UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

Form 6-K

Report of Foreign Private Issuer
Pursuant to Rule 13a-16 or 15d-16
under the Securities Exchange Act of 1934

For the month of June, 2022

Commission File Number: 001-41106

Incannex Healthcare Limited

(Exact name of Registrant as specified in its charter)

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not applicable
(Translation of Registrant's name into English)

Australia
(Jurisdiction of incorporation or organization)

Joel Latham
Chief Executive Officer and Managing Director
Level 39, Rialto South Tower
525 Collins Street
Melbourne 3000
Australia
(Address of principal executive offices)

Indicate by check mark whether the registrant files or will file annual reports under cover Form 20-F or Form 40-F:

Form 20-F ☒ Form 40-F ☐

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(1):

Yes ☐ No ☒

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(7):

Yes ☐ No ☒

INFORMATION CONTAINED IN THIS REPORT ON FORM 6-K

On June 03, 2022, Incannex Healthcare Limited filed with the Australian Securities Exchange an announcement captioned “Positive final results from IHL-42X phase 2 trial”, a copy of which announcement is attached to this Form 6-K as Exhibit 99.1.

On June 03, 2022, Incannex Healthcare Limited filed with the Australian Securities Exchange an announcement captioned “IHL-42X phase 2 clinical trial presentation”, a copy of which announcement is attached to this Form 6-K as Exhibit 99.2.

Signatures

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

Incannex Healthcare Limited

Date: June 03, 2022

By: /s/ Joel Latham
Name: Joel Latham
Title: Chief Executive Officer and Managing Director

INDEX TO EXHIBITS

Exhibit No.	
99.1	ASX Announcement, dated June 03, 2022 – Positive final results from IHL-42X phase 2 trial
99.2	ASX Announcement, dated June 03, 2022 – IHL-42X phase 2 clinical trial presentation

Date: June 03, 2022
Public Announcement (NASDAQ: IXHL) (ASX: IHL)

Incannex announces positive results from phase 2 clinical trial investigating the effect of IHL-42X for treatment of obstructive sleep apnoea

Highlights:

- IHL-42X reduced primary endpoint apnoea hypopnea index relative to baseline at all three doses that were assessed
- Low dose IHL-42X exhibited superior safety and efficacy metrics to mid and high doses
- Low dose IHL-42X reduced AHI by an average of 50.7% compared to baseline with 25% of participants experiencing a reduction in the apnoea hypopnea index of greater that 80%
- Oxygen desaturation index was reduced by 59.7% relative to baseline while taking low dose IHL-42X, improving sleep quality and reducing cardiovascular stress
- In low dose IHL-42X samples, THC concentrations in blood were well below the limits for impaired driving the morning after dose administration
- IHL-42X was well tolerated – low dose IHL-42X was observed to have a lower number of total treatment emergent adverse events than placebo
- Low dose IHL-42X reduced AHI substantially more effectively than is reported for the component active pharmaceutical ingredients, dronabinol and acetazolamide, as unregistered monotherapies.

Melbourne, Australia, June 3, 2022 – Incannex Healthcare Limited (Nasdaq: IXHL) (ASX: IHL), ('Incannex' or the 'Company') a clinical-stage pharmaceutical company developing unique medicinal cannabinoid pharmaceutical products and psychedelic medicine therapies for unmet medical needs, is pleased to announce that it has completed analysis of data from the phase 2 proof-of-concept clinical trial investigating IHL-42X for treatment of obstructive sleep apnoea ('OSA'). IHL-42X reduced apnoea hypopnoea index ('AHI'), improved patient reported sleep quality and was well tolerated.

The clinical trial assessed three doses of IHL-42X at reducing the AHI in patients who suffered from OSA. Data was also collected for other aspects of sleep quality, THC clearance and safety. Trial participants received each of the three doses of IHL-42X and placebo across four seven-day treatment periods, separated by one week washout periods. At the end of each treatment period, they attended the clinic for an overnight sleep study where AHI was determined, along with other measures of sleep quality, quality of life and drug safety.

The study was conducted at the University of Western Australia Centre for Sleep Science and The Alfred Hospital. A total of eleven participants were recruited to the study and ten participants completed treatment periods. The crossover design of the study permitted Incannex to generate high quality data with a reduced participant number compared to a conventional parallel arm study. Each participant serves as their own internal control and inter-participant variation is eliminated. Data analysis was completed by Novotech, the contract research organisation responsible for management of the study, as well as the Incannex scientific research team, led by Chief Scientific Officer Dr Mark Bleackley. The findings of the clinical trial are presented below.

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Effect of IHL-42X on apnoea hypopnoea index (AHI)

AHI is a measure of the number of times per hour a subject's airway is blocked (apnoea) or partially blocked (hypopnoea). It is the main criteria used to diagnose and monitor OSA. AHI data was collected during overnight polysomnography on night seven of the treatment periods.

