



APIRx Pharmaceuticals Acquisition May 2022

Exciting projects, strategic
patents, cannabinoid expertise
and synergies.

ASX Ticker: IHL | NASDAQ Ticker: IXHL

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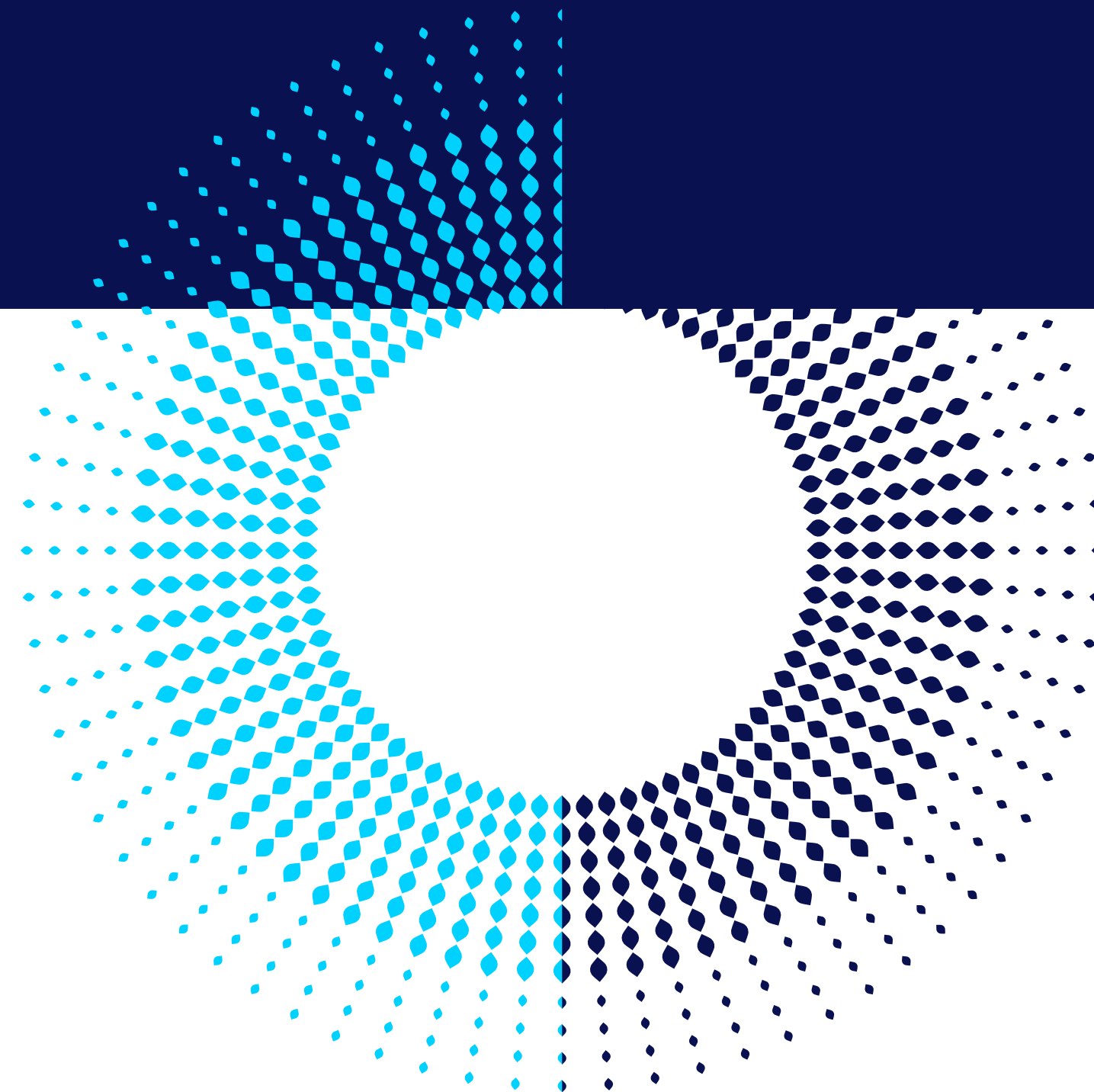
The acquisition of APIRx delivers a strong portfolio of patented drug candidates, with 22 development programs covering a total addressable market of US\$400B per annum.

Together, Incannex and APIRx will form the world's largest portfolio of patented medicinal cannabinoid drug formulations and psychedelic treatment protocols.

The APIRx takeover is anticipated to be seamless, as the development of assets is congruent with current operational capabilities and our pharmaceutical development strategy targeting FDA registration.

Acquisition of APIRx Pharmaceuticals USA, LLC

Progress of existing Incannex development programs will not be affected by the addition of new projects resulting from the APIRx acquisition.



- Binding share purchase agreement executed to acquire 100% of APIRx Pharmaceutical USA, LLC ‘(APIRx)’.
- APIRx has 22 active clinical and pre-clinical research and development projects underpinned by 19 granted and 23 pending patents.

- Subject to shareholder vote at Extraordinary General Meeting In June 2022.

- Drug candidates are expertly designed to target irritable bowel syndrome, addiction disorders, spasticity and pain in multiple sclerosis, nausea and vomiting in chemotherapy, inflammatory bowel disease, periodontal disease and gingivitis, skin conditions, ophthalmic conditions, dementia, Parkinson’s disease, restless legs syndrome, among others.

- Acquisition of APIRx made by all scrip transaction of 218M IHL shares at VWAP calculation of approx. \$A0.573c per share (approx. US\$10.05 per ADS).

Benefits of the APIRx Acquisition

01.

Substantial IP portfolio covering active pharmaceutical ingredients, formulations and methods of use to secure commercial exclusivity.

- Developed technologies and IP at all stages of cannabinoid drug development from extraction to therapeutic uses.

02.

Clinical stage: Proof of concept and formulations have been established for APIRx drug products.

- Multiple completed pre-clinical, phase 1 and phase 2 clinical trials.
- Favorable interactions with the FDA and other major regulators.
- Several pre-IND meetings completed and INDs open.

03.

Diversified portfolio of treatment solutions will expand our global addressable market opportunity by over US\$ 400B per annum.

04.

