NEXIEN BIOPHARMA INC

The Future of Cannabinoid Biotechnology

Investor Presentation

March 2019

OTCQB: NXEN

FORWARD LOOKING STATEMENTS

This presentation contains "forward-looking statements" as that term is defined in the Private Securities Litigation Reform Act of 1995. For this purpose, any statements contained herein or which are otherwise made by or on behalf of the Company that are not statements of historical facts may be deemed forward-looking statements. Without limiting the generality of the foregoing, words such as "may," "will," "to," "plan," "expect," "believe," "anticipate," "intend," "could," "should," "would," "estimate," or "continue," or the negative or other variations thereof or comparable terminology are intended to identify forward-looking statements. Readers are cautioned that all forward-looking statements involve risk and uncertainties which may cause results to differ materially from those set forth in the statements. Such risks and uncertainties include, but are not limited to the following: the success of research and development activities and the speed with which regulatory authorizations and product launches may be achieved; government regulation generally; competitive developments; the ability to successfully market products domestically and internationally; difficulties or delays in manufacturing or issues relating to manufacturing capacity; commercial obstacles to the successful introduction of brand products generally; legal defense costs, insurance expenses, settlement costs, and the risk of an adverse decision or settlement relating to product liability, patent protection, governmental investigations, and other legal proceedings; the Company's ability to acquire and protect patents and other intellectual property both domestically and internationally; the absence of certainty regarding the receipt of required regulatory approval or the timing, costs, or terms of such approvals; any changes in business, political and economic conditions; business interruption due to hurricanes or other events outside of the Company's control; and the Company's access to and receipt of sufficient capital to be able to pursue its business and business objectives. Readers are cautioned not to place reliance on these forward-looking statements, which are valid only as of the date they were made. The Company undertakes no obligation to update or revise any forward-looking statements to reflect new information or the occurrence of unanticipated events or otherwise, except as expressly required by law.

MISSION AND VISION

MISSION

To develop and commercialize the next generation cannabinoid pharmaceuticals, drug delivery systems, and related technologies.

VISION

In accordance with domestic and international federal regulatory and approval pathways, Nexien is pioneering initial investigation of novel cannabinoid biotechnologies.

Nexien is a discovery, R&D, and innovation platform committed to providing patients with primary and adjunct therapies using advanced drug formulation and delivery modalities for a portfolio of targeted indications.

Nexien's formulations and delivery systems are designed to outperform existing standard of care therapies and existing cannabinoid pharmaceutical therapies.

WHO IS **NEXIEN BIOPHARMA**?

- We are a **next generation biopharmaceutical company** focused on research, development and commercialization of novel FDA-compliant **cannabinoid pharmaceuticals** and related **drug delivery systems.**
- We are utilizing cannabinoids as the Active Pharmaceutical Ingredients (APIs) to develop **synthetic** pharmaceuticals in **strict accordance with U.S. FDA** pre-clinical and clinical pathways.
- Our **flagship R&D programs** are advancing formulations that have the potential to significantly improve the treatment of certain **convulsive disorders** and **myotonic dystrophy**.
- Sponsored, **pre-clinical research collaboration** with a leading **Ivy League University Medical School** addressing convulsive disorders

Cannabinoid – *A cannabinoid is one of a class of diverse chemical compounds that acts on cannabinoid receptors in cells that alter neurotransmitter release in the brain. Ligands for these receptor proteins include the endocannabinoids (produced naturally in the body by animals), the phytocannabinoids (found in cannabis and some other plants), and synthetic cannabinoids (manufactured artificially). The most notable cannabinoid is the phytocannabinoid tetrahydrocannabinol (THC), the primary psychoactive compound in cannabis. Cannabidiol (CBD) is another major constituent of the plant. There are at least 113 different cannabinoids isolated from cannabis, exhibiting varied effects.*

THREE-PRONGED **GROWTH STRATEGY**

PATH ONE

Developing, licensing and commercializing cannabinoid based medications for specific medical conditions and disorders. Our drug development activities are undertaken in accordance with Food and Drug Administration (FDA) or comparable development pathways in other countries.

Our intent is that any medications we develop will be physician prescribed.

PATH TWO

The development and licensing of proprietary delivery systems for cannabinoid medications. In addition to the Company's precision parenteral formulations, the Company's advanced tablet technology provides for the accurate oral and sublingual dosing of cannabinoid API's for both human and veterinary applications.

