936/

PATHWAY TO REGISTRATION (FDA NDA)

Following in the footsteps of existing approvals
Leveraging existing data via FDA's 505(b)(2) } reduces risk, time and cost



Time to approval – only 3 to 5 years

HIGHLIGHTS & SUMMARY

Tender process underway for Ph2 (211) and Ph1 (616a), and non-clinical is being mapped out in consultation with Clendon Capital. **This step is not impacting the critical path.**

Slashed Cash Burn and recent change to BOD by over 70% since January 2024. Management Team is limited to myself, Dr Rob Jenny (CSO), and Dr Sud Agarwal (Medical Advisor), we also welcomed Ron Wise as a NED this week

Spec adjustment and trial batch manufacturing planned out and the permitting is underway for both Ph2 (211) and Ph1 (616a).

Funding Partner Secured the company has access of up to unique and exciting $38m in funding to accelerate our clinical development plans.

Defined pathway with the FDA the PIND meetings validated our planned primary endpoints.

Timelines and associated costs mapped out extending right up to the Phase 3 multinational studies.

Patent Attorney reviewing mechanism of use and PCT potential.

Scoping new opportunities to add another asset to the pipeline.

THANK YOU

Please contact me at:

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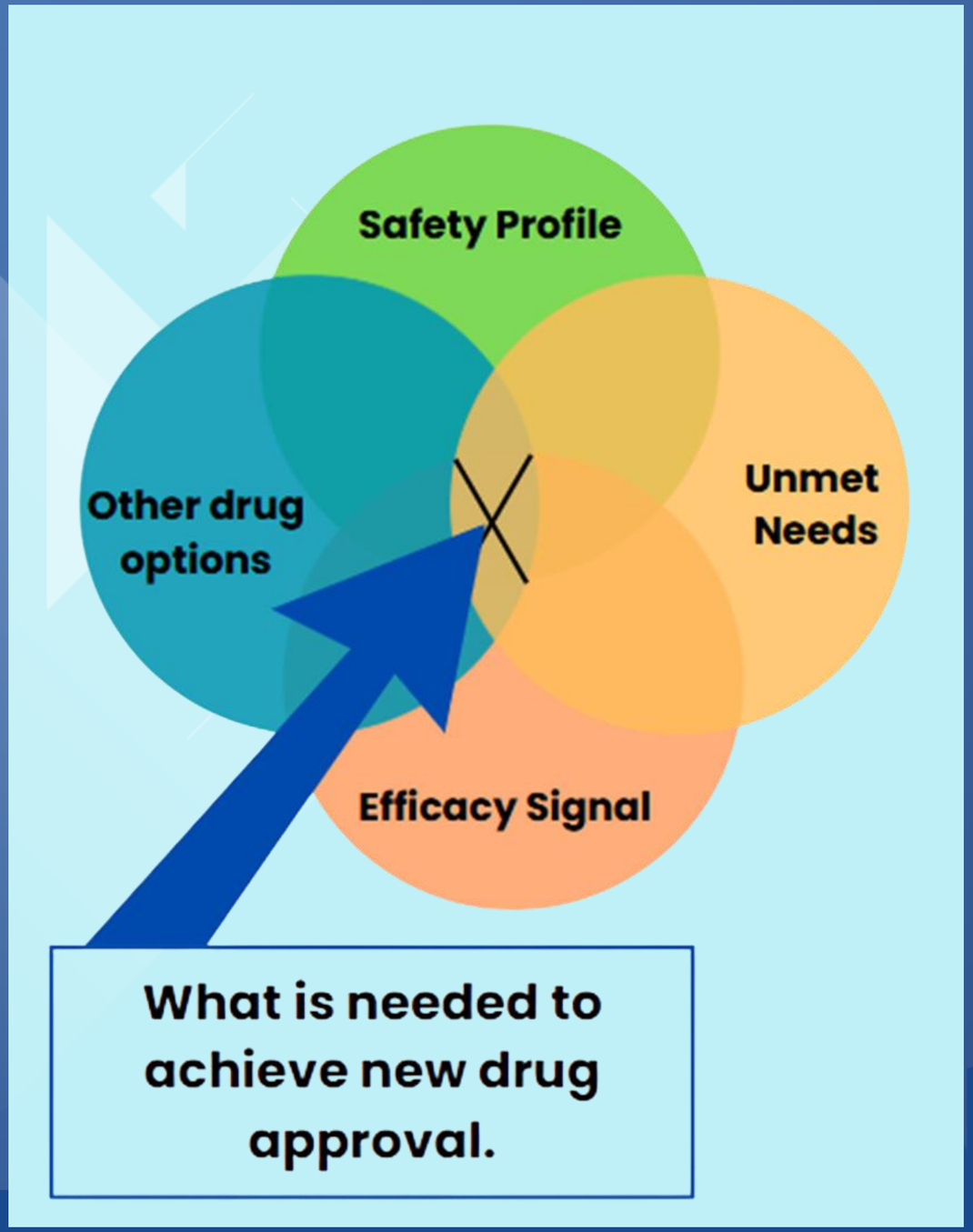


IRX - Clinical Trial Analysis

This presentation explores key factors influencing clinical trial success, focusing on IRX211 and IRX616.

We'll examine their approval pathways, efficient trial designs, and market potential.