Potential for short runways to market by leveraging public data on existing FDA or EMA registered pharmaceutical cannabinoid products **Sativex** and **Marinol**. (owned by Jazz Pharmaceuticals, formerly GW Pharmaceuticals, and AbbVie Inc respectively)

- Short pathway to registration and commercial launch for MedChew™ Rx and MedChew™ Dronabinol, as the active pharmaceutical ingredient is the same as approved products but with a novel dosage form (medicated chewing gum for increased bioavailability and extended release).
- **Discussions with regulatory agencies for registration will focus on a request for a single bridging clinical trial for MedChew™ Rx and MedChew™ Dronabinol.**

05.

Commercially exclusive patented drug delivery technologies expand potential applications for established compounds and IHL-675A multi-use anti-inflammatory cannabinoid combination drug. Some of these technologies include:

- Medicated chewing gums and chewable tablets.
- High bioavailability oral mucosa delivery mechanisms.
- Super slow-release delivery formulations.
- Topical and ophthalmic formulations.

Benefits of the APIRx Acquisition

06.

Over-the-counter (OTC) patented CBD chewable tablet relevant to a range of ailments being planned for the CheWell high-bioavailability oral mucosa dosage form.

- Therapeutic Goods Administration (TGA) limits on daily CBD dosage for OTC cannabinoid products necessitate high bioavailability formulation such as CheWell being acquired by Incannex.
- Generic CBD oils have low bioavailability, due to low solubility, gastrointestinal loss, first pass metabolism and potentially low effectiveness.
- Opportunity to leverage favourable phase 1 and phase 2 trial data to expedite the TGA approval process.

07.

APIRx management team have extensive expertise in multiple aspects of cannabinoid development including: extraction, formulation, IP generation and clinical/regulatory development.

- Extensive international network of academic and industry partnerships to accelerate development of all drug candidates.



08.

All research and development of APIRx assets in Australia will be eligible for the R&D tax rebate of 43.5% for R&D spend.

22 Projects

over which proof of concept has been established in either pre-clinical, phase 1 or phase 2 clinical studies.

Established drug formulations with data packages necessary for regulatory applications.

Proof of concept data from pre-clinical and clinical studies supporting the proposed therapeutic applications.

Regulatory filings for multiple drug products.

Granted and pending patents for manufacturing methods, drug formulations and methods of use to treat a range of conditions.

- Covers the entire drug development process from raw materials to patient dosing.

Different cannabinoid development strategy than IHL’s current programs.

- APIRx focuses on unique cannabinoid formulations whereas IHL programs are cannabinoid combination products.

Clinical Project	Addressable Market Opportunity (in US\$)	Stage of Development	Regulatory Stage of Development	Next Steps	Relevant Patents
MedChew™-1401 Pain and Spasticity in Multiple Sclerosis	\$62B (Global) in '21 (a)	Pre-clinical	Pre-IND completed in NL and Switzerland	Phase 1	Granted
MedChew™ GB Post-herpatic Neuralgia	\$3.7B (U.S.) by '27 (n)	Pre-clinical	FDA Pre-IND	Phase 1	Granted
MedChew™-1502 Parkinson's Disease	\$8.05B (Global) by '27; 6.5% CAGR (l)	Pre-clinical	FDA Pre-IND	Phase 1	Granted
MedChew™-1503 Dementia	\$23.9B (Global) by '28; 7.9% CAGR (m)	Pre-clinical	FDA Pre-IND	Phase 1	Granted
MedChew™ RL Restless Legs Syndrome	12.1.% prevalence of U.S. pop. (j)	Pre-clinical	FDA Pre-IND	Phase 1	Granted
MedChew™ Dronabinol Nausea and Vomiting in Chemotherapy	\$3.1B (Global) by '24 (e)	Phase 1A completed	FDA Pre-IND completed	Phase 1B	Granted
APIRx 1505 Flotex Gastro: Chrohn's Disease	\$12.6B (Global) by '24 (k)	Pre-clinical	Pre-regulatory	Phase 1	Drafting
CanChew Plus Gastro: IBS	\$40B (U.S.) in '21 (d)	Phase 2A Completed	Pre-IND, ethical approval	Phase 2B	Granted
CanChew RX Gastro: IBD	\$2.78B (U.S.) by '28 (r)	Pre-clinical	Pre-regulatory	Phase 1	Granted
SuppoCan (Suppository) Gastro: IBD	\$2.78B (U.S.) by 28 (r)	Pre-clinical	Pre-regulatory	Phase 1	Granted
Oraximax Gingivitis and Periodontitis	\$42B (U.S. and Europe) in '21 (a)	Clinical Stage	510(k) pre-market submission to FDA	Phase 2	Granted

(a) Frost & Sullivan Market Report as commissioned by APIRx, Sept. 2021
(d) Frost & Sullivan Market Report as commissioned by APIRx, Sept. 2021, market opportunity is Irritable Bowel Syndrome / Disease
(e) Healdkeepers, "Chemotherapy Induced Nausea and Vomiting (CINV) Drugs Market Research Report, History and Forecast 2022-2027", Jan. 2, 2022
(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
(r) Coherent Market Insights "Inflammatory Bowel Disease Market Analysis", Sept. 2021.

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Clinical Project	Addressable Market Opportunity (in US\$)	Stage of Development	Regulatory Stage of Development	Next Steps	Relevant Patents
CheWell Addiction: Cannabis Dependence	\$64B (U.S.) in '21 (c)	Pre-clinical	Pre-IND ready for submission	Phase 1	Drafting
CanQuit Addiction: Tobacco Smoking Cessation	\$47.75B (Global) by '24, 17.3% CAGR (o)	Pre-clinical	Pre-regulatory	Phase 1	Granted
CanQuit O Addiction: Opioid Addiction	\$64B (U.S.) in '21 (c)	Pre-clinical	Pre-regulatory	Phase 1	Granted
APIRx-1601 Skin: Vitiligo	\$0.1B (Global) in '21 (b)	Phase 2 completed	Pre-IND drafting	Phase 1	2x Granted, 1x Pending
APIRx-1602 Skin: Psoriasis	\$0.5B (Global) in '21 (b)	Phase 2A completed	Pre-IND drafting	Phase 1	2x Granted, 1x Pending
APIRx-1603 Skin: Atopic Dermatitis	\$1.1B (Global) in '21 (b)	Phase 2A completed	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 Ultrapure THC	\$31.5B (Global) by '30; 18.6% CAGR (q)	Developed			Granted
APIRx-1802 Ultrapure CBD	\$31.5B (Global) by '30; 18.6% CAGR (q)	Developed			Granted
APIRx-1803 Ultrapure CBG	\$31.5B (Global) by '30; 18.6% CAGR (q)	Developed			Granted