PATH THREE

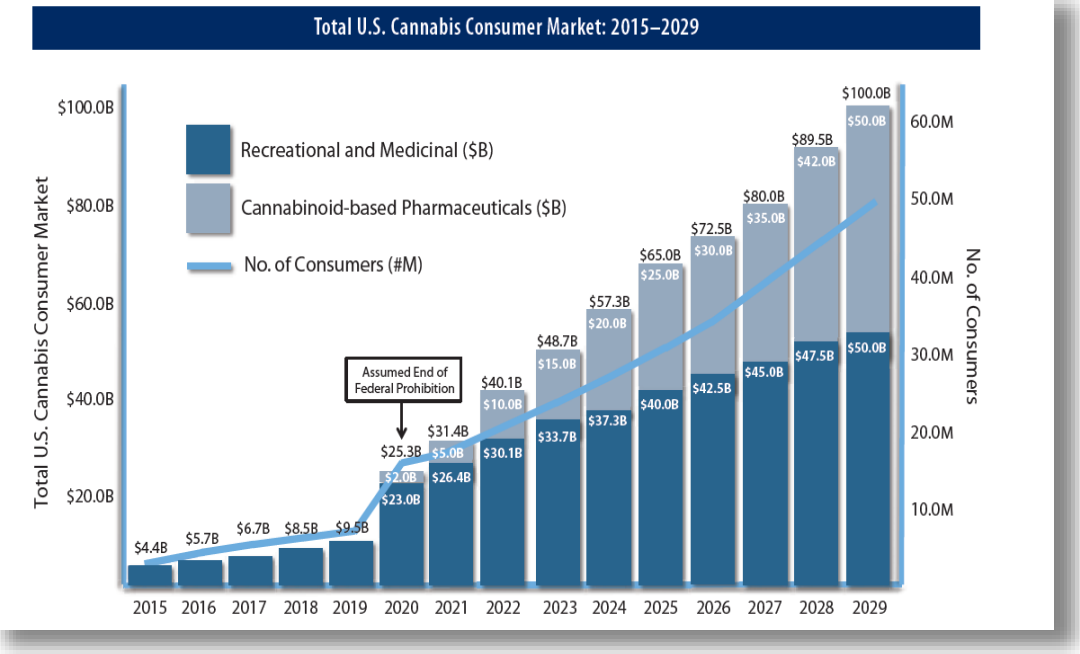
Investments in companies, and the acquisition of technologies, or medications, focused on cannabinoid-based research, through Special Purpose Vehicles (SPV) controlled by Nexien BioPharma Inc.

INVESTMENT HIGHLIGHTS

- **Significant Greenfield Opportunity in the Cannabinoid Pharmaceutical Space**
- **Experienced Management Team with Proven Industry Track Record**
- **Advancing Novel Drug Formulations with Differentiated Therapeutic Benefits**
  (Compared to Existing FDA-Approved Cannabinoid Pharmaceuticals)
- **Flagship R&D Programs with Multiple Potential Catalysts over the Next 1-2 Years**
- **Opportunity to Sub-License Delivery Technology for Cannabinoid-Based Applications**

A SIGNIFICANT OPPORTUNITY IN **GREENFIELD PHARMACEUTICAL CLASS: CANNABINOIDS**

Cannabinoid pharmaceuticals will be as large as recreational and medicinal market within 15 years



*Source: Ackrell Capital, LLC

Medical Marijuana:

- Federally illegal (DEA Sch. 1)
- State medical markets gravitate toward adult use markets
- QA/QC Issues
- Regulatory challenges

Rx Cannabinoid Pharmaceuticals:

- Federally legal
- Robust QA/QC
- Globally scalable
- FDA regulated

Nexien's Focus Area

FDA's Response to December 2018 Enactment of the Farm Bill, which Legalizes Hemp Production and Cultivation:
"Congress explicitly preserved the agency's current authority to regulate products containing cannabis or cannabis-derived compounds... the FDA requires a cannabis product (hemp-derived or otherwise) that is marketed with a claim of therapeutic benefit, or with any other disease claim, to be approved by the FDA for its intended use before it may be introduced into interstate commerce... the FDA will continue to take steps to make the pathways for the lawful marketing of these products more efficient."

NEXIEN'S R&D ARCHITECTURE

- The determination of medical conditions and disorders that could prospectively benefit from cannabinoid-based formulations
- Conducting 'freedom to operate' investigations on these conditions
- The preparation of patent applications and the pursuit of such applications and/or the licensing of existing patents and technologies
- Identifying regulatory pathways with the FDA
- Proceeding with pre-clinical and clinical development activities in accordance with FDA protocols for submission to obtain approval for branded drug product(s)

Nexien initially is targeting the development of drugs that qualify for orphan drug designation under the Orphan Drug Act of 1983

NEXIEN'S DISTINCT TECHNOLOGY ADVANTAGES

Fast Acting Parenteral Formulation Technology: The first non-hospital, non-psychoactive, and non-habit forming cannabinoid auto-injection rescue treatment for the Company's target indications.

Sustained Release Parenteral Formulation Technology: A non-psychoactive, non-habit forming, clinically administered slow release intramuscular cannabinoid depot formulation to help manage and reduce symptoms.

Advanced Sublingual Formulation Technology: A non-psychoactive, non-habit forming, self administered advanced sublingual cannabinoid formulation to help manage and reduce symptoms during long term treatment.

SUMMARY OF **DRUG DEVELOPMENT PIPELINE:** FLAGSHIP PROGRAMS

Therapeutic Areas	Patent Identifiers	Formulation Identifiers
Convulsive Disorders	**NXEN01**	**NX01R1, NX02R2, NX01L1, NX01L2, NX04S1, NX04S2**
Myotonic Dystrophy	**NXEN04**	**NX04S1, NX04S2**
Organophosphate/Carbamate Toxicity	NXEN08	2019 TBD
Pain Disorders	NXEN03	NX01R1, NX02R2, NX01L1, NX01L2, NX04S1, NX04S2
Chronic Traumatic Encephalopathy	NXEN02	NX01R1, NX02R2, NX01L1, NX01L2, NX04S1, NX04S2

Flagship development programs

Nexien has a total of 8 patents for 8 targeted indications.

