

Incannex to Acquire APIRx Pharmaceuticals USA, LLC

Highlights:

- APIRx has twenty-two (22) active clinical and pre-clinical research and development projects
- therapeutic candidates are targeted at treating pain, dementia, Parkinson's disease, restless leg syndrome, gastrointestinal diseases, periodontitis, addiction disorders, skin conditions and ophthalmic conditions
- therapeutic candidates are underpinned by an extensive intellectual property portfolio that includes 19 granted patents and 23 pending patents
- proposed acquisition price of US\$93.3M in all scrip transaction
- the transaction affirms Incannex's position as a global leader in the fields of cannabinoid, psychedelic, and combination pharmaceuticals.

Melbourne, Australia, March 24, 2022 – Incannex Healthcare Limited (Nasdaq: IXHL) (ASX: IHL), ('Incannex' or the 'Company') a clinical-stage pharmaceutical company developing unique medicinal cannabis pharmaceutical products and psychedelic medicine therapies for unmet medical needs, today announced that it has executed a term sheet with binding commercial terms to wholly acquire APIRx Pharmaceutical USA, LLC ('APIRx'), subject to shareholder approval under ASX listing Rule 7.1.

About APIRx – First Mover in Pharmaceutical Medicinal Cannabinoid Product Development

APIRx is an innovative biotechnology company focused on research, development, and production of prescription pharmaceutical cannabinoid medicines. It has twenty-two (22) active clinical and pre-clinical research and development projects utilising proprietary technologies. The acquisition of APIRx brings to Incannex a diverse portfolio of promising therapeutic candidates targeted at treating an extensive range of conditions including pain, dementia, Parkinson's Disease, restless leg syndrome, gastrointestinal diseases, periodontitis, addiction disorders, skin conditions and ophthalmic conditions. A comprehensive table of the therapeutic candidates, their stage of development and their significant addressable markets are listed in **Appendix A**.

APIRx was established as a corporate entity in the Netherlands to amalgamate the intellectual property assets of medicinal cannabis pioneers, and APIRx co-founders, Dr George Anastassov and Mr Lekhram Changoer. Dr Anastassov and Mr Changoer have collaborated since 2003 to develop the largest privately held patent portfolio pertaining to pharmaceutical cannabinoid inventions globally. They previously licensed their technology to AXIM Biotechnologies Inc., where they were part of the lead management team, overseeing a peak market capitalisation of approximately US\$1.2B in 2017 prior to the assets being privatised by APIRx.

Numerous pre-clinical studies and clinical trials over the APIRx therapeutic candidates have been undertaken to justify the intellectual property portfolio, which includes 19 granted patents and 23

pending patents. Key patents (detailed in **Appendix B**) relate to sustained oral mucosal delivery of cannabinoids and cannabinoid combinations through chewing gum, oral care cannabinoid compositions, cannabinoid ophthalmic solutions, topical compositions containing cannabinoids and cannabinoid extraction technologies.

Medicated chewing gum ('MCG') is a novel drug delivery system growing in favour amongst the medical community due to widespread potential applications as an extended-release dosage form that provides a continuous release of the medicine contained. MCGs are fast acting as they release the active ingredients into the oral mucosa, reducing the potential for gastric intolerance amongst patients. These qualities, amongst others, make MCGs an excellent delivery system for medicinal combinations designed to treat sustaining pain and addiction disorders.

An example of a successful MCG is over-the-counter nicotine chewing gum (i.e., Nicabate for nicotine craving relief – noting this is not an APIRx product). A focus of the combined APIRx and Incannex group will be the ongoing development of APIRx's CheWell, CanQuit and CanQuit-O cannabinoid combination MCGs to treat cannabis addiction, nicotine addiction and opioid addiction.

Strategic Rationale

The acquisition of APIRx will significantly strengthen Incannex's position as a market leader at the forefront of cannabinoid and psychedelic treatment development. It will:

- Add a large portfolio of intellectual property with granted and pending patents
- Expand Incannex's addressable markets globally and addressable market sizes by over US\$400bn per annum
- Further enhance Incannex's technical and drug development capability by adding some of the industry's longest standing and best-known scientists to the Incannex team.
- Expand the Company's drug delivery capability to include APIRx's patented delivery technologies.

APIRx will be entitled to nominate one board member to Incannex after completion of the proposed transaction.