(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

(c) Frost & Sullivan Market Report as commissioned by APIRx, Sept. 2021, market opportunity is Adolescent Substance Abuse

(g) ResearchandMarkets, "Outlook on the Glaucoma Therapeutics Global Market", 2020-2026", Oct. 22. 2021

(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

APIRx Intellectual Property Families

19 granted and 23 pending patents to secure commercial exclusivity and our R&D investment.
Some patents meet more than one of the categories below:



Cannabinoid drug development pipeline

Formulation/Extraction

- Chewing gum (also combo products)
- Ultra-high bioavailability chewing gum / chewable tablet
- Oral care
- Ophthalmic solutions
- Suppositories
- Extraction of THC, CBD, CBG
- Cannabinoid sugar alcohol
- Microencapsulation of cannabinoids
- Sustained release technology

Methods of use

- Treat glaucoma and conjunctivitis
- Treat atopic dermatitis
- Antimicrobial
- Treat Vitiligo
- Treat Osteonecrosis of the jaw
- Treat psoriasis

Cannabinoid delivery methods with increased bioavailability and altered release profiles which provide opportunity to develop unique cannabinoid products and or products with advantages over established cannabinoid medicines.

APIRx Leadership Team

George Anastassov, MD DDS, MBA Co-founder and CEO



Dr. Anastassov is responsible for the Company's commercial operations, strategic decision-making, and oversight of all clinical development assets. He is one of the developers of the first-in-the-world cannabinoid-containing chewing gum-based delivery system among a number of other systems and formulations. Previously, he was CEO and Co-founder of AXIM Biotechnologies, driving market capitalization to over US\$ 1.2B.

Lekhram Changoer, MSc Co-founder and COO



Mr. Changoer is responsible for the Company's R&D, clinical & product development, commercial operations, quality assurance and Sales & Marketing of technical, consumer healthcare and pharmaceutical products. He has co-developed several patents in the cannabinoid field. Previously, he was CTO and Co-founder of AXIM Biotechnologies, driving market capitalization to over US\$ 1.2B.

Eric H. Kim, MBA CFO



Mr. Kim is responsible for the Company's financial strategy and corporate development. His prior experience includes Corporate Finance at Google, Inc., Investment Banking at Bank of America Merrill Lynch and Lumos Partners, and CEO of ELK Partners. Mr. Kim earned his MBA from The Wharton School at the University of Pennsylvania and is a member of American Mensa.

Advisors

Professor Dr. John Zajicek MD PhD Univ. of St. Andrews, UK



John's diverse and extensive medical honours and experience includes: MD, Cambridge and St. Mary's Hospital PhD, Cell Biology at Cambridge and Professor of Medicine at University of St Andrew's. He is the Chief Investigator in several large multicentre trials, including the cannabinoid use to slow neurodegeneration. John has Authored many papers on cannabinoids, multiple sclerosis, Alzheimer's and Parkinson's diseases.

Renger Witkamp, PhD University of Wageningen, NL



Professor and chair in Nutrition and Pharmacology, combining research and teaching in medical nutrition and the interfaces between foods and medicines. PhD from the University of Utrecht (the Netherlands). His research interests focus on the role of nutrition in determining physiological resilience and the adaptive response of the body (gut, muscle and brain) to ageing, chronic disease and exercise.

Dr. Arno Hazekamp, PhD Cannabis Researcher, NL



An internationally acclaimed cannabis researcher, and former Head of Research and Education at Bedrocan BV – the official grower of medicinal cannabis in the Netherlands. Arno earned his Bachelor's degree in Molecular Biology, followed by an MSc and PhD degree in Biopharmaceutical Sciences at Leiden University, the Netherlands. Specialist in quality control, product development and clinical trial design for the Dutch national medicinal cannabis program. An active international lecturer and medicinal cannabis advocate, and creator of the annual Masterclass Medicinal Cannabis.

Dr. Marcus Meinardi Mauritsclinics, NL



Dr. Marcus Meinardi has been working as a dermatologist at the Mauritskliniek, The Hague since 2005. He studied medicine in Rotterdam and then trained as a dermatologist at the University of Amsterdam. In 1992 he became head of the department of dermatology and allergology. Dr. Meinardi has a PhD in research into the treatment of psoriasis. Dr. Meinardi has specialized in dermatology in allergology and allergic reactions of the skin.

APIRx Research Collaborations



**Free University of Amsterdam,
The Netherlands**

Academic research with the Dept. of Neurology on effects of cannabinoids and chewing, in particular pain and spasticity in MS. MedChew™ Rx project.



**University of Wageningen; Gelderse Vallei
Hospital The Netherlands**

All GI projects – IBS, IBS, Crohn's & UC.



University of St. Andrews, UK

MS, Neurodegenerative diseases and pain.



University of Plymouth, UK

Dept. of Neurology - MS site for MedChew™ Rx projects.



University of Nijmegen, The Netherlands

Dept. of Infectious Diseases. Cannabinoids and infectious diseases - MRSA, MDRSA.



University of Nijmegen, The Netherlands

Dept. of Psychiatry - Adolescent drug addiction treatment.



Univ. of British Columbia, Canada

Dept. of Neurology and Psychiatry - Treatment of Drug Addiction and Psychosis.



University Salzburg, Austria

Dept. of Biochemistry - Development of high-potency, conjugated cannabinoids; GI.



**The National Autonomous
University of Mexico**

Dept. of Gastroenterology - IBS study.



New York University, USA

Dept. of Psychiatry - Treatment of alcohol and drug addiction.



**Glaucnix and the Univ. of Albany,
New York, USA**

Cannabinoids and Glaucoma and treatment of Sicca Syndrome projects.