- All doses of IHL-42X reduced AHI in patients with sleep apnoea compared to baseline (Table 1). This reduction was substantially greater than observed for placebo.
- At the group level the difference relative to baseline with low dose and medium dose was statistically significant ($p<0.05$)
- When comparing directly to baseline within subjects the difference in AHI compared to baseline between all three doses and placebo was statistically significant ($p<0.001$) (Table 2)
- Low dose IHL-42X reduced AHI by >50% relative to baseline in 62.5% of subjects and by >80% in 25% of subjects (Table 2).
- Low dose IHL-42X reduced AHI to the greatest extent at both the group level and when comparing the within subject reduction relative to baseline
- Low dose IHL-42X reduced AHI to a greater extent than predicted based on published data for dronabinol and acetazolamide alone (Table 3).

The reduction in AHI observed during IHL-42X treatment periods means that when treated with Incannex's proprietary drug, subject's breathing was interrupted less frequently during sleep. This supports Incannex's hypothesis that IHL-42X is an effective treatment for OSA. The observation that low dose IHL-42X was the most effective at reducing AHI is encouraging for the development of IHL-42X as a pharmaceutical as a lower dose will reduce risk of side effects and the cost of goods.

Furthermore, greater reduction in AHI with low dose IHL-42X compared to dronabinol and acetazolamide at equivalent doses supports Incannex's hypothesis that the two drugs are acting synergistically to reduce AHI and provides confidence that IHL-42X will meet the FDA's combination rule where both APIs must contribute to the therapeutic effect of a fixed dose combination product.

Table 1. Average AHI data for baseline and each treatment period

	Baseline	Placebo	Low	Medium	High
Average AHI	42.84	40.08	21.13	22.22	27.78
Standard deviation	20.33	18.16	15.92	15.52	17.61
% Reduction relative to baseline	N/A	6.44	50.69	48.13	35.16
p value compared to baseline	N/A	0.76	0.029	0.031	0.12

Table 2. Change in AHI from baseline within subject (least square mean)

	Average change in AHI from baseline	p-value relative to placebo (Bonferroni adjusted)	Proportion of subjects with AHI reduction >50% relative to baseline (%)	Proportion of subjects with AHI reduction >80% relative to baseline (%)
Placebo	1.95	N/A	10	0
Low	17.51	<0.001	62.5	25
Medium	14.86	<0.001	33.3	11.1
High	16.18	<0.001	22.2	11.1

Table 3. Comparison of reduction in AHI relative to baseline with low dose IHL-42X and the predicted reduction with component drugs as monotherapies at equivalent doses based on reported data.

	Reduction in AHI compared to baseline (%)
2.5 mg dronabinol (1)	23.4
125 mg acetazolamide (2)	23.4
Low dose IHL-42X	50.7

Effect of IHL-42X on oxygen desaturation index (ODI)

Oxygen desaturation index ('ODI') is the number of episodes of oxygen desaturation per hour of sleep, with oxygen desaturation defined as a decrease in blood oxygen saturation (SpO_2) to lower than 3% below baseline. Reduced oxygen uptake is a key component of the pathology of OSA and contributes to daytime sleepiness and the long-term health consequences associated with OSA. ODI data was collected during overnight polysomnography on night seven of the treatment periods.

- All three doses of IHL-42X reduced ODI compared to baseline to a greater extent than placebo.
- For low and medium dose IHL-42X the difference in reduction in ODI relative to baseline compared to placebo was statistically significant ($p<0.05$)

The greater reduction in ODI during IHL-42X treatment periods compared to placebo means that there is more oxygen in the subject's blood during sleep while taking IHL-42X. This improves sleep quality and reduces risks of oxidative stress, bursts of the stress hormone cortisol, insulin resistance, altered metabolism and cardiovascular disease.

Table 4. Reduction in ODI compared to baseline during each treatment period.

	Reduction in ODI relative to baseline (least squares mean)	Reduction in ODI relative to baseline (%)	p value compared to placebo (Bonferroni adjusted)
Placebo	1.8	18.3	N/A
Low	11.7	59.7	0.021
Medium	12	59.0	0.012
High	8.32	28.5	0.162

Plasma THC levels the morning after IHL-42X dosing

Countries that have set limits for THC above which driving is illegal have set those limits at 1-2 ng/mL (3-6). It is important to understand the clearance of THC after dosing with IHL-42X to determine where there will be an impact on ability to drive in countries where THC limits are in place. Plasma samples were collected 2 hours post dose 1 and the morning after dose 7 for each treatment period. Samples were analysed for concentration of THC using liquid chromatography with tandem mass spectrometry (LC-MS-MS).

The morning after dose 7, THC levels in the low dose IHL-42X samples had an average of 0.20 ng/mL and a maximum of 0.45 ng/mL. Both of which are below the thresholds for impaired driving. With medium and high dose IHL-42X the average THC concentrations the morning after dose 7 were 0.86 and 0.52 respectively.