APIRx Management – Dr George Anastassov and Mr Lekhram Changoer

Dr Anastassov and Mr Changoer are experienced clinical researchers with medical and scientific backgrounds. They will be employed by Incannex on a full-time basis following completion of the acquisition and will continue to drive the development of APIRx projects, whilst also assisting with the development of the Company's existing projects. They are experienced with liaising and negotiating with the U.S. Food and Drug Administration ('FDA'), having undertaken numerous pre-investigational new drug ('IND') meetings, and opening two (2) IND applications for the MedChew RL and the MedChew Dronabinol medicinal product candidates. Furthermore, APIRx has strong relationships with international academic institutions and research hospitals including Mount Sinai School of Medicine, New York (USA), University of St. Andrews (UK), Free University of Amsterdam (NL), University of Wageningen (NL), and Mauritsclinics (NL).

“We believe that bringing together Incannex and APIRx will bolster our position as a leader in the medicinal cannabinoid sector and will further set IHL apart from other players in the industry”, stated CEO and Managing Director of Incannex, Mr. Joel Latham. “With sizeable addressable markets and intellectual property spanning a multitude of unmet medical needs, we’re positioning Incannex to be a significant player in the pharmaceutical sectors of the future. I’m excited by this acquisition opportunity on multiple fronts and look forward to working with the APIRx team to deliver on our vision of providing treatments which will make genuine differences to the lives of millions of people”.

APIRx co-founder, Dr George Anastassov said; “We are delighted to partner with the IHL team as we believe that our extensive experience and broad IP asset base is perfectly positioned for further development and expansion within the IHL organization. Both companies have proven track records to deliver innovative projects and the goal of this transaction to create the global leader in the cannabinoid, psychedelic, and combination pharmaceuticals space. We intend to do this by innovatively addressing conditions for which there are only modest, or no safe and effective, treatment options”.

APIRx co-founder, Mr Lekhram Changoer said; “APIRx is bringing new drug delivery technologies backed by patents that, when combined with Incannex’s existing intellectual property, will result in IHL being a state-of-the-art, industry-leading cannabinoid and psychedelic platform. The drug products developed utilising this broader portfolio of technologies gives us the opportunity to develop, in the clinic, a diverse range of innovative products addressing significant unmet medical needs. A post-acquisition Incannex will also have greater presence in the United States and Europe, which may benefit the Company to more efficiently undertake multi-site clinical trials that will ultimately be required for FDA clinical trial programs aimed at drug approval”.

Next Steps

Incannex has commenced the documentation of the long form contract required to complete the proposed transaction. Shareholder approval will be sought by means of an extraordinary general meeting (‘EGM’) of shareholders. The EGM will be called and announced in due course. Key terms of the acquisition are detailed in **Appendix C** below. In anticipation of the completion of the transaction, the Incannex medical and scientific team continue thorough assessment of the APIRx projects to best prioritise the development of the APIRx therapeutic candidates. Incannex anticipates budgeting approximately A\$5.0M of expenditure on the APIRx product suite in the first 12 months. However, the budget may be re-assessed to up to A\$10M following the conclusion, in April, of the Loyalty Option Offer, that could raise up to approximately A\$28M in development capital for the Company.

The proposed acquisition transaction is not a related party transaction.

This announcement has been approved for release to ASX by the Incannex Board of Directors.

END



Date: March 24, 2022
Public Announcement (NASDAQ: IXHL) (ASX: IHL)

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. IHL 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.

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.

Contact Information

Incannex Healthcare Limited

Mr Joel Latham
Managing Director and Chief Executive Officer
+61 409 840 786
joel@incannex.com.au