University of Milano, Italy

Dept. of Gastroenterology. IBS and IBD projects.



Basel University, Switzerland

Pain, Drug addiction.



University of Tasmania, Australia

Pain, Drug Addiction.



Maurits Clinic, The Netherlands

Dermatological indications, (Vitiligo, Atopic Dermatitis, Psoriasis).

Research priorities

Combined with Incannex, the APIRx drug portfolio is positioned to yield patent protected products with marketing approval from regulatory agencies across a range of therapeutic areas.

The programs outlined on the subsequent slides have been identified as lead assets for development in the short term.

Lead programs were selected based on their commercial value and ease of path to market, which is a combination of data that has already been generated and the regulatory strategy.

The goal is to

- Provide patients with access to new, evidence-based cannabinoid therapeutics as soon as possible.
- Reward investors with faster path to approved drug product and revenue.

APIRx expertise in Drug Delivery Systems

Ideal Delivery System Characteristics

- Improved / similar Pharmacokinetic (PK)/Pharmacodynamic (PD) profile to smoked form.
- Broader Therapeutic Index.
- Control of release depending on indications (rapid vs. depot).
- Provision of additional benefits besides the ones directly attributed to the API (functionality).
- Reduced cost.

Existing Forms of Delivery

- Smoking – rapid onset and decline, socially unacceptable.
- Oral spray (Sativex™) – solution contains alcohol and other ingredients to cause dry mouth.
- Ingestible (tablets, capsules, oils and edibles) – low bioavailability, gastrointestinal complaints.
- **Transmucosal, Controlled Release (CanChew™, CanChew Plus™, MedChew™, HempChew™)**
- **Suppositories (SuppoCann™ controlled release of API)**
- **Oral topical: Oraximax™**
- **Transdermal: ReneCann™, Cannonych™, Cannamycin™**
- **Transconjunctival: OphtoCann™, CannBleph™**

Property of APIRx

APIRx forms of delivery potentially applicable to Incannex drug combinations.

Why cannabinoid oral delivery via medicated chewing gum and chewable tablets

Medicated chewing gum and chewable tablets ('MCGT') is a 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. MCGTs 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 MCGTs an excellent delivery system for medicinal combinations designed to treat sustaining pain and addiction disorders.

Extended release of cannabinoid and other pharmaceutical ingredients while chewing.

APIRx have a patented procedure for conversion of cannabinoids to their hydrophilic form.

**Well tolerated by patients.
No capsules to swallow or
messy liquids to administer.**

Cannabinoid absorbed via oral mucosa (mouth)

- Avoids first pass metabolism in the liver, a major factor that reduces the oral bioavailability of cannabinoids.
- Avoids gastrointestinal intolerance of pharmaceutical ingredients.
- Increased bioavailability leads to increased therapeutic effect and/or reduced cost of goods due to reduced dose.

Benefits of Mastication*

- Improved cerebral circulation
- Anxiety reduction effect: De-stress or "eustress"
- Hypothalamic-hypophyseal-adrenal axis (HPA) coordination/ attenuation
- Memory coordination/ improvement
- Neuroprotection
- Analgesic effect
- "Physical exercise" effect

* Weijenberg, Roxane Anthea Francesca, and Frank Lobbezoo. "Chew the pain away: oral habits to cope with pain and stress and to stimulate cognition." *BioMed research international* 2015 (2015).

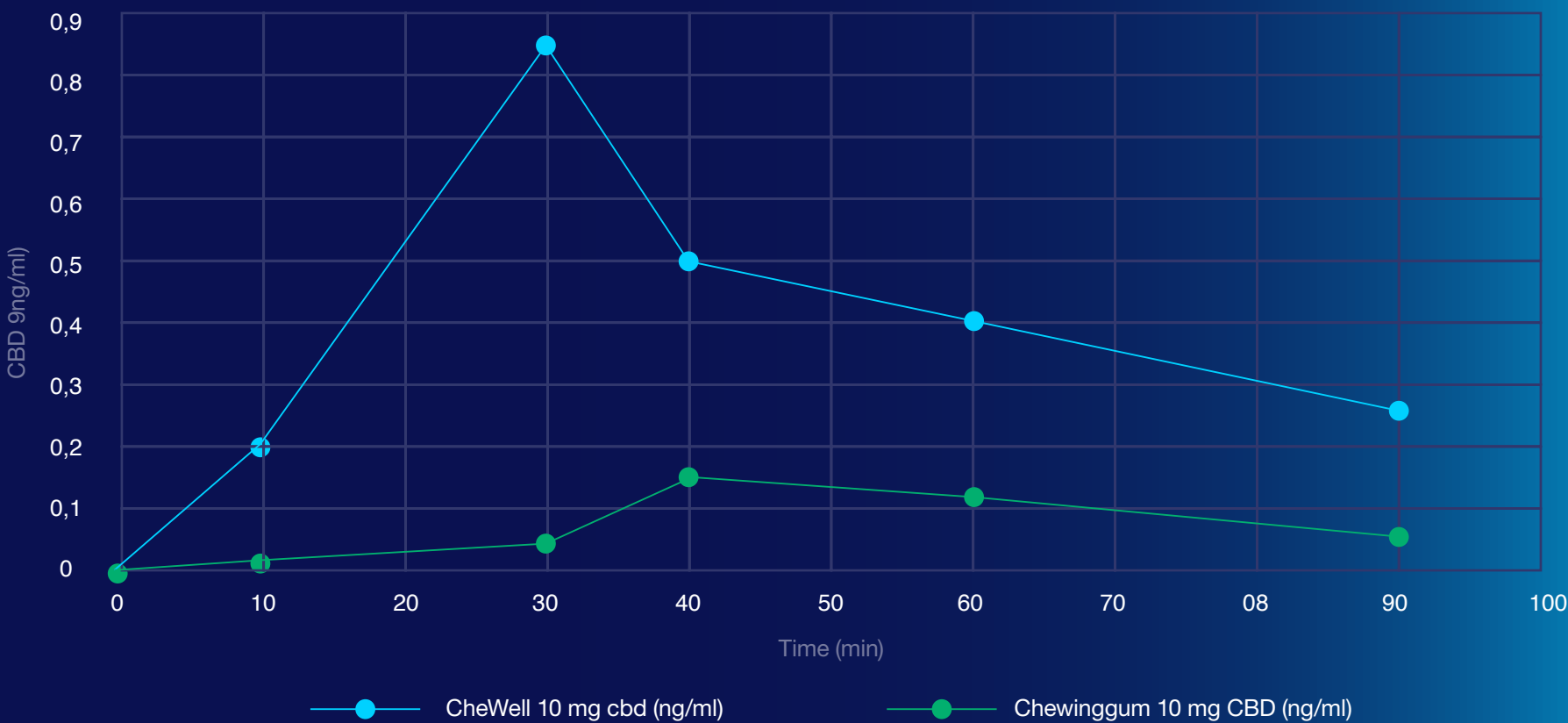
Canchew and Chewell patented MCGTs for Over-the-Counter ('OTC') and Prescription markets

- 01. MCGTs, using APIRx patented formulation technology, with potential to develop as OTC products in Australia and other jurisdictions (U.S., EU, UK, et cetera).
- 02. Phase 1 Pharmacokinetic (PK) study demonstrated that the patented CheWell formulation led to >10x increase in CBD bioavailability compared to the standard CBD chewing gum delivery mechanisms.
- 03. Therapeutic effect and commercial considerations will dictate whether to administer CBD via CheWell chewable tablet or CanChew chewing gum dosage forms.
- 04. Data from 36 patient phase 2 proof of concept trial observed a 50% reduction in abdominal pain in CheWell treated Irritable bowel syndrome (IBS) patients, supporting a therepeutic effect in IBS.
- 05. Therapeutic claims from the phase 2 clinical trial and proven high bioavailability increases marketability.
- 06. International regulatory analysis being undertaken to identify what is required for commercial launch.
- 07. Potential to develop CheWell for treatment of pain and cannabis addiction.

Lead Assets



Bioavailability CheWell vs Chewingum



1) Analysis of CheWell shows an early onset and 10-fold higher CBD bioavailability than in a non-microencapsulated chewing gum.

Improved bioavailability means that even small doses of CBD within MCGTs could be highly effective even without a prescription from a doctor. That is, they would meet the TGA requirements for an OTC product.

Increased bioavailability also reduces cost of goods, which increases margins.

First marketing claim could be for IBS, however, could be suitable for a range of indications for which CBD may currently assist patients.

Cannabinoid Chewing Gums and chewable tablets for Treatment of Addiction

APIRx has multiple patents for cannabinoid based drug candidates designed for treatment of addiction to different drug classes.

Marijuana addiction

CheWell for Cannabis Dependence

APIRx has a patented CBD chewable tablet high-bioavailability that can be used in treatment of marijuana addiction.

- Cannabis dependence is predicted to be the fastest growing segment of drug dependence market.
- Preliminary data suggest a possible beneficial impact of CBD on mitigating the craving effect of cannabis; while a case report has shown positive outcomes for one patient treated with CBD during the withdrawal and relapse phase of cannabis dependence.
- Pre-IND with FDA is pending.

Smoking cessation

CanQuit – Nicotine Addiction

APIRx patented chewing gum that combines cannabinoids with reducing doses of nicotine.

- OTC product to be trialled for effectiveness against existing nicotine medicated chewing gums.
- A more-effective and cost effective cannabinoid + nicotine gum may disrupt the incumbent global nicotine gum market, which had sales of US\$ 5.2B in 2020.
- By combining nicotine and cannabinoids, patented APIRx product CanQuit is designed to better assist addicted smokers to quit smoking.

Opioid addiction

CanQuit O – Opioid Addiction

APIRx patented chewing gum that combines cannabinoids with opioid agonists and/or antagonists.

- A prescription product to combat the opioid addiction for which the annual market size in the United States alone is expected to reach US\$ 64B by 2028.
- The act of mastication (chewing) aids neuroprotection, has an analgesic and anti-anxiety effect, which should also assist to suppress opioid cravings.

Lead Assets



Opioid use disorder
addressable market

US\$ 64B*

Nicotine chewing
gum market sales of

US\$ 5.2B
in 2020**

MCGs for nicotine addiction
already accepted in the real world.

* Frost & Sullivan Market Report as commissioned by APIRx; and other publicly available information

** <https://www.imarcgroup.com/nicotine-gum-market>

MedChew™ Rx (CBD and THC) for Pain and Spasticity in Multiple Sclerosis (MS)

Problem

Up to 84% of people suffering from MS also experience spasticity, which causes involuntary muscle stiffness and spasms. Pain is also a common symptom in MS, with up to two-thirds of people with MS reporting pain in worldwide studies.

Solution

MedChew™ Rx is absorbed through the oral mucosal membrane and bypasses the liver, and first pass metabolism. No cannabinoid-based drug approved for pain management in MS or other pain producing conditions.

Patents

- 1) Granted: Chewing gum comprising cannabinoids.
- 2) Granted: Process to extract and purify delta-9-THC.

Competitive Advantage

MedChew™ Rx contains the same constituents as Sativex, however provides extended dosing, reducing the need to readminister, which for Sativex is up to 12 times per day, MedChew™ Rx does not contain alcohol, which Sativex does, and will not exacerbate the dry mouth that is offer associated by MS pharmacotherapy.

Sativex (nabiximols, THC+CBD)

- Approved for use in Europe and Canada.
- Oromucosal spray approved in multiple jurisdictions in Europe and Canada (not U.S. currently) for treatment of spasticity associated with MS.
- Although it targets oral mucosa, it has recently been suggested that the drug is partially washed away by saliva and absorbed in the GI tract.
- Administered too frequently - up to 12 times per day.
- Alcohol in formulation exacerbates dry mouth symptoms associated with MS pharmacotherapy.

MedChew™ Rx (THC+CBD)

- MedChew™ Rx is absorbed in oral mucosa, bypassing first pass metabolism, increasing bioavailability.
- Increased bioavailability may also mean that MedChew™ Rx is effective at treating pain associated with MS, a claim that Sativex does not have in many regions.
- The MedChew™ Rx formulation has been developed and patented by APIRx.
- MedChew™ Rx provides extended dosing, reducing need to readminister frequently.
- MedChew™ Rx does not contain any alcohol.
- Pre-IND meetings completed with Swiss-Medic (Switzerland) and CBG-MEG (Netherlands).