Effect of IHL-42X on patient reported sleep quality

Each morning of the clinical trial, subjects recorded their sleep quality for the previous night as very poor, poor, fair, good, or very good. To compare patient reported sleep quality, the proportion of subjects who reported good or very good sleep each night was averaged across each treatment period. During the IHL-42X treatment periods subjects more frequently reported that their sleep quality was good or very good than placebo. The highest level of patient reported sleep quality was observed with low and high dose IHL-42X (Table 5).

Table 5. Patient reported sleep quality during each treatment period

	Proportion of subjects reporting good or very good sleep quality
Placebo	26.50%
Low	49.49%
Medium	38.47%
High	50.13%

Sleep metrics captured by actigraphy

For the duration of the clinical trial, subjects wore an Actiwatch, a watch-like device that uses actigraphy to capture data on activity and sleep. IHL-42X at all doses improved sleep efficiency (what percentage of time in bed a subject is asleep), the number of awakenings per night, and the total minutes the subject was awake during the night (WASO) compared to placebo (Table 6). These improvements were greatest for low and high dose IHL-42X. This means that while taking IHL-42X subjects were asleep for a greater proportion of time they were in bed and woke up less often.

Table 6. Sleep metrics captured by actigraphy

		Placebo	Low	Medium	High
Sleep efficiency	**average**	76.83	84.81	81.34	84.17
	p value compared to placebo	N/A	0.0048	0.058	0.0078
Awakenings per night	**average**	49.31	35.8	41.44	37.33
	p value compared to placebo	N/A	0.0053	0.055	0.012
WASO (min)	**average**	62.59	37.55	47.22	38.55
	p value compared to placebo	NA	0.00011	0.0031	0.0010

Safety considerations

Adverse events were recorded from the time the subjects enrolled in the trial until their end of study visit. After recording of treatment emergent adverse events (TEAE) the study team, including investigators and medical monitors, reviewed the TEAEs to determine whether they were likely related to the investigational product. The TEAEs were consistent with what has been reported for dronabinol and acetazolamide alone. For each treatment period the proportion of subjects reporting one or more TEAEs (Table 7) as well as the total number of TEAEs (Table 8) were extracted from the clinical study report. Low dose IHL-42X had a similar proportion of subjects reporting TEAEs and a lower number of total TEAEs than placebo. This indicated that low dose IHL-42X is well tolerated.

Table 7. Proportion subjects of TEAEs reported for each treatment period

	Placebo	Low	Medium	High
Total TEAE (%)	81.8	33.3	55.6	66.7
Related TEAE (%)	27.3	22.2	44.4	55.6

Table 8. Total number of TEAEs reported during each treatment period

	Placebo	Low	Medium	High
Total TEAE	15	6	22	16
Related TEAE	7	4	16	12

References:

1. Carley DW, Prasad B, Reid KJ, Malkani R, Attarian H, Abbott SM, Vern B, Xie H, Yuan C, Zee PC. 2018. Pharmacotherapy of apnea by cannabimimetic enhancement, the PACE clinical trial: Effects of dronabinol in obstructive sleep apnea. Sleep 41.

2. Schmickl CN, Landry SA, Orr JE, Chin K, Murase K, Verbraecken J, Javaheri S, Edwards BA, Owens RL, Malhotra A. 2020. Acetazolamide for OSA and central sleep apnea: a comprehensive systematic review and meta-analysis. Chest 158:2632–2645.

3. https://www.justice.gc.ca/eng/cj-jp/sidl-rlcfa/qa2-qr2.html

4. Vindenes, V., et al., (2012) Impairment based legislative limits for driving under the influence of non-alcohol drugs in Norway, Forensic Science International 219(1-3,)1-11

5. Wolff, K, et al., Driving Under the Influence of Drugs: Report from the Expert Panel on Drug Driving, Department of Transport, London, 2013.

6. https://www.vifm.org/wp-content/uploads/VIFM-Annual-Report-2019-2020.pdf

This announcement has been approved for release to ASX by the Incannex board of directors.

END

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About Incannex Healthcare Limited

Incannex is a clinical stage pharmaceutical development company that is developing unique medicinal cannabis pharmaceutical products and psychedelic medicine therapies for the treatment of anxiety disorders, obstructive sleep apnoea (OSA), traumatic brain injury (TBI)/concussion, lung inflammation (ARDS, COPD, asthma, bronchitis), rheumatoid arthritis and inflammatory bowel disease. U.S. FDA approval and registration, subject to ongoing clinical success, is being pursued for each drug and therapy under development. Each indication represents major global markets and currently have no, or limited, existing registered pharmacotherapy (drug) treatments available to the public.

Incannex has a strong patent filing strategy in place as it develops its products and therapies in conjunction with its medical and scientific advisory board and partners. Incannex is listed on the Australian Stock Exchange (ASX) with stock code “IHL” and also has American Depository Shares listed on NASDAQ under code “IXHL”.

