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INCANNEX HEALTHCARE LIMITED
ASX: IHL

Changing lives through innovation

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MISSION STATEMENT

Our Mission is to create first-in-class pharmaceutical drugs and therapies for patients with unmet medical needs.

We aim to be recognised as a leading specialty drug development company at the forefront of innovation, committed to restoring health and transforming the lives of patients through the development of novel pharmaceutical products and treatments.

The company is developing targeted and scientifically validated products, creating long term value for our patients and shareholders.

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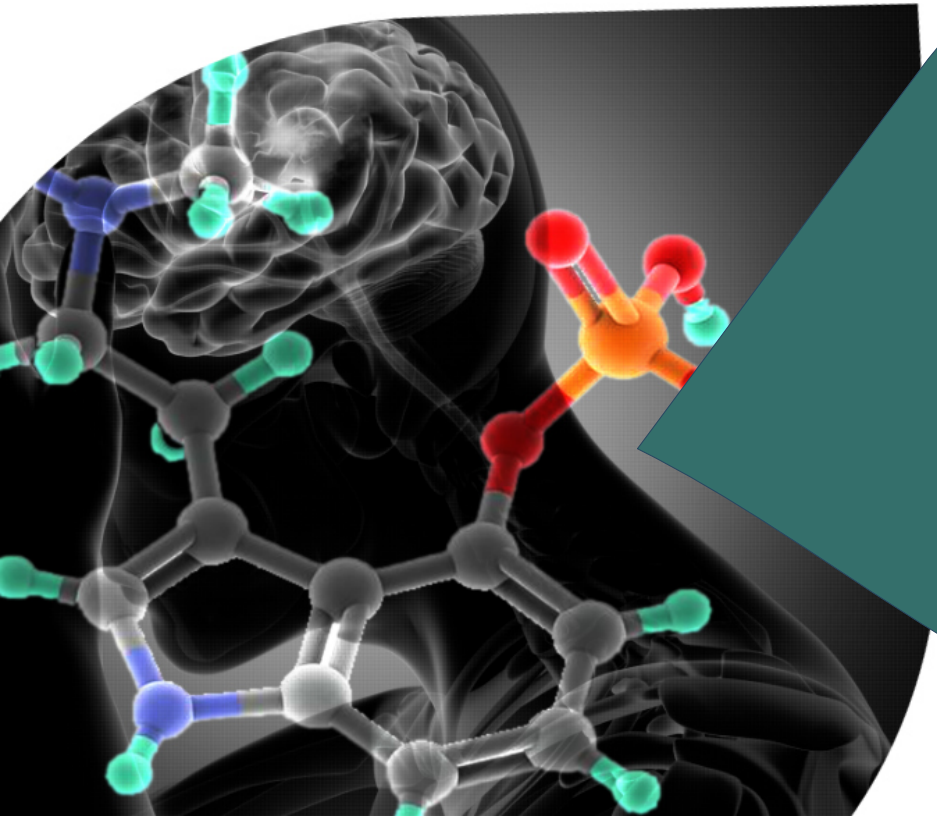
UNIQUE VALUE PROPOSITION



- Diversified strategy – 4 x drug development programs
- The first and only ASX listed company to investigate psychedelics in combination with psychotherapy
- Multiple income streams – immediate revenue via SAS sales and also from future drug sales post-registration
- Accelerated FDA registration strategy to shorten time to commercialisation
- Strong cash position and fully funded for Phase 2 clinical trials
- Strong patent portfolio
- Positive preclinical results across multiple programs

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CORPORATE SNAPSHOT

FINANCIALS

Share price: $0.17
52w Range: ..... $0.029 - 0.195
Market Capitalisation: ..... A$176m
Cash (as of 31st Dec 2020): A$11.8m

CAPITAL STRUCTURE

Director Holdings: 11.04%
Top 20 Share Holders:..... 32.45%
Shares on Issue: 1,040.3m

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STRATEGIC OUTLOOK

Multi-pronged strategy to advance novel leading medicines and treatments in emerging global markets.