Addressable Market

Lead Assets



US\$ 62B*

Associated Total Global Direct
Healthcare Costs in '21

50%

Increase in Global MS
Prevalence 2013 to 2020

* Frost & Sullivan Market Report as commissioned by APIRx, Oct. 2021

Next Steps:

- Step 1 - Potential fastrack to EMA drug approval with bioequivalent phase 1 bridging study* to bridge to Sativex CBD/THC oral spray safety and efficacy data.
- Step 2 - Additional late stage (phase 3 or 4) clinical trials to support extension of label claims to additional indications where THC+CBD is reported to have a therapeutic benefit.

*a bridging study is a study designed to demonstrate that an investigational product is sufficiently similar to an approved product and establish a bridge to data, safety and/or efficacy, that is already accepted by the regulatory authority for the approved drug product

MedChew™ Dronabinol

Nausea and Vomiting in Chemotherapy

Problem

According to the WHO, cancer is one of the leading causes for death. Chemotherapy is utilized by 10 million cancer patients each year. This number will grow by 53% by 2040. Nausea and vomiting are two of the most dreaded cancer treatment-related side effects.

Solution

MedChew™ Dronabinol treatment for Chemotherapy-related nausea and vomiting.

Clinical Trial Results

- 1) All subjects showed a release of dronabinol starting at 10 minutes, providing evidence of oro-mucosal absorption.
- 2) In most of the study’s subjects, the dronabinol Pharmacokinetic (PK) profile reflected a sustained released effect for four to eight hours after administration.
- 3) No serious side effects reported.

Competitive Advantage

- Product fully formulated.
- Completed IND with the FDA.
- Completed Pharmacokinetic (PK)/ Pharmacodynamic (PD) studies.

Dronabinol

- Approved for treatment of chemotherapy associated nausea and vomiting as well as anorexia associated with HIV/AIDS.
- Oral dronabinol is taken up slowly, 1-2.5 h to reach peak plasma concentration, and subject to first pass metabolism, which means that only 10-20% of the dose reaches the circulation.
- Global dronabinol market was US\$ 147.2M in 2020. CAGR of 4.5% during 2021-2026 leading to projected market of US\$ 191.9M by 2026.

MedChew™ Dronabinol

- Absorption through the oral mucosa bypasses first pass metabolism, increasing bioavailability.
- The formulation has been developed and is patented by APIRx.
- In a phase 1A study THC appears in circulation within 10 min and a sustained release profile was observed in most study subjects so that the product is more useful in the time in which it is required.
- IND open with FDA.

Addressable Market ^(a)

Lead Assets



US\$ 3.1B

Chemotherapy Induced Nausea and Vomiting Drugs (Global) by '24

7.5%

CAGR from 2018 – 2024

a) Brisk Insights, “Chemotherapy Induced Nausea And Vomiting Treatment Market, 2018-2026”, Sept. 8, 2021

Next Steps:

- Step 1 - Conduct Bioavailability/Bioequivalence clinical study to support application for approval by bridging to publicly available data on Marinol.
- Step 2 - Additional late stage (phase 3 and 4) clinical trials to support additional indications where THC is reported to have a therapeutic benefit.

CanChew Rx and SuppoCan for Inflammatory Bowel Disease

Problem

68 million people suffer from Inflammatory Bowel Disease globally. Signs and symptoms of both Crohn's disease and ulcerative colitis include diarrhea, fatigue, and abdominal pain and cramping, reduced appetite, and unintended weight loss. Heretofore, the main medications for IBD are anti-inflammatory medications and analgesics.

Solution

CanChew Rx (CBD-containing controlled-release, functional chewing gum) and Suppocan (CBD-containing suppositories) for treatment for IBD. Therefore, systemic as well as local delivery of cannabinoids is accomplished.

Competitive Advantage

- Combination therapy orally and suppository discussed and approved by the clinical investigators.
- Combination therapy not available.

Patents

- 1) Granted: Chewing gum comprising cannabinoids.
- 2) Granted: Suppositories comprising cannabinoids.

Efficacy / Results

- 1) CBD has shown efficacy in animal species treating IBD.
- 2) Ultimate formulation in combination with novel API which shows also positive effects on intestinal inflammation and gut barrier function.

Next Step:

- Commence phase 1 clinical trial.

Addressable Market

Lead Assets



US\$ 20B+*

Global market size in 2021

68M**

Prevalence in Global Population

* <https://www.grandviewresearch.com/industry-analysis/inflammatory-bowel-disease-ibd-treatment-market>

** Coherent Market Insights report, base year 2020



OraxiMax™ Periodontal Disease and Gingivitis (Toothpaste and Mouthwash)

Problem

Up to 50% of adults suffer from moderate to severe periodontitis and/or gingivitis. Heretofore, periodontal disease treatment has been limited to professional dental cleaning and the use of systemic antibiotics.

Solution

OraxiMax Toothpaste and Mouthwash, backed by fully granted IP protection, provides for disruption of dental plaque formation, therefore preventing gingivitis and periodontitis. Due to its proprietary formulation the local availability of APIs are increased while systemic absorption is kept to minimum.

Competitive Advantage

Currently no approved similar products on the market. Clinical Stage CE/510(k). Bioavailability data completed and very encouraging.

To be registered as a medical device (shorter approval pathway).

Patents

Granted: Oral care compositions comprising cannabinoids (CBD) and Cannabigerol (CBG).

Efficacy / Results

- 1) CBD / Cannabigerol (CBG) proven effective in reducing bacterial load in dental plaque.
- 2) CBG effective against multi-drug-resistant flora, e.g. MRSA.
- 3) Due to its proprietary formulation the Cannabinoid APIs are increased locally while systemic absorption is kept to a minimum.
- 4.) The Toothpaste and Mouthwash shows a Log CFU reduction of 1,11 resp. 0,29 in comparison with 0,07 of the placebo.

Benefits of CBD include:

- Reduces inflammation that can lead to gum diseases.
- Attacks bacteria associated with tooth decay.
- Fights bad breath.
- Relieves sensitivity.
- Reduces risk of cavities.
- Encourages tooth remineralizing.
- Restores pH balance.

Addressable Market ^(a)

Lead Assets



US\$ 42B

Associated Total Direct
Healthcare Costs
(U.S., Europe) in '21

46%

Prevalence in U.S. of
Adult Population

a) Frost & Sullivan Market Report as commissioned by APIRx, Oct. 2021

Next Steps:

- Coordination of phase 2 clinical trial followed by commercial preparations for product launch.

Topical cannabinoid development

Problem

Hundreds of millions of people suffer with skin diseases that involve inflammation and/or microbial infection.

Solution

APIRx has developed and patented a combination of CBD and CBG, a minor cannabinoid that also has potent anti-inflammatory activity, in a topical formulation.

Combines anti-inflammatory activity with antimicrobial activity of CBD/CBG to treat skin diseases.

Competitive Advantage

There are no topical cannabinoid products that currently have regulatory approval for any condition.

Results

APIRx has formulated a topical CBD/CBG product and completed in-human proof of concept studies in three different skin diseases.

Proof of concept clinical data with dosing for 6 weeks

Vitiligo 10% improvement	Psoriasis up to 33% improvement	Atopic dermatitis up to 22% improvement	Drug product was well tolerated
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Patents pending for compositions and methods of use for treatment of each of the three indications.

Next Steps:

- Pre-IND meeting with FDA.

Addressable Market ^(a) Lead Assets



Vitiligo
US\$ 1.2B¹

Psoriasis
US\$ 26.4B²

Atopic dermatitis
US\$ 11.8B³

→ Associated Total Direct Healthcare Costs (U.S.) of Skin Disease in '21

a) Frost & Sullivan Market Report as commissioned by APIRx, Oct. 2021

Ophthalmic conditions

Problem

Hundres of millions of people suffer from eye diseases and disorders where inflammation is a contributing factor.

Available treatments have inadequate response for many patients and often have unwanted side effects.

Solution

- APIRx has two granted patents for ophthalmic formulations of cannabinoids.
- Anecdotal evidence to support therapeutic benefit for cannabis and cannabinoids in treatment of ophthalmic conditions including:
 - Glaucoma
 - Conjunctivitis
 - Age related macular degeneration
 - Dry eye syndrome
- Proposed therapeutic effect is derived from the neuroprotective, anti-inflammatory and anti-microbial activities of cannabinoids.

Competitive Advantage

There are no approved ophthalmic cannabinoid formulations for any indication.

Next Step:

- Phase 1 - Safety and proof of concept clinical trials.

1) [https://www.researchandmarkets.com/reports/5441857/glaucoma-therapeutics-market-global-industry?utm_source=BW&utm_medium=PressRelease&utm_code=b2jfrg&utm_campaign=1608079+-+Global+Glaucoma+Therapeutics+Market+\(2021+to+2026\)+-+Industry+Trends%2c+Share%2c+Size%2c+Growth%2c+Opportunity+and+Forecasts&utm_exec=jamu273prd](https://www.researchandmarkets.com/reports/5441857/glaucoma-therapeutics-market-global-industry?utm_source=BW&utm_medium=PressRelease&utm_code=b2jfrg&utm_campaign=1608079+-+Global+Glaucoma+Therapeutics+Market+(2021+to+2026)+-+Industry+Trends%2c+Share%2c+Size%2c+Growth%2c+Opportunity+and+Forecasts&utm_exec=jamu273prd)
2) <https://www.fortunebusinessinsights.com/conjunctivitis-treatment-market-103488#:~:text=The%20global%20>
3) <https://www.verifiedmarketresearch.com/product/macular-degeneration-treatment-market/ conjunctivitis%20treatment%20market,inner%20surface%20of%20the%20eyelid>
4) <https://www.fortunebusinessinsights.com/dry-eye-syndrome-market-102413>

Addressable Market ^(a)

Lead Assets
●●●●●●●●

Glaucoma **US\$ 6.8B¹** in 2020

Conjunctivitis **US\$ 3.9B²** in 2019

AMD **US\$ 7.5B³** in 2020

Dry eye **US\$ 5.2B⁴** in 2019

Total **US\$ 23.4B**

a) Frost & Sullivan Market Report as commissioned by APIRx, Oct. 2021

APIRx cannabinoid extraction Intellectual Property

Proprietary “Ultrapure” extraction methods have the potential to markedly reduce the cost pharmaceutical (cGMP) grade CBD, THC and Cannabigerol (CBG) to reduce the cost of goods for all Incannex products and to ensure that OTC products are price competitive.

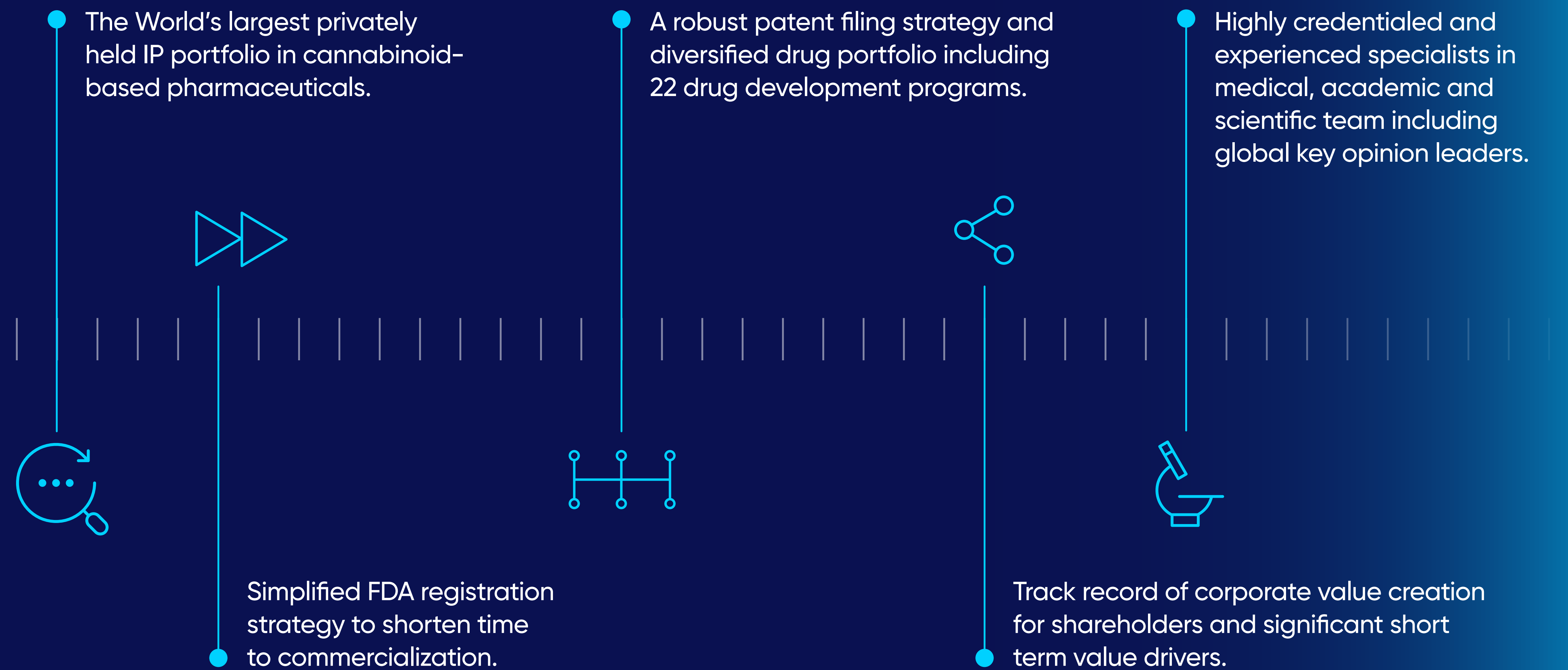
Microencapsulation improves water solubility, which improves bioavailability and increases formulation options – addressing challenges around hydrophobicity of cannabinoids.

Cannabinoid sugar alcohol patent provides unique possibilities for drug delivery.

Potential for out licensing of all technologies.



APIRx Competitive Advantage



Short term priorities and value drivers

Program	Value driver	Next steps
CheWell for treatment of IBS	– OTC product for Australia with potential to extend to global markets	– Meeting with TGA to discuss clinical data requirements for CheWell™ to become an OTC CBD product in Australia
CanQuit (addiction products)	– Step change on established market for use of chewing gum for treatment of addiction	– Pre-IND meeting with FDA and clinical trial preparations
MedChew™ Rx	– Fast path to market by bridging to Sativex regulatory data	– Regulatory approval application following bridging clinical trial
MedChew™ Dronabinol	– Fast path to market by bridging to Dronabinol regulatory data	– Regulatory approval application following bridging clinical trial
CanChew Rx/SuppoCan for treatment of IBD	– Unique route of delivery for treatment of gastrointestinal disorders	– Phase 1 clinical trial to understand bioavailability of CBD suppository
Oraximax for treatment of periodontal disease and gingivitis	– Fast path to market due to regulation of mouthwash products as a “medical device”	– Phase 2 clinical trial to support efficacy and potentially product registration
Topical CBD formulation	– Patented formulation with proof of concept clinical trial data – No approved cannabinoid products with a similar delivery route	– Pre-IND meeting with FDA
Opthalmic formulation	– Patented formulation – No approved cannabinoid products with a similar delivery route	– Phase 1 and proof of concept clinical trials
IHL-42X for treatment of obstructive sleep apnoea	– Patented drug product that treats a condition for which there are no approved pharmacotherapies – Proof on concept clinical trial supports safety and efficacy of IHL-42X	– Pre-IND meeting and multisite, international pivotal phase 2 clinical trial
IHL-675A for treatment of rheumatoid arthritis	– Patented drug product that provides evidence-based cannabinoid product to rheumatoid arthritis market	– Completion of Phase 1 clinical trial to confirm safety of the drug product and planning for Phase 2 clinical trial to demonstrate efficacy in rheumatoid arthritis
IHL-675A for treatment of inflammatory bowel disease (IBD)	– Patented drug product that provides evidence-based cannabinoid product to IBD market	– Completion of Phase 1 clinical trial to confirm safety of the drug product and planning for Phase 2 clinical trial to demonstrate efficacy in IBD
IHL-675A for treatment of lung inflammation	– Patented drug product that provides evidence-based cannabinoid product to lung inflammation market	– Completion of Phase 1 clinical trial to confirm safety of the drug product and planning for Phase 2 clinical trial to demonstrate efficacy in lung inflammation
IHL-216A for treatment of traumatic brain injury	– Patented drug product for treatment of a condition for which there are no approved pharmacotherapies	– Pre-IND meeting with FDA and clinical trial preparations
Psilocybin assisted psychotherapy for treatment of generalized anxiety disorder	– Combination of a unique psychotherapy with psilocybin to address underlying cause of disorder and build new mental connections reduce disease severity	– Completion of Phase 2 clinical trial at Monash University

Development of IHL’s six current programs will continue as previously described. Progress will not be disrupted by proposed acquisition.

Opportunity

APIRx has a collection of patents, formulations, clinical trial data and regulatory filings for cannabinoid medicines that provide direct and faster paths to drug product approval.

Patients will benefit from earlier access to evidence-based cannabinoid therapies across therapeutic areas that employ APIRx patented technologies for active pharmaceutical ingredient extraction and modification, formulation and methods of use.

Shareholders will benefit from a shorter time to commercialisation of drug products targeting major addressable markets globally.

APIRx development projects complement IHL's established strategy and fill unique niches the Company's cannabinoid drug development portfolio.

The total addressable market for the treatment of these unmet medical needs is **US\$ 400B, annually.**

Credible market opportunities within an extensive development pipeline.

- Nausea and Vomiting in Chemotherapy
- Vitiligo
- Psoriasis
- Atopic Dermatitis
- Addiction (opioid, nicotine and marijuana)
- Neurodegenerative Disorders (RLS, Postherpetic Neuralgia)
- Pain & Spasticity
- Adolescent Drug Addiction
- Periodontal Disease and Gingivitis
- Irritable Bowel Syndrome
- Inflammatory Bowel Disease
- Glaucoma
- Dry Eye Syndrome



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