IRX211: BREAKTHROUGH CANCER PAIN PATHWAY

SPID-30 Endpoint

FDA requires 1-point improvement on SPID-30 scale as primary endpoint.

Unmet Need

BTcP has limited non-opioid options, making modest efficacy highly valuable.

IRX211 Advantages

Non-opioid formulation eliminates risks like dependency and respiratory depression.

Simplified Trial

Potential single pivotal study focused on SPID-30 reduces trial complexity.

IRX616: PANIC DISORDER APPROVAL STRATEGY

PDSS ENDPOINT

Measures panic attack frequency, severity, and functional impairment for FDA approval.

RISK-BENEFIT PROFILE

Rapid relief outweighs minimal risk; CBD's safety data minimizes regulatory hurdles.

INHALED CBD ADVANTAGE

Rapid absorption offers immediate symptom relief compared to oral therapies.

COMPETITIVE EDGE

Fast-acting inhaled therapy offers significant advantage in time-to-relief versus alternatives.

EFFICIENT CLINICAL TRIAL DESIGN

Efficacy Endpoint Study

IRX211: SPID-30 as sole primary endpoint.

IRX616: Focused on PDSS endpoint.

Leveraging Prior Data

- Utilizes pre-existing cannabinoid safety and pharmacokinetic data.
- Reduces time and cost through 505(b)(2) reliance.

INSURANCE CLAIMABILITY AND MARKET ACCESS

FDA Approval Advantage

FDA-approved therapies are insurance-eligible, enabling broader patient access.

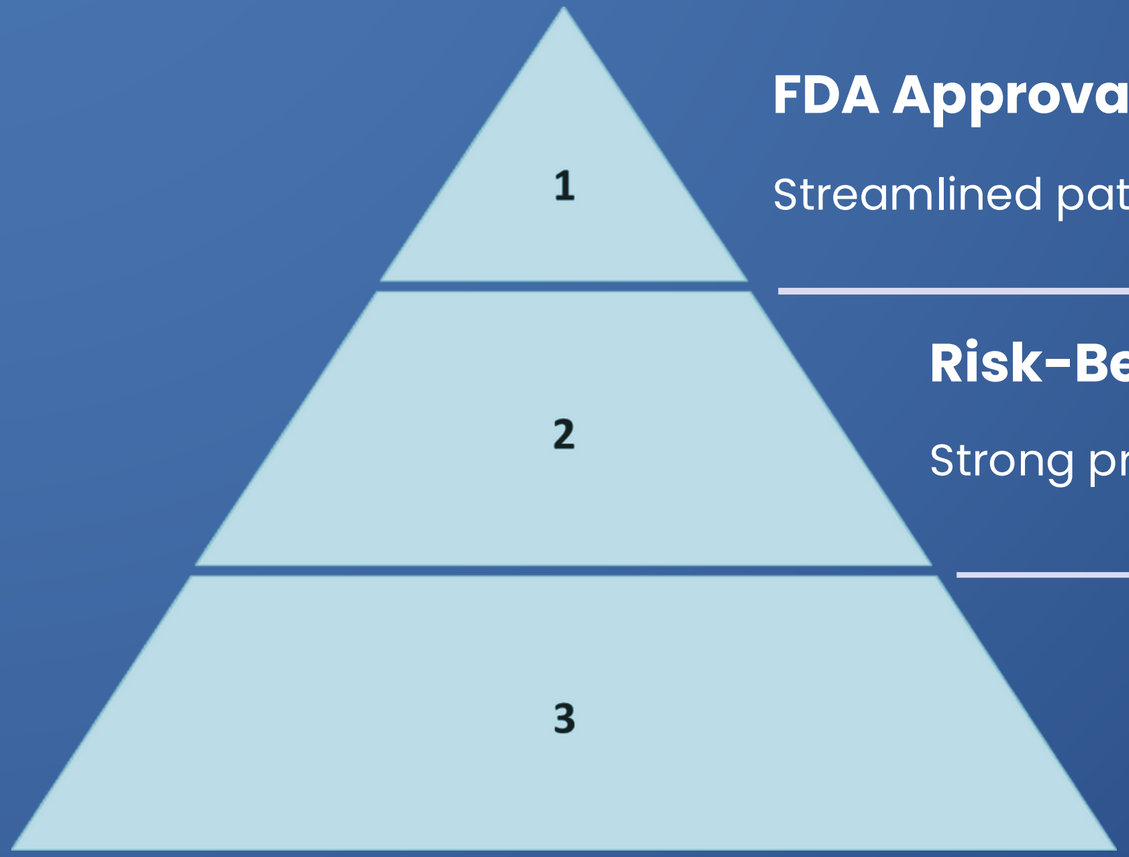
Market Implications

IRX211 and IRX616 positioned for payer adoption and widespread use.

Physician Adoption

FDA sanctioning builds prescriber confidence and encourages widespread use.

CONCLUSION:
OPTIMIZED APPROVAL PATHWAYS



FDA Approval

Streamlined path with focused endpoints and single pivotal study strategy.

Risk-Benefit Profile

Strong profiles for both IRX211 and IRX616.

Market Readiness

Insurance-backed, FDA-approved options positioned to disrupt markets.

"IRX211 and IRX616 exemplify innovation in trial design and regulatory strategy, setting new benchmarks for efficiency and patient impact in their therapeutic areas."