Website: www.incannex.com.au
Investors: investors@incannex.com.au

Forward-looking statements

This press release contains "forward-looking statements" within the meaning of the "safe harbor" provisions of the U.S. Private Securities Litigation Reform Act of 1995. These forward-looking statements are made as of the date they were first issued and were based on current expectations and estimates, as well as the beliefs and assumptions of management. The forward-looking statements included in this press release represent Incannex's views as of the date of this press release. Incannex anticipates that subsequent events and developments may cause its views to change. Incannex undertakes no intention or obligation to update or revise any forward-looking statements, whether as of a result of new information, future events or otherwise. These forward-looking statements should not be relied upon as representing Incannex's views as of any date after the date of this press release.

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Incannex
IHL-42X
for treatment of obstructive sleep apnoea
Phase II proof of concept clinical trial results.
ASX Ticker: IHL | NASDAQ Ticker: IXHL
03 June 2022

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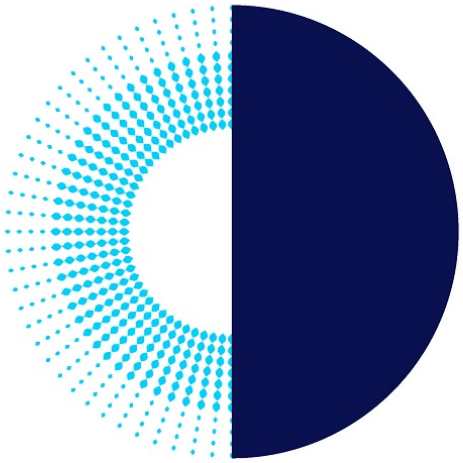
Company statement on clinical trial results

IHL42x has exceeded our expectations. It has shown substantial clinical benefit to people with obstructive sleep apnoea at the lowest dose given.

This not only means people can get the full benefit with a reduced risk of side effects, but also, during the low dose treatment period every subject was substantially below the legal driving limits for THC in their blood the morning after dosing, thus removing a significant hurdle for IHL-42X's widespread use.



Unmet Medical Need

Obstructive sleep apnoea ('OSA')

OSA involves the narrowing of the upper airway during sleep, which interferes with a person's breathing. Decreased oxygen uptake results in poor-quality sleep.

Untreated OSA leads to serious long-term adverse health outcomes including hypertension, cardiovascular disease, heart attack, cognitive impairments, anxiety and depression, irritability and daytime fatigue increasing the risk of accidents.

There are no pharmacotherapy (drug) treatments available to those afflicted. The current 'standard of care' is the Continuous Positive Airway Pressure (CPAP) machine, however, patient compliance to CPAP is low due to various factors related to patient discomfort.

Opportunity

IHL-42X Obstructive Sleep Apnea

Problem

OSA leads to serious long term adverse health outcomes but is also grossly undertreated. It is a highly prevalent condition and current treatment options (machines and devices) have poor patient compliance.

Solution

IHL-42X has two pharmaceutical ingredients (THC and Acetazolamide) that target different aspects of OSA. Combined, these ingredients create a synergistic therapeutic effect, reducing the effects of OSA with low doses of each compound, minimising potential side effects and satisfying THC limits for impaired driving.

No available pharmacotherapies

US **$10B**[1] Addressable market

6.2%[1] Annual Growth Rate

OVER **900M** people globally have sleep apnoea

(1) https://www.grandviewresearch.com/industry-analysis/sleep-apnea-devices-market

Clinical development status

Unblinded and confidential interim clinical data provided to the patent examiner.

Patent claims considered novel and inventive.

Asset	Preclinical	Australian Phase 2 POC	FDA Pre-IND	FDA IND	FDA bioequivalence study	FDA Phase 2	FDA Phase 3	Anticipated Milestones
IHL-42X Obstructive Sleep Apnea*								Proposed open IND Q4 2022

IHL-42X Development Progress

Milestones achieved

Completed proof of concept phase 2 clinical trial

- Results indicate that IHL-42X is effective at reducing AHI in patients with OSA and is well tolerated.
- IHL-42X also reduced oxygen desaturation index, and improved patient reported sleep quality and the number of awakenings during the night.
- The morning after dosing with low dose IHL-42X, THC levels in blood were below the prohibited limit for driving.

Feedback received from FDA at pre-IND meeting

- Incannex do not require animal studies to open IND
- Guidance was provided on the data that needs to be included in the IND application as well as design of pivotal clinical trials.

IHL-42X patent filed and international search report and opinion deemed key claims to be novel and inventive.

Opportunity

Key Observations from phase 2 clinical trial – patients treated and concept confirmed

01.

IHL-42X in low dose form outperformed medium and high dose with respect to sleep, THC clearance and safety.

02.

Low dose IHL-42X reduced average Apnoea Hypopnea Index ('AHI') by an average of 50.7% versus baseline; 25% of participants experienced greater than 80% reduction in AHI.

03.

In low dose IHL-42X samples, THC concentrations in blood were below the limits for impaired driving the morning after dose administration on night 7.

04.

No serious treatment emergent adverse events were reported during the clinical trial.

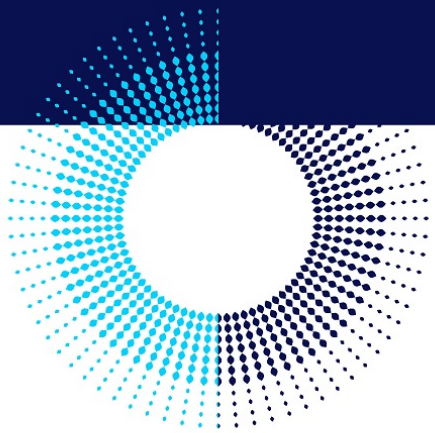
Apnoea hypopnea index (AHI) is the main measure for diagnosis and monitoring of disease, in patients with OSA. It is a serious sleep disorder in which breathing repeatedly stops and starts.

Strategic composition of dronabinol and acetazolamide makes IHL-42X an exciting novel potential treatment for OSA.

Low dose IHL-42X (2.5 mg dronabinol and 125 mg acetazolamide) reduced AHI to a greater extent than reported for its constituent pharmaceutical ingredients. Low Dose IHL-42X was observed to reduce AHI by an average of 50.7%, indicating synergistic effect and a novel patent opportunity.

Dronabinol

- Synthetic form of (-)-trans-Δ9-tetrahydrocannabinol (THC).
- Approved in US for treatment of HIV/AIDS induced anorexia and chemotherapy induced nausea and vomiting.
- Dampens afferent vagal feedback, stabilizes respiratory patterns and dilates upper airway
- Two clinical trials to demonstrate effectiveness in reducing AHI in patients with OSA.
- AHI reduction with 2.5 mg dronabinol was 23.4 %.



Acetazolamide

- Carbonic anhydrase inhibitor.
- Used to treat glaucoma, altitude sickness, epilepsy and other indications.
- Increases the difference between prevailing PCO2 and apnoeic PCO2.
- Demonstrated as an effective treatment for OSA in 14 clinical studies.
- AHI reduction was 23.9-27.6% relative to baseline with 250 mg dose.

Clinical Trial

IHLOSAPOC1

Incannex's proof of concept clinical trial to assess the safety and efficacy of IHL-42X in patients with OSA.

Compared three doses of IHL-42X to placebo at reducing AHI compared to baseline (primary endpoint).

Other assessments included:

- Oxygen desaturation index
- Plasma THC levels
- Patient reported sleep quality
- Sleep metrics captured by actigraphy
- Safety

Study Design

Observation

- Four period cross over study.
- Participants had OSA confirmed at baseline, once eligibility was confirmed they completed a single blind placebo treatment period followed by three double blind IHL-42X treatment periods.
- Each treatment period was seven days with an overnight sleep study on night seven to determine AHI and collect secondary endpoint data.
- Treatment periods were separated by seven-day washout periods.
- Adverse events were recorded and monitored for the duration of the study.

Participant demographics

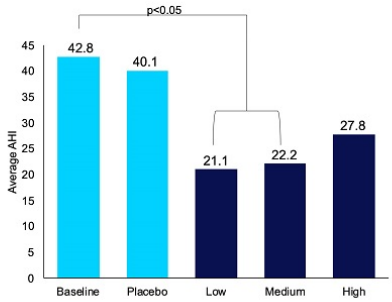
Demographic	Results (Mean (Range))
Age	51.82 (39-64)
Sex (female)	3/11
Childbearing Potential (Yes)	1/11
Race	10 White, 1 Asian
Ethnicity	Not Hispanic or Latino 100%
Height (cm)	178.16 (160-187.3)
Weight (kg)	92.23 (66.8-117)
BMI	28.93 (24.9-36.9)
Education (coded from 1-6)*	3.73 (1-6)
Marital Status	5 Married, 1 Never Married, 3 Divorced, 2 Domestic Partner
Handedness (Right)	10/11
English as Native Language (Yes)	10/11
AHI at baseline	42.8

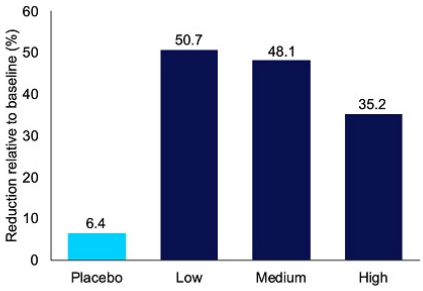
**Education was coded with the following: 1 = 9th Grade; 2 = 12th Grade Diploma or GED; 3 = Some College, No Degree; 4 = Academic Associate Degree; 5 = Bachelor's Degree; 6 = Master's Degree*

Results

IHL-42X ⟶ reduced AHI at a group level.

- Low dose IHL-42X was the most effective dose strength with an average reduction in AHI of 50.7% compared to the baseline.
- When comparing the means of the treatment groups, the difference observed for both low and medium dose compared to baseline was statistically significant ($p<0.05$).

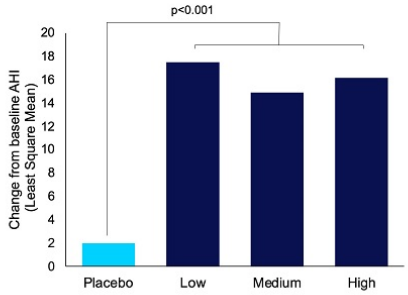


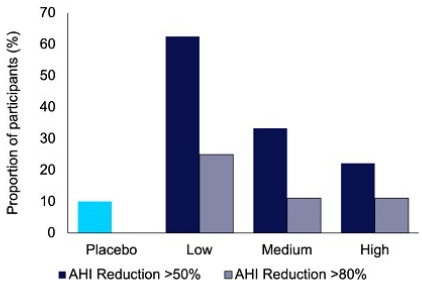


Results

IHL-42X ⟶ reduced AHI when compared within participants.

- 25% of participants experienced greater than 80% reduction in AHI.
- All three doses of IHL-42X led to a statistically significant (p<0.001) reduction in AHI compared to placebo when calculated directly to each participant's baseline.
- Low dose IHL-42X treatment led to a reduction relative to baseline in AHI of >50 % in 62.5% of participants and >80% in 25% of participants.





Summary of AHI data

During IHL-42X treatment periods AHI was reduced compared to baseline and placebo treatment periods.

- This means that when treated with IHL-42X, the subjects' breathing was interrupted less frequently during sleep.
- This supports Incannex's hypothesis that IHL-42X is an effective treatment for OSA.

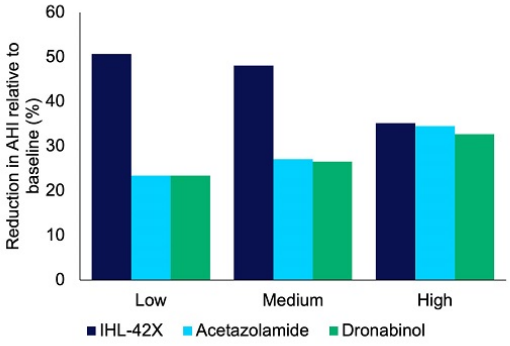
Low dose IHL-42X was more effective at reducing AHI than either the medium or the high dose.

- This is encouraging for Incannex's development of IHL-42X as a lower dose will reduce the risk of side effects and the cost of goods.

Results

IHL-42X ⟶ reduced AHI to a greater extent than reported for acetazolomide and dronabinol as monotherapies.

– IHL-42X at a low and medium dose reduce AHI to a greater extent relative to baseline than acetazolamide (1) and dronabinol (2) at equivalent doses (based on extrapolation of published data with linear dose response curves with R2 values of 0.93 and 1 for acetazolomide and dronabinol respectively).



1. Schmickl CN,et. al. 2020. Acetazolamide for OSA and central sleep apnea: a comprehensive systematic review and meta-analysis. Chest 158:2632–2645.
2. Carley DW,et. al. 2018. Pharmacotherapy of apnea by cannabimimetic enhancement, the PACE clinical trial: Effects of dronabinol in obstructive sleep apnea. Sleep 41

Summary of comparison with dronabinol and acetazolamide

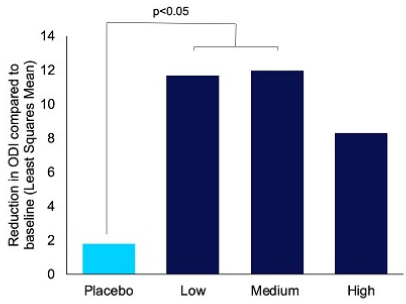
Low and medium dose IHL-42X reduced AHI to a greater extent than reported for dronabinol and acetazolamide monotherapies at equivalent doses.

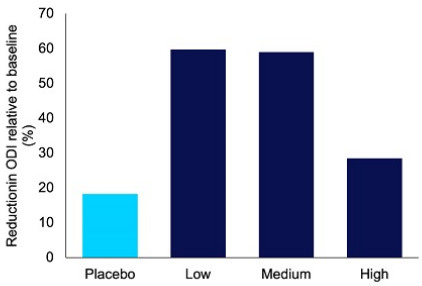
- This supports Incannex's hypothesis that dronabinol and acetazolamide are acting synergistically to treat OSA.
- This data provides Incannex with confidence that IHL-42X will meet the FDA's combination rule where both APIs must contribute to the therapeutic effect of a fixed dose combination product.
- This supports Incannex's hypothesis that IHL-42X is an effective treatment for OSA.

Results

IHL-42X ⟶ reduces oxygen desaturation index (ODI).

- IHL-42X at a low and medium dose led to reduction in ODI of 59.7 and 59.0% respectively. These reductions were statistically significant (p<0.05).





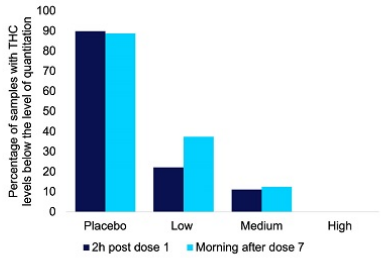
Summary of ODI data

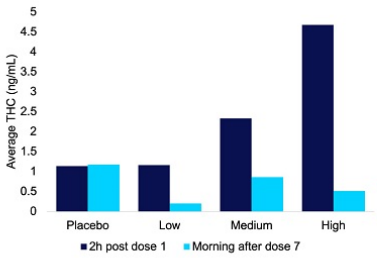
Low and medium dose IHL-42X significantly reduced oxygen desaturation index during sleep.

- This means that during low and medium dose IHL-42X treatment, subjects had more oxygen in their blood
- Low oxygen saturation, or high oxygen desaturation, can lead to:
  - *oxidative stress which can damage cells and tissues*
  - *bursts of the stress hormone cortisol*
  - *insulin resistance and increased risk of diabetes*
  - *altered metabolism*
  - *Increased risk of cardiovascular disease*

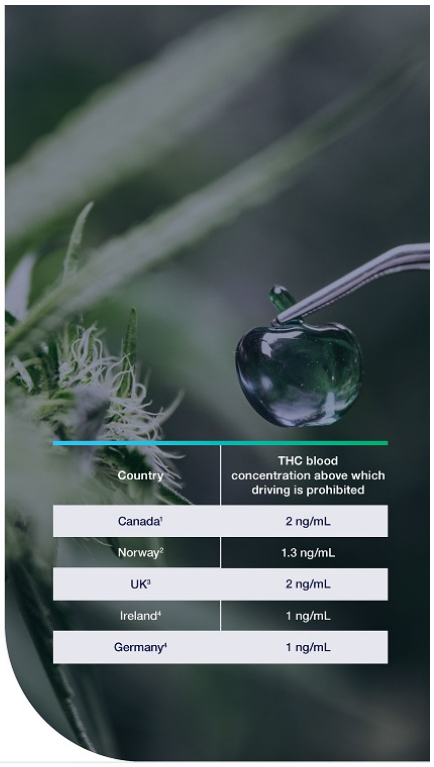
Results

THC clearance





- THC levels in blood samples collected the morning after dose 7 were below the limit of detection (0.1 ng/mL) in 37.5 % of low dose IHL-42X samples.
- The average THC concentration in blood samples from the morning after night 7 in the low dose IHL-42X treatment period was 0.20 ng/mL.
- The highest THC concentration detected in a sample from the low dose group was 0.45 ng/mL.



Country	THC blood concentration above which driving is prohibited
Canada[1]	2 ng/mL
Norway[2]	1.3 ng/mL
UK[3]	2 ng/mL
Ireland[4]	1 ng/mL
Germany[4]	1 ng/mL

1. https://www.justice.gc.ca/eng/cj-jp/sidl-rlcfa/qa2-qr2.html
2. Vindenes, V., et al., (2012) Impairment based legislative limits for driving under the influence of non-alcohol drugs in Norway, Forensic Science International 219(1-3),1-11
3. Wolff, K, et al., Driving Under the Influence of Drugs: Report from the Expert Panel on Drug Driving, Department of Transport, London, 2013.
4. https://www.vifm.org/wp-content/uploads/VIFM-Annual-Report-2019-2020.pdf

Summary of THC clearance

Countries that have levels of THC in blood above which driving is prohibited have set limits at 1-2 ng/mL.

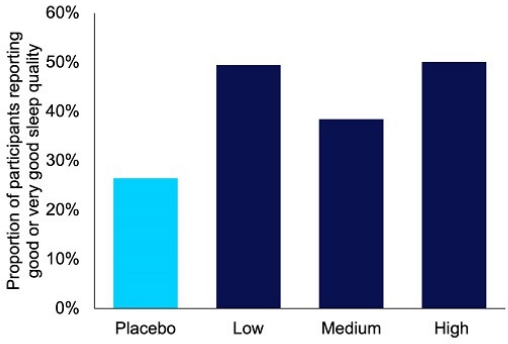
The morning after low dose IHL-42X 37.5% of subjects had no detectable THC in their blood.

In the low dose blood samples that did have detectable THC the average concentration was 0.20 ng/mL and the maximum was 0.45 ng/mL, both of which are below the permissible limits.

The THC clearance data indicates that low dose IHL-42X is unlikely to pose a risk for patients to legally drive while using the drug to treat their sleep apnoea.

IHL-42X ⟶ improved patient reported sleep quality.

- Participants recorded their sleep quality or satisfaction every night through out the study as very poor, poor, fair, good or very good.
- During IHL-42X treatment periods, the percentage of participants that ranked their sleep as good or very good was increased, compared to placebo. This is an average across the seven nights of each treatment period, for all the participants.



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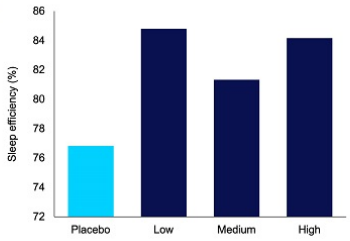
2. Carley DW,et. al. 2018. Pharmacotherapy of apnea by cannabimimetic enhancement, the PACE clinical trial: Effects of dronabinol in obstructive sleep apnea. Sleep 41

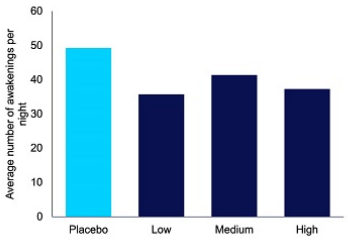
Results

IHL-42X ⟶ improved sleep metrics captured by actigraphy (wearable sleep monitor).

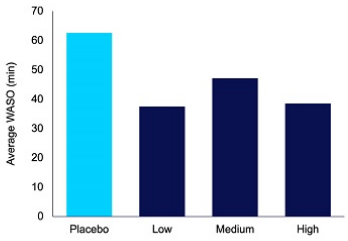
(1)



(2)



(3)



During IHL-42X treatment periods, subjects were asleep for a greater proportion of their time in bed (sleep efficiency)
(1) woke up fewer times
(2) and were awake for less time (wake after sleep onset (WASO)
(3) than during the placebo treatment period.

Summary of sleep quality

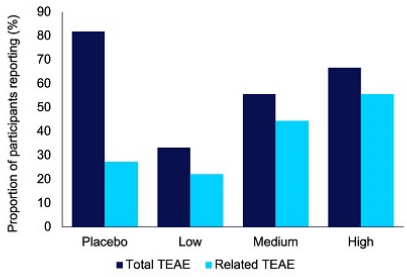
During IHL-42X treatment periods subjects reported a higher level of sleep satisfaction than placebo periods.

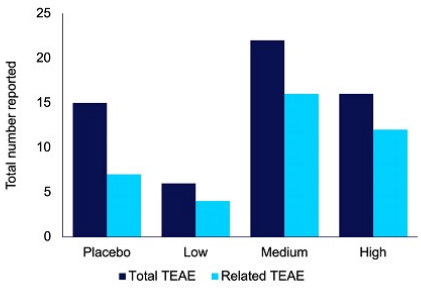
Data from the Actiwatch indicated that subjects were sleeping through the night better than during the placebo period.

These data support that IHL-42X improved sleep quality, despite a lack of improvement in secondary endpoints that focused on sleepiness, mood and quality of life.

IHL-42X ⟶ was well tolerated.

- No serious treatment emergent adverse events (TEAE) were reported during the study.
- Low dose IHL-42X had the lowest proportion of participants reporting TEAEs and the fewest number of total TEAEs compared to other treatment groups.
- One participant on high dose IHL-42X had a TEAE that caused them to be withdrawn from the study. However, they tested positive for illicit substances other than cannabis.
- One participant on placebo had a severe TEAE that was not linked to the study drug.





Safety summary

IHL-42X was well tolerated across all three dose levels.

- No serious adverse events (side effects) were reported during the study.
- The only severe adverse event was reported during the placebo treatment period and was not linked to the study drug.

Adverse event rates during the low dose IHL-42X treatment period were lower than even placebo.

These results support Incannex's hypothesis that combining dronabinol and acetazolamide into IHL-42X will reduce the potential for side effects.

Results

Conclusions

01.

Data from phase 2 proof of concept clinical trial supports the potential of IHL-42X as an effective and well tolerated treatment for OSA, meeting the unmet needs of millions of people.

02.

IHL-42X reduced AHI, improved sleep quality with respect to both patient reported outcome and actigraphy, and did not lead to any adverse events beyond those expected based on what was expected from dronabinol and acetazolamide.

03.

Low dose IHL-42X was the most effective of the doses tested in this study.

- It reduced AHI by over half (on average) in trial participants and 25% of participants saw an 80% reduction in AHI.
- Low dose IHL-42X has the lowest number of reported adverse events, even lower than placebo.
- Low observed THC blood concentration amongst participants below limits for impairment to drive.

04.

Patent application for IHL-42X considered "novel and inventive" by international patent examiner.

05.

Pre-IND meeting completed with FDA and the next major development milestone for IHL-42X will be the commencement of the IND opening clinical trial.

Acknowledgments

Dr Jen Walsh and the team at UWA Centre for Sleep Science for work as a clinical trial site.

Prof Terry O'Brien and the team at The Alfred for work as a clinical trial site.

Novotech for managing the trial and study data.

Agilex for analysis of samples for THC and metabolite levels.

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