US IR Contact

Rx Communications Group
Michael Miller
+1-917-633-6086
mmiller@rxir.com

Appendix A: Details of Therapeutic Candidates

Clinical Project	Addressable Market Opportunity (\$US)	Stage of Development	Regulatory Stage of Development	Next Steps	Relevant Patents
Medchew-1401					
Pain and Spasticity in Multiple Sclerosis	\$62 Bn (Global) in '21 (a)	Pre-clinical	Pre-IND completed in NL and Switzerland	Phase 1	Granted
Medchew GB					
Post-herpetic Neuralgia	\$3.7 Bn (U.S.) by '27 (n)	Pre-clinical	FDA Pre-IND	Phase 1	Granted
Medchew-1502					
Parkinson's Disease	\$8.05 Bn (Global) by '27; 6.5% CAGR (l)	Pre-clinical	FDA Pre-IND	Phase 1	Granted
Medchew-1503					
Dementia	\$23.9 Bn (Global) by '28; 7.9% CAGR (m)	Pre-clinical	FDA Pre-IND	Phase 1	Granted
Medchew RL					
Restless Leg Syndrome	12.1.% prevalence of US pop. (j)	Pre-clinical	FDA Pre-IND	Phase 1	Granted
Medchew Dronabinol					
Nausea and Vomiting in Chemotherapy	\$3.1 Bn (Global) by '24 (e)	Phase 1A completed	FDA Pre-IND complete	Phase 1B	Granted
APIRx 1505 Flotex					
Gastro: Crohn's Disease	\$12.6 Bn (Global) by '24 (k)	Pre-clinical	Pre-regulatory	Phase 1	Drafting
CanChew Plus					
Gastro: IBS	\$40 Bn (U.S.) in '21 (d)	Phase 2A Completed	Pre-IND, ethic's approval	Phase 2B	Granted
CanChew RX					
Gastro: IBD	\$2.7B Bn (U.S.) by '28 (r)	Pre-clinical	Pre-regulatory	Phase 1	Granted
SuppoCan (Suppository)					
Gastro: IBD	\$2.7B Bn (U.S.) by '28 (r)	Pre-clinical	Pre-regulatory	Phase 1	Granted
Oraximax					
Gingivitis and Periodontitis	\$42 Bn (U.S. and Europe) in '21 (a)	Clinical Stage	510K pre-market submission to FDA	Phase 2	Granted
CheWell					
Addiction: Cannabis Dependence	\$64 Bn (U.S.) in '21 (c)	Pre-clinical	Pre-IND ready for submission	Phase 1	Drafting
CanQuit					
Addiction: Tobacco Smoking Cessation	\$47.75 Bn (Global) by '24, 17.3% CAGR (o)	Pre-clinical	Pre-regulatory	Phase 1	Granted
CanQuit O					
Addiction: Opioid Addiction	\$64 Bn (U.S.) in '21 (c)	Pre-clinical	Pre-regulatory	Phase 1	Granted
APIRx-1601					
Skin: Vitiligo	\$0.1B (Global) in '21 (b)	Phase 2 complete	Pre-IND drafting	Phase 1	2x granted, 1x pending
APIRx-1602					
Skin: Psoriasis	\$0.5B (Global) in '21 (b)	Phase 2A complete	Pre-IND drafting	Phase 1	2x granted, 1x pending
APIRx-1603					
Skin: Atopic Dermatitis	\$1.1B (Global) in '21 (b)	Phase 2A complete	Pre-IND drafting	Phase 1	2x granted, 1x pending
APIRx-1701					
Ophth: Glaucoma	\$10.4B (Global) by '26, 6.3% CAGR (g)	Pre-clinical	Pre-regulatory	in vitro studies	Granted
APIRx-1702					
Ophth: Dry Eye Syndrome	\$6.6B (Global) by '27, 6.4% CAGR (p)	Pre-clinical	Pre-regulatory	in vitro studies	Granted
APIRx-1801					
Ultrapur THC	\$31.5 Bn (Global) by '30; 18.6% CAGR (q)	Developed			Granted
APIRx-1802					
Ultrapur CBD	\$31.5 Bn (Global) by '30; 18.6% CAGR (q)	Developed			Granted
APIRx-1803					
Ultrapur CBG	\$31.5 Bn (Global) by '30; 18.6% CAGR (q)	Developed			Granted

Addressable Market Opportunity – Sources:

- (a) Frost & Sullivan Market Report as commissioned by APIRx, Sept. 2021
- (b) Frost & Sullivan Market Report as commissioned by APIRx, Sept. 2021, market opportunity is medications and other, where other includes visits to physicians, in/out patient costs
- ® Frost & Sullivan Market Report as commissioned by APIRx, Sept. 2021, market opportunity is Adolescent Substance Abuse
- (d) Frost & Sullivan Market Report as commissioned by APIRx, Sept. 2021, market opportunity is Irritable Bowel Syndrome / Disease
- ® Healdkeepers, "Chemotherapy Induced Nausea and Vomiting (CINV) Drugs Market Research Report, History and Forecast 2022-2027", Jan. 2, 2022
- (f) Brisk Insights, "Chemotherapy Induced Nausea And Vomiting Treatment Market", 2018-2026", Sept. 8, 2021
- (g) ResearchandMarkets, "Outlook on the Glaucoma Therapeutics Global Market", 2020-2026", Oct. 22, 2021
- (h) VerifiedMarketResearch, "Global Glaucoma Treatment Market", 2021-2028", Aug. 2021
- (i) Garica-Borreguero and Williams study (2014) on Restless Leg Syndrome / Willis Ekbohm Disease
- (j) Straits Research: Home Care Sleep Screening Devices Market
- (k) Heraldkeepers, "Crohn's Disease Drugs Market Research Report 2022: Prospects, Trends Analysis, Market Size and Forecasts to 2027", Jan. 2, 2022
- (l) Global Market Insights, "Parkinson's Disease Therapeutics Market", Base Year 2020
- (m) Accurize Market Research, "Dementia Drugs Treatment Market", Nov. 27, 2021
- (n) Comserve, "U.S. Shingles Vaccine Market", Jan. 4, 2022
- (o) Worldwide Market Reports, "Smoking Cessation and Nicotine De-Addiction Products Market", May 2018
- (p) Future Market Insights, "Dry Eye Syndrome Treatment Market", July 2017
- (q) Precedence Research "Cannabis Extract Market", Mar. 2020; includes THC, CBD, CBG and other
- (r) Coherent Market Insights "Inflammatory Bowel Disease Market Analysis", Sept. 2021.

Please note that some reports on addressable market opportunity have been commissioned by APIRx and are non-public. Individual reports are available on request to Incannex Company Secretary Mr Madhukar Bhalla, whose email address is madhu@incannex.com.au. Addressable market size estimates listed in Appendix B detail direct costs associated with the indication, including medicine sales, on an annual basis.