CONVULSIVE DISORDERS: EPILEPSY & REFRACTORY EPILEPSY
INDICATION OVERVIEW

DEFINITIONS

Epilepsy & Refractory Epilepsy

Epilepsy: A neurological disorder marked by sudden recurrent episodes of sensory disturbance, loss of consciousness, or convulsions, associated with abnormal electrical activity in the brain. Epilepsy is caused by an imbalance in inhibitory and excitatory neurotransmission resulting in synchronous neural activity.

Refractory Epilepsy: Refractory epilepsy occurs when standard of care medicine isn't bringing seizures under control. The condition may be called by some other names, such as uncontrolled, intractable, or drug-resistant epilepsy. It is not age specific. Up to 1 of every 3 epilepsy patients will develop what is considered refractory epilepsy.

Epilepsy Neuropathology

Often associated with:

- Birth asphyxia
- Perinatal brain damage
- Hydrocephalus
- Autosomal disorder
- Benign tumors in the CNS
- Intracranial tumors
- Vascular malformations
- Various infections, and head trauma among others

CONVULSIVE DISORDERS: EPILEPSY & REFRACTORY EPILEPSY
MARKET OVERVIEW

3.4 million

People with epilepsy (US)

In 2015, 1.2% of the US Population had active epilepsy (95% CI* = 1.1-1.4)

50 million

People are affected by epilepsy worldwide

30-40%

Of patients with epileptic seizures fail to respond to antiepileptic drugs

World Health Organization (WHO)"Epilepsy". WHO Factsheet, October 2012: number 999. (2014).

Laxer, K. D., Trinka, E., Hirsch, L. J., Cendes, F., Langfitt, J., Delanty, N., . . . Benbadis, S. R. (2014). The consequences of refractory epilepsy and its treatment. Epilepsy & Behavior,37, 59-70. doi:10.1016/j.yebeh.2014.05.031

CONVULSIVE DISORDERS: EPILEPSY & REFRACTORY EPILEPSY
TREATMENT MARKET

Epilepsy

Refractory Epilepsy

COST OF TREATMENT

Treatment costs specific to epilepsy per patient:

Up to → $19,749/year

Total costs per patient (all sub-groups):

Up to → $47,862/year

Begley, C. E. and Durgin, T. L. (2015), The direct cost of epilepsy in the United States: A systematic review of estimates. Epilepsia, 56: 1376-1387. doi:10.1111/epi.13084

August 10, 2018 | Source: Zion Market Research

Problem

Lack of FDA-approved treatment options for refractory epilepsy with rapid intervention capability.

Existing Cannabinoid pharmaceutical treatment options can take up to 2-3 months for efficacy and symptom relief.

Epidiolex®, expected to be the first cannabidiol "on-rescue" treatment for epilepsy has an oral-mucosal route of administration w/ only 6% bioavailability

Patients and care-givers are often seeking cannabidiol via federally illegal sources, with questionable quality control

Nexien's Solution

Refractory epilepsy is poorly treated by existing stand of care. Existing standard of care promotes unwanted side effects and physiological addiction potential.

Pharmaceutical-grade cannabinoid matrix can be adapted to advanced formulation techniques (i.e. nano, sterile, IM parenteral), allowing for optimized Cmax of Cannabinoids far more rapidly than oral administration.

An auto-injected intramuscular, combination, fast-release cannabinoid matrix and slow-release cannabinoid matrix with true "rescue" potential against refractory epilepsy and up to 100% bioavailability

Nexien's formulations will be produced in a full US-GMP-certified, DEA-licensed formulation facility with all necessary pre-clinical animal toxicity, IND-enabling, and early first-In-human clinical studies completed pursuant to US-GCP and ICH guidelines

Benefit

Patient Quality of Life

Pk/Pd Optimization

Bioavailability

Regulatory/Quality Control

CONVULSIVE DISORDERS: EPILEPSY & REFRACTORY EPILEPSY
NEXIEN'S DISTINCT OPPORTUNITY

Current standard of care poorly treats our target indications

+

GWPH's research and approval of Epidiolex® increases greenfield outlook for additional FDA approval of cannabinoid therapies

+

Nexien solves intrinsic limitations of oral and oral-mucosal cannabinoid delivery modalities

CONVULSIVE DISORDERS: EPILEPSY & REFRACTORY EPILEPSY
NEXIEN'S 2019 PRE-CLINICAL RESEARCH OBJECTIVES

Sponsored Research Collaboration with a Leading Ivy League University Medical School

Study Design: Two Parts

- **Part (1)** – Maximum Tolerated Dose and PK/PD method development and sample analysis in mice plasma and brain tissue
- **Part (2)** – Efficacy studies in transgenic mice