CREATING FIRST-IN-CLASS, INNOVATIVE PHARMACUTICAL DRUGS WHERE THE THERAPEUTIC CLASS SHARES SEVERAL COMMON PROPERTIES

1. 3 novel cannabinoid and 1 psychedelic innovative research programs underway
2. Total addressable market of each therapeutic area > $1 billion
3. Global export potential
4. Established research evidence supporting hypothesis for benefit of cannabinoids in the chosen therapeutic area.
5. A variety of near-term catalysts resulting from extensive multi-pronged clinical program, including open label studies, patent filings, in vivo, in vitro, human clinical trials etc.
6. Accelerated commercialisation pathways remain available (e.g. early sales under Australian Special Access Scheme prescribed by willing doctors prior to full product registration)
7. No existing pharmacotherapy options are currently available, improving the probability that a drug discovery will be eligible for public subsidies (e.g. PBS in Australia)

3 FOLD BUSINESS MODEL

1. Development of targeted & scientifically validated products
2. Potential early out licensing of specialist products, allowing for fast-tracked commercialisation
3. Immediate revenue opportunities through the Australian SAS and similar regulatory bodies

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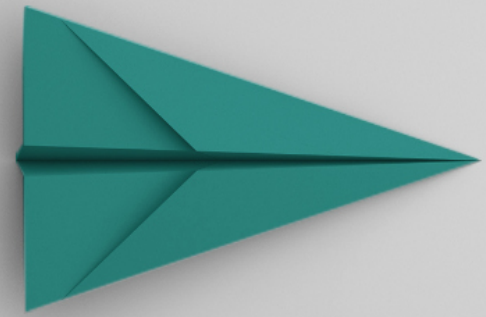
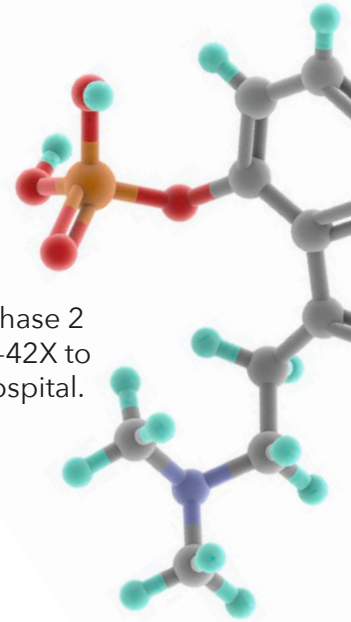
COMPETITIVE ADVANTAGE

- A highly credentialed and experienced specialist medical and scientific team, including global key opinion leaders
- Accelerated commercialisation with a clear go-to-market strategy for the development of novel pharmaceuticals
- A unique suite of four approved clinical programs covering proprietary formulations that address large global markets with unmet needs
- IP protection with a robust patent filing strategy - Three patents filed, additional patents in the pipeline
- Shareholder value creation - with news flow imminent for each program over the next 1-18 months



RECENT ACHIEVEMENTS



2020

September

Receives ethics approval for Phase 2 OSA clinical trial to assess IHL-42X to be conducted at the Alfred Hospital.

November

Positive preclinical results that IHL-675A exhibits significantly stronger anti-inflammatory properties than cannabidiol alone. Company engages Camargo Pharmaceuticals to call an FDA pre-IND meeting.

December

Positive results from preclinical IHL-216A TBI/concussion study.

December

Initiates phase 2 clinical trial using psilocybin and proprietary psychotherapy for the treatment of Generalised Anxiety Disorder (GAD) being conducted at Brain Park, Monash University, Melbourne.

December

First patients recruited for IHL-42X (OSA) Trial.

Leadership Team

TROY VALENTINE
Chairman

JOEL LATHAM
CEO and Managing Director

DR SUD AGARWAL
Chief Medical Officer and Director

PETER WIDDOWS
Director

GLENN FOWLES
Company Secretary

Research Team

Dr Mark Bleackley
Chief Scientific Officer

Mrs Rosemarie Walsh
Clinical Research Manager

Dr Paul Liknaitzky
Principal investigator, Psi-GAD-1 and Psychedelic Lead

Trial Principal Investigators

Professor Terence O'Brien
Independent Principal investigator from The Alfred hospital - OSA Study

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ORGANISATIONS WE ARE WORKING WITH

CAMARGO PHARMACEUTICALS is an integrated strategy, regulatory, and development partner with expertise in the FDA 505(b)2 drug registration pathway.

Incannex are collaborating with **Camargo Pharmaceuticals** on the regulatory strategies across the development programs.

THE ALFRED is one of Australia's top hospitals with proven expertise in clinical trials.

Incannex has engaged **The Alfred** hospital as a trial site for the IHL-42X for treatment of obstructive sleep apnoea.

MONASH is one of the top universities in Australia and are consistently ranked in the world's top 100 universities.

Incannex are collaborating with **Monash University** on the clinical development of psychedelics.

BRAINPARK is a world-first neuroscience research clinic dedicated to improving the physical, mental and brain health of Australians.

Incannex are collaborating with **BrainPark** on the clinical development of psychedelics.

MARKET POTENTIAL

Targeting major unmet medical conditions with significant commercial opportunity

ESTIMATED COMBINED MARKET OF USD $33B PER ANNUM FOR INDICATIONS BEING SOUGHT

OSA – The global sleep apnoea market size was valued at **USD $5.9 billion in 2019** and is projected to expand at a CAGR of 7.4% over the forecast period.

TBI – The global traumatic brain injury assessment and management market size was valued at **USD $2.7 billion in 2019** and is expected to grow at a compound annual growth rate (CAGR) of 7.3% from 2020 to 2027.

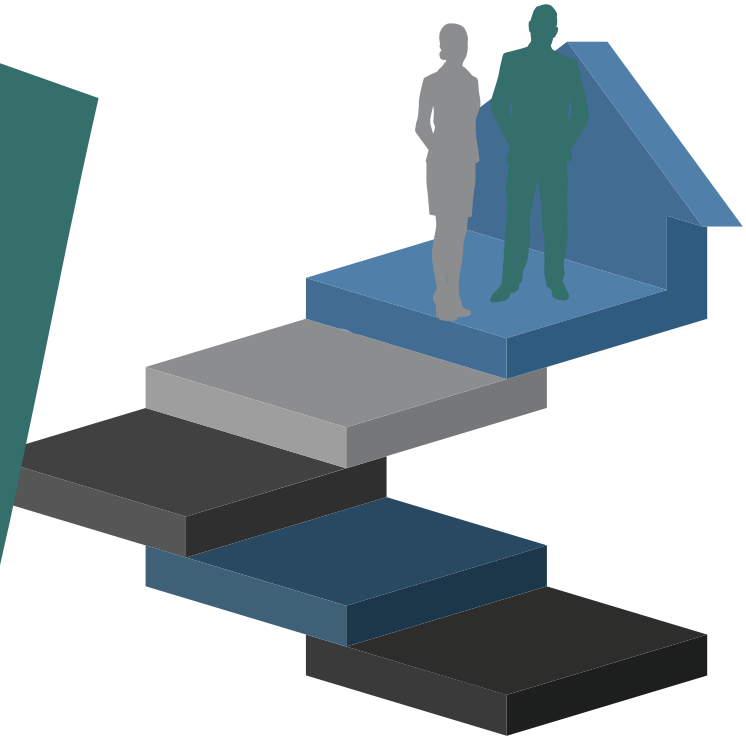
SAARDS - The global market for acute respiratory distress syndrome devices anticipated to attain **USD $16.9 billion by 2027**, expanding at a CAGR of 7.2% over the forecast period.

GAD - Global Generalised Anxiety Disorder Market is Estimated to Grow at 2.5% CAGR to reach **USD $7.5 Billion by 2023.**

www.ihealthcareanalyst.com/global-acute-respiratory-distress-syndrome-devices-market/
www.grandviewresearch.com/industry-analysis/sleep-apnea-devices-market
www.prnewswire.com/news-releases/global-generalized-anxiety-disorder-market-is-estimated-to-grow-at-25-cagr-to-reach-75-billion-by-2023-679279763.html
www.grandviewresearch.com/industry-analysis/traumatic-brain-injuries-tbi-assessment-management-devices-market

PHARMACEUTICAL DEVELOPMENT PLAN

- IHL is pursuing FDA registration of all of its development assets - all preclinical and clinical trials are geared towards this end.
- FDA registration means that all doctors are entitled to prescribe the product and it also entitles the company to marketing exclusivity over its formulations over a period of time (minimum 5 years).
- Once FDA registration is granted, IHL will pursue registration in other regions including Europe and Australia.
- In addition to FDA marketing exclusivity, IHL is generating patent protection over its formulations and therapies. Granted patents provide the company with 20 years of exclusivity over its formulations and facilitates the opportunity to be the sole provider of a therapy, subject to ongoing clinical success.
- Furthermore, as IHL receives more pre-clinical and clinical data on its assets as it pursues registration, the products will be eligible for sale under various global special medicines access schemes, including the Australian special access scheme. This will facilitate sales of our proprietary products even prior to registration, creating a significant market opportunity for us to develop.



IHL-675A

SEPSIS ASSOCIATED ACUTE RESPIRATORY DISTRESS SYNDROME (SAARDS)

A proprietary anti-inflammatory pharmaceutical

IHL-675A SAARDS OVERVIEW

POSITIVE RESULTS

- IHL-675A significantly outperformed the component drugs cannabidiol and hydroxychloroquine at reducing inflammatory cytokine levels in both in vitro and animal studies.
- IHL-675A reduced in vitro inflammatory cytokine levels 87% to 767% more than was predicted based on the activity of each drug alone.
- IHL-675A reduced in vivo inflammatory cytokine levels 26% to 86% more than was predicted based on the activity of each drug alone.
- Incannex are the first company to discover the synergistic anti-inflammatory activity between CBD and hydroxychloroquine.

To view the recent positive results, **click here**

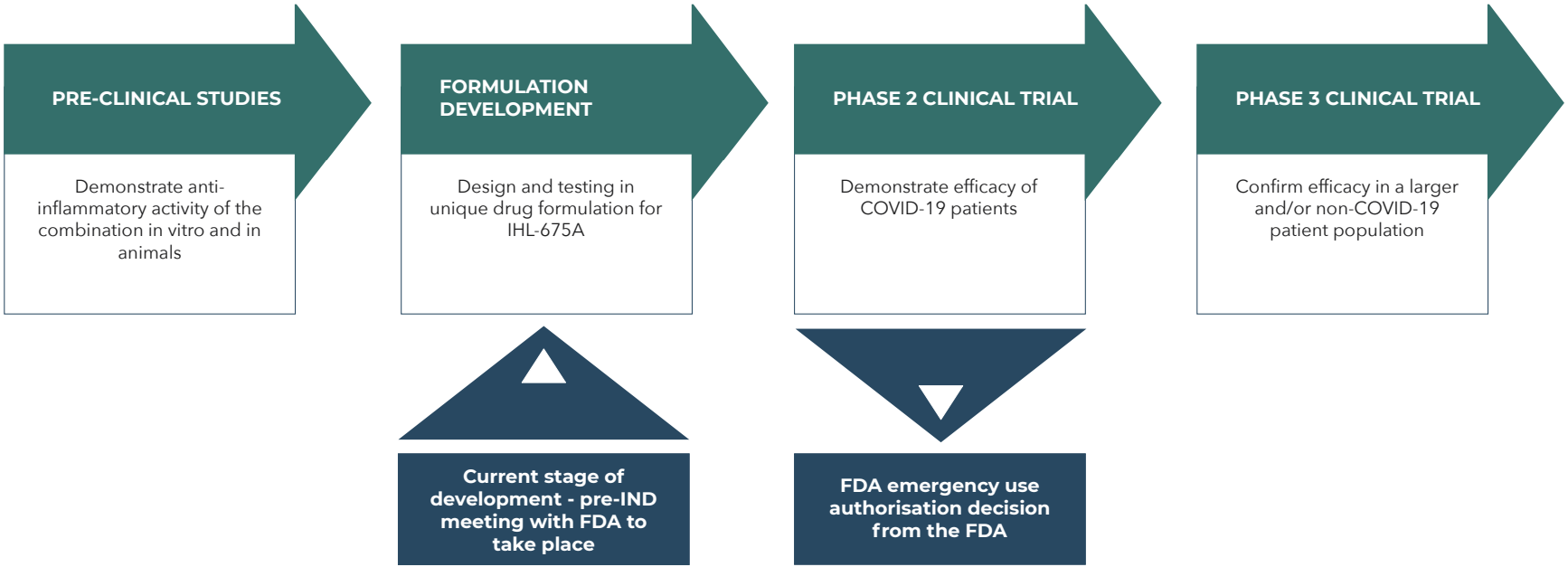
MARKET SIZE AND DRUG POTENTIAL

- SAARDS has a mortality rate generally of 30-40%, in spite of ICU care and hence the strategy is to use IHL-675A prophylactically (preventatively) in patients with moderate-severe sepsis of any cause.
- Based on a conservative pricing of $15,000 per course of therapy, and an estimated US annual incidence of 45,000, the total addressable market for SAARDS is $675m.
- This estimate extrapolates to a total addressable market of more than $2Bn in the 7 major markets.
- These estimates are likely to remain stable given that there have been no substantive changes in the incidence of SAARDS in more than 4 decades, despite improvements in routine supportive care measures in the critical care environment.

REGULATORY STRATEGY & IP

- Novelty and inventiveness of the synergistic anti-inflammatory activity of CBD and hydroxychloroquine allow Incannex to secure an IP position for IHL-675A.
- Provisional patent on the anti-inflammatory activity of IHL-675A with a focus on treatment and prevention of SAARDS has been lodged.
- Complete specification to be submitted mid 2021.
- A pre-IND meeting request to the FDA for opening a program to investigate the use of IHL-675A is being drafted with support from Camargo Pharmaceuticals.
- Due to the high mortality of SAARDS, IHL-675A may qualify for 4 FDA vouchers: Priority Review, Fast Track, Breakthrough Designation, Accelerated Approval.

IHL-675A DEVELOPMENT PLAN



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IHL-42X

OBSTRUCTIVE SLEEP APNOEA (OSA)

Patients need new options - a pharmaceutical alternative to existing mechanical treatment devices

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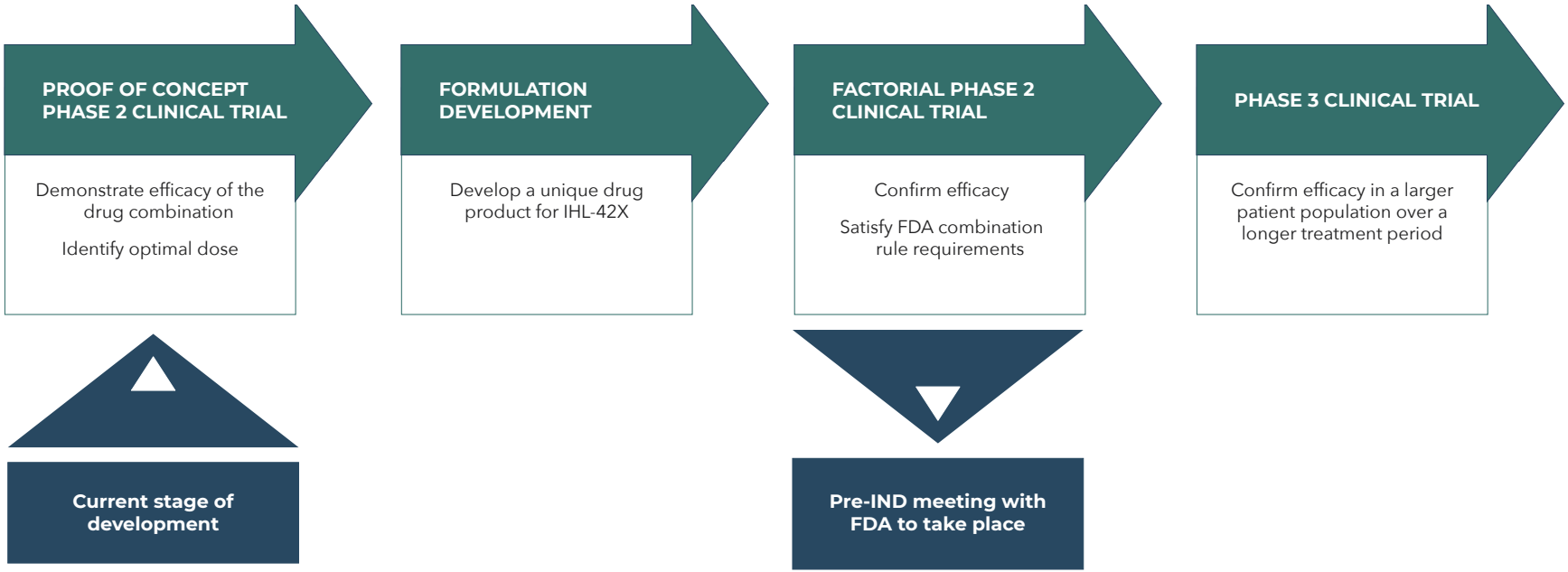
IHL-42X DEVELOPMENT PLAN



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IHL-42X OSA OVERVIEW

RECENT DEVELOPMENTS

- A proof-of-concept clinical trial investigating IHL-42X for the treatment of obstructive sleep apnoea has commenced at The Alfred.
- Approval to run the study was granted by the Human Research Ethics Committee in September 2020.
- Drug products and placebos were sourced, packaged, randomised and shipped to site.
- Patient enrolment commenced December 2020.

To view the recent positive results, **click here**

MARKET SIZE AND DRUG POTENTIAL

- IHL-42X is intended to be the first-in-class and first-line treatment for mild-moderate OSA.
- OSA affects up to 10% of the adult population in most developed countries in the world with an estimated addressable market of 40 Million adults in the USA alone and predicted earning capacity of > $5Bn per annum sales after approval.
- Additional pathology secondary to OSA includes:

  - Diabetes
  - Ischaemic Heart Disease
  - Atrial Fibrillation
  - Sudden Death
  - Increased risk of Road Trauma
  - Financial impact from missed work days

REGULATORY STRATEGY & IP

- Provisional patent on the use of IHL-42X in treatment of OSA has been lodged.
- Data from the proof-of-concept study will be used to support the claims made in the provisional patent.
- The complete specification will be submitted mid 2021.
- Strategic assessment by Camargo Pharmaceuticals indicated that IHL-42X is a strong candidate for the FDA 505(b)2 pathway for registration.
- Untreated OSA has significant medical, social and financial consequences and so is a potential candidate for the following FDA accelerator programmes: Breakthrough Designation, Accelerated Approval, Priority Review, Fast-track.

IHL-216A

TRAUMATIC BRAIN INJURY AND CONCUSSION (TBI)

A first of its kind treatment to reduce secondary brain injuries associated with head trauma

IHL-216A TBI OVERVIEW

POSITIVE RESULTS

- IHL-216A out performed the component drugs cannabidiol and isoflurane at reducing detrimental effects of TBI on cognitive and motor function as well as neuronal damage and neuroinflammation.
- IHL-216A improved study outcomes across assessments by 10% to 87% more than was predicted based on the activity of each drug alone.
- Incannex are the first company to discover the synergistic neuroprotective activity between CBD and isoflurane.

To view the recent positive results, **click here**

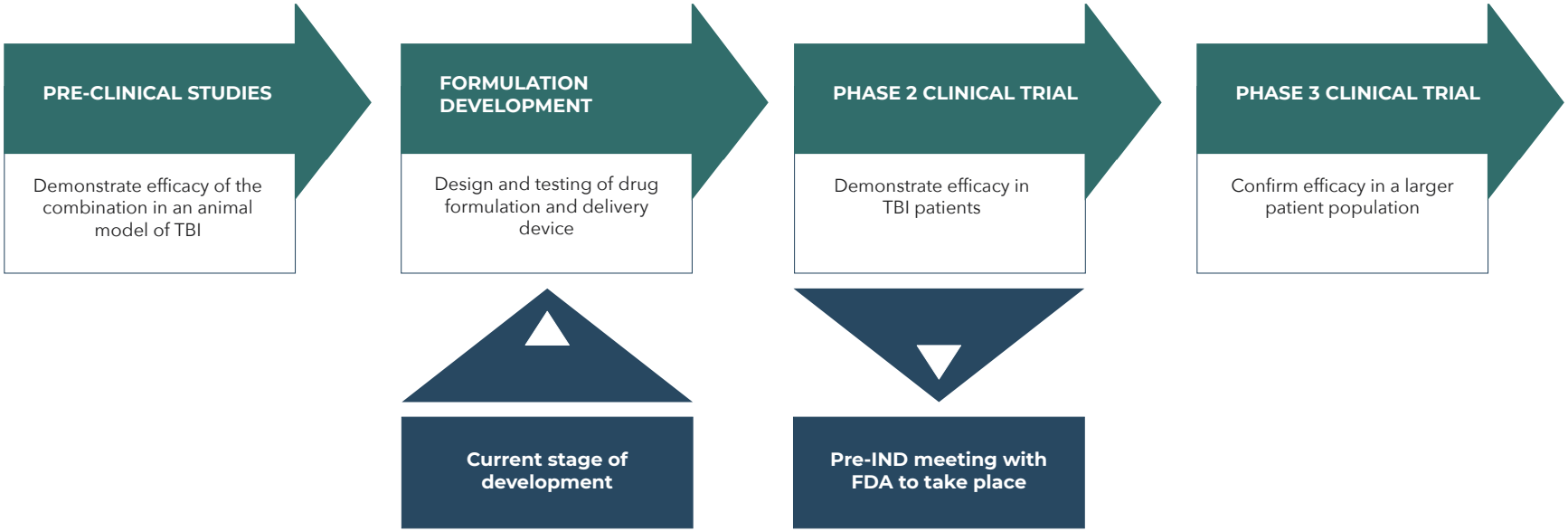
MARKET SIZE AND DRUG POTENTIAL

- The annual incidence of severe TBI requiring hospitalization is approximately 3 per 100K, translating to 10K Americans and nearly 30K patients throughout the 7 major markets. At present, there are no approved drugs for the treatment of TBI.
- Given this major unmet medical need and the absence of competition by an approved agent, a reimbursement rate of US$15K per clinical course is anticipated. This constitutes potential sales revenue in the 7 major markets of $450M per annum.
- If the indication is expanded to include moderate-to-severe head injury, then we can expect the revenue to likely be 10x the above prediction and will be expected to be >$5Bn.
- CDC estimates that there are 1.6-3.8 million concussions in the US per year.

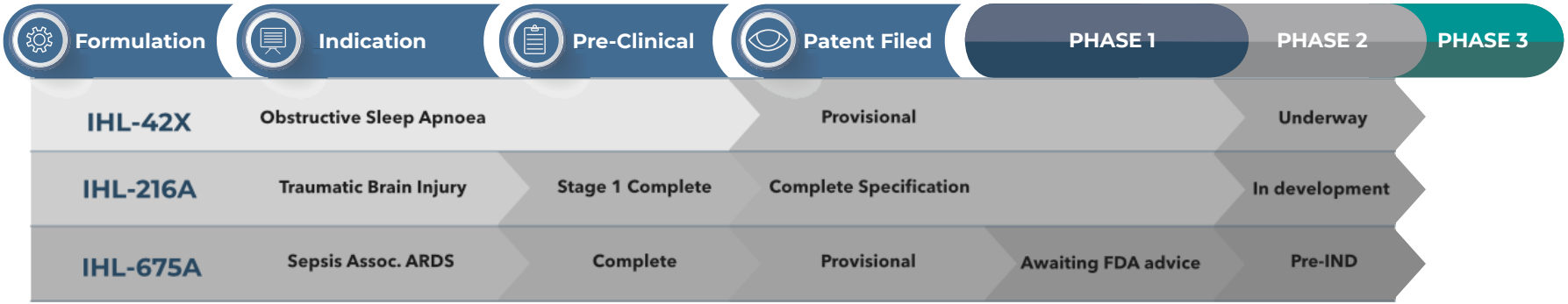
REGULATORY STRATEGY & IP

- Novelty and inventiveness of the synergistic neuroprotective activity of CBD and isoflurane allow Incannex to secure an IP position for IHL-216A.
- An international patent application was filed on the use of IHL-216 for treatment and prevention of TBI.
- The international examiner considered the claims directed to IHL-216A and methods for treatment and prevention of TBI are novel, inventive and meet the requirements for industrial applicability.

IHL-216A TBI DEVELOPMENT PLAN



DIVERSIFIED CANNABINOID DRUG DEVELOPMENT PIPELINE



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CANNABINOID OILS DISTRIBUTION UPDATE

GENERIC OILS SALES

- Commenced Dec19 quarter.
- Five consecutive quarters of growing sales through Special Access Scheme ("SAS") prescription based sales.

FUTURE UNCERTAIN DUE TO CHANGING AUSTRALIAN REGULATORY ENVIRONMENT

- Pure CBD being deregulated to allow 'over the counter' pharmacy sales.
- 90% of IHL oils' sales are pure CBD.
- Investigating schedule 3 sales opportunities relating to particular indications vis a vis generic oil sales through SAS which are likely to be significantly impacted through the legislative changes.

REVIEWING OPPORTUNITIES FOR INCANNEX OILS' BUSINESS

- Given the changing landscape of generic oils in Australia, IHL is currently conducting a full review on the distribution of generic cannabinoid products, including various Schedule 3 opportunities.
- Long term value creation remains product registration and IP protection – these factors will be considered during the evaluation process.
- The primary market opportunity for Incannex is to expedite the development of its own products which will in turn result in high margin sales through the SAS in Australia and other regulatory bodies ahead of global registration and sales.

CLINICAL TRIAL

PSILOCYBIN-ASSISTED PSYCHOTHERAPY FOR GENERALISED ANXIETY DISORDER

A world-first clinical trial testing a highly promising treatment for a novel indication

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WHAT IS GENERALISED ANXIETY DISORDER?

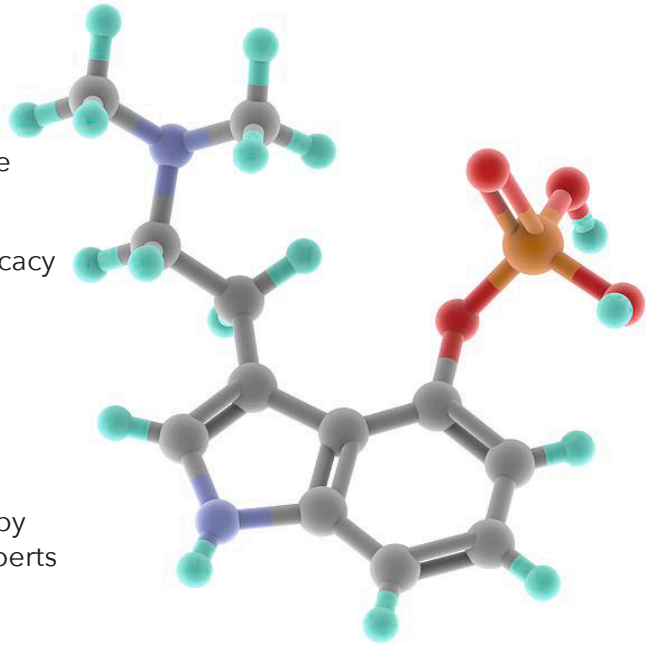
- Persistent and excessive worry (not restricted to any particular triggers); nervousness, restlessness, difficulty concentrating, and a range of somatic manifestations
- Interferes with daily activities
- High (6-9%) lifetime prevalence in Australia/US
- Inadequate treatment response, major unmet need

CLINICAL TRIAL SUMMARY

World first testing psilocybin for a primary anxiety disorder

Psilocybin-assisted psychotherapy for Generalised Anxiety Disorder (Psi-GAD-1)

- Perhaps the most promising psychiatric treatment in decades, targeting a high prevalence and often intractable condition
- Phase 2 randomised active-placebo-controlled double-blind trial to assess safety and efficacy (n=72)
- Multiple dosing sessions alongside short program of specialised psychotherapy
- Key innovations in treatment, development of therapist training program, treatment guidelines for Psi-GAD, cohort of trained and supervised therapists
- Independent highly rigorous research in partnership with Monash University, conducted by Australian leaders in psychedelic research, with substantial support from international experts



PRECEDENT FOR A WORLD FIRST

- Previous psychedelic research in both first (1950-1970) and second (2000-current) waves of research indicate promise in treatment of anxiety symptoms.
- Eg, Weston et al (2020) reviewed 30 psychedelic studies before 2000, ~65% of 145 patients with neurotic-anxiety diagnoses showed moderate to full recovery.
- Eg, Griffiths et al (2016) and Ross et al (2016) showed psilocybin-assisted psychotherapy produced clinically significant reductions in anxiety (associated with terminal diagnosis) in ~80% following treatment and 6 months later.

NEXT STEPS

- Further details on the Psi-GAD-1 clinical trial will be released relatively soon as we continue to lay the groundwork for the trial.
- FDA regulatory strategy is now underway, further updates to follow in the near future.
- A second psychedelic medicine trial into a significant under-treated indication has been largely advanced with further details to be released to market as soon as appropriate.
- Davies Collinson Cave engaged regarding the program's intellectual property considerations.
- IHL is also pursuing a number of ethical, transparent, and well-controlled options to provide psilocybin-assisted psychotherapy prior to full drug registration, through the SAS once therapists have been trained.

Monash University - BrainPark Facility

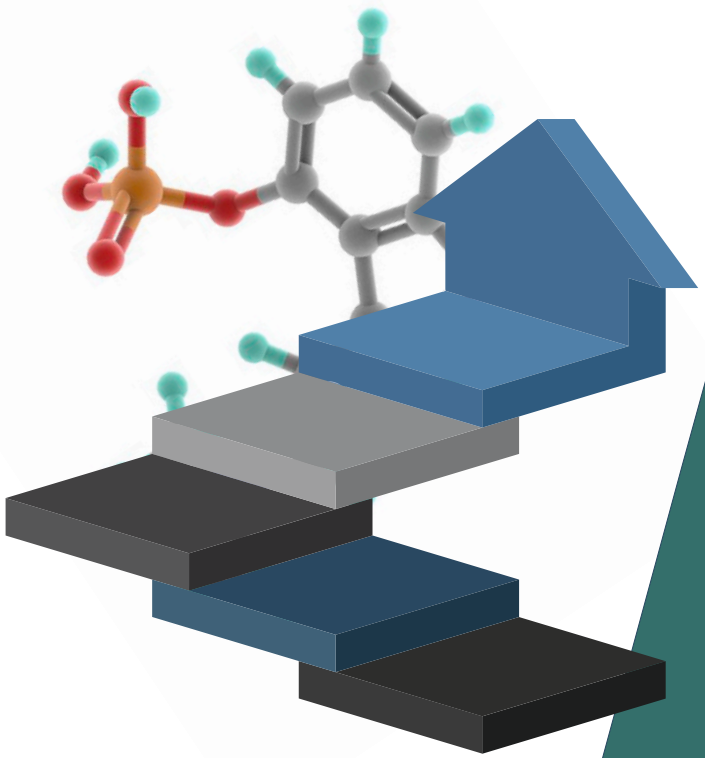
- State-of-the-art research platform at Monash's Turner Institute for Brain and Mental Health and Biomedical Imaging Facility

- Highly conducive environment for unique psychedelic treatment – unparalleled in an Australian university research context

THERAPIST TRAINING

- Substantive therapist training for qualified and experienced mental healthcare workers (e.g., psychiatrists, psychologists, psychotherapists)
- Facilitated by leading Australia and international clinicians and researchers
- Online Course; in-person intensives covering theory, didactic, experiential, and role play; Supervision and evaluation

RECENT ADVANCES



- Phase 2 psychedelic trial results show remarkable clinical outcomes (large, fast, sustained for months)
- MDMA +psychotherapy highly promising for PTSD, Phase 3 trial half complete (MAPS)
- Psilocybin +psychotherapy promising for depression, anxiety, addictions (multiple groups)
- Two psilocybin for depression trials granted FDA 'Breakthrough therapy' status: fast-tracked (Compass Pathways and Usona)
- Massive development over last few years: over $100M raised in philanthropy; many new psychedelic therapeutics companies listed on public markets, some with market caps >$1B

CONTACT DETAILS

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Mr Joel Latham

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