Appendix B: Key Patent Details

Title	Application No.	Status	Country
ORAL CARE COMPOSITION COMPRISING CANNABINOIDS	14/970,322	Granted	US
ORAL CARE COMPOSITION COMPRISING CANNABINOIDS	16/920,065	Pending	US
ORAL CARE COMPOSITION COMPRISING CANNABINOIDS	21165551.9	Pending	EP
ORAL CARE COMPOSITION COMPRISING CANNABINOIDS	18103553.3	Pending	HK
OPHTHALMIC SOLUTIONS FOR GLAUCOMA AND CONJUNCTIVITIS TREATMENT	14/982,610	Granted	US
OPHTHALMIC SOLUTIONS FOR GLAUCOMA AND CONJUNCTIVITIS TREATMENT	15/728,283	Granted	US
CANNABINOID AND SUGAR ALCOHOL COMPLEX, METHODS TO MAKE AND USE	16/653,416	Pending	US
CANNABINOID AND SUGAR ALCOHOL COMPLEX, METHODS TO MAKE AND USE	16747053	Pending	EP
CANNABINOID AND SUGAR ALCOHOL COMPLEX, METHODS TO MAKE AND USE	18106393.0	Pending	HK
COSMETIC AND TOPICAL COMPOSITIONS COMPRISING CANNABIGEROL	16/784,086	Pending	US
COSMETIC AND TOPICAL COMPOSITIONS COMPRISING CANNABIGEROL	16752852	Granted	EP
COSMETIC AND TOPICAL COMPOSITIONS COMPRISING CANNABIGEROL	18107903.1	Granted	HK
PROCESS TO EXTRACT AND PURIFY DELTA-9-TETRAHYDROCANNABINOL	15/146,668	Granted	US
PROCESS TO EXTRACT AND PURIFY DELTA-9-TETRAHYDROCANNABINOL	16/052,150	Granted	US
PROCESS TO EXTRACT AND PURIFY DELTA-9-TETRAHYDROCANNABINOL	16/774,959	Granted	US
PROCESS TO EXTRACT AND PURIFY DELTA-9-TETRAHYDROCANNABINOL	16789992.1	Pending	EP
ANTI-MICROBIAL COMPOSITIONS COMPRISING CANNABINOIDS	16/293,136	Granted	US
ANTI-MICROBIAL COMPOSITIONS COMPRISING CANNABINOIDS	16/545,808	Granted	US
ANTI-MICROBIAL COMPOSITIONS COMPRISING CANNABINOIDS	16815133	Pending	EP
ANTI-MICROBIAL COMPOSITIONS COMPRISING CANNABINOIDS	18113899.5	Pending	HK
COMPOSITION CONTAINING CANNABINOIDS FOR USE IN A METHOD FOR THE TREATMENT OF PSORIASIS	16/106,420	Pending	US
COMPOSITION CONTAINING CANNABINOIDS FOR USE IN A METHOD FOR THE TREATMENT OF PSORIASIS	18190959	Pending	EP
METHOD FOR THE TREATMENT OF ATOPIC DERMATITIS	16/106,524	Granted	US
COMPOSITION CONTAINING CANNABINOIDS FOR USE IN A METHOD FOR THE TREATMENT OF ATOPIC DERMATITIS	18190961	Pending	EP
COMPOSITION CONTAINING CANNABINOIDS FOR USE IN A METHOD FOR THE TREATMENT OF VITILIGO	16/106,591	Pending	US
COMPOSITION CONTAINING CANNABINOIDS FOR USE IN A METHOD FOR THE TREATMENT OF VITILIGO	18190967	Pending	EP
CHEWING GUM COMPOSITION COMPRISING CANNABINOIDS AND NICOTINE	15/494,514	Granted	US
CHEWING GUM COMPOSITION COMPRISING CANNABINOIDS AND NICOTINE	17790163	Pending	EP
CHEWING GUM COMPOSITION COMPRISING CANNABINOIDS AND GABAPENTIN	15/824,184	Pending	US
CHEWING GUM COMPOSITION COMPRISING CANNABINOIDS AND GABAPENTIN	17876342.1	Pending	EP
CHEWING GUM COMPOSITION COMPRISING CANNABINOIDS AND OPIOID AGONISTS AND/OR ANTAGONISTS	15/787,498	Pending	US
CHEWING GUM COMPOSITION COMPRISING CANNABINOIDS AND OPIOID AGONISTS AND/OR ANTAGONISTS	17863114	Pending	EP
SUPPOSITORIES COMPRISING CANNABINOIDS	15/787,978	Granted	US
SUPPOSITORIES COMPRISING CANNABINOIDS	16/122,079	Granted	US
SUPPOSITORIES COMPRISING CANNABINOIDS	16/710,183	Granted	US
SUPPOSITORIES COMPRISING CANNABINOIDS	17/214,868	Pending	US
SUPPOSITORIES COMPRISING CANNABINOIDS	17862753	Pending	EP
CHEWING GUM COMPRISING CANNABINOIDS	12/934633	Granted	US
CHEWING GUM COMPRISING CANNABINOIDS	14/684109	Granted	US
CHEWING GUM COMPRISING CANNABINOIDS	MX/a/2010/010607	Granted	MX
CHEWING GUM COMPRISING CANNABINOIDS	7336/DELNP/2010	Granted	IN
CHEWING GUM COMPRISING CANNABINOIDS	PI 0910094-6	Pending	BR

Appendix C – Key Terms of the APIRx Acquisition

The proposed acquisition is for 100% of the issued share capital in APIRx Pharmaceutical USA, LLC ('APIRx') by Incannex Healthcare Limited from the APIRx shareholders.

Consideration of US\$93.3M is payable in the form scrip consideration at the 7-day volume-weighted-average-price (VWAP) immediately prior to the execution of the term sheet for the acquisition.

Completion of the proposed transaction is conditional upon the satisfaction of conditions precedent, including but not limited to the following:

- (a) Incannex having completed due diligence investigations to its satisfaction;
- (b) Incannex obtaining any approvals or consents required in connection with the proposed transaction (including for the avoidance of any doubt any government, regulatory (including ASX, ASIC and Nasdaq) and shareholder approvals);
- (c) Acquisition of the entire issued share capital of APIRx Pharmaceuticals B.V (such that APIRx Pharmaceuticals B.V will be the wholly owned subsidiary of Incannex);
- (d) Acquisition of the pharmaceutical and non-pharmaceutical assets of the APIRx and APIRx Pharmaceuticals B.V; and
- (e) the execution of the long-form transaction documents.

At completion of the proposed transaction, the sellers of APIRx will each be required to enter a voluntary escrow deed for the IHL shares to be issued as scrip consideration pursuant to which all the IHL shares issued to the sellers at completion will be subject to voluntary escrow for a period of 12 months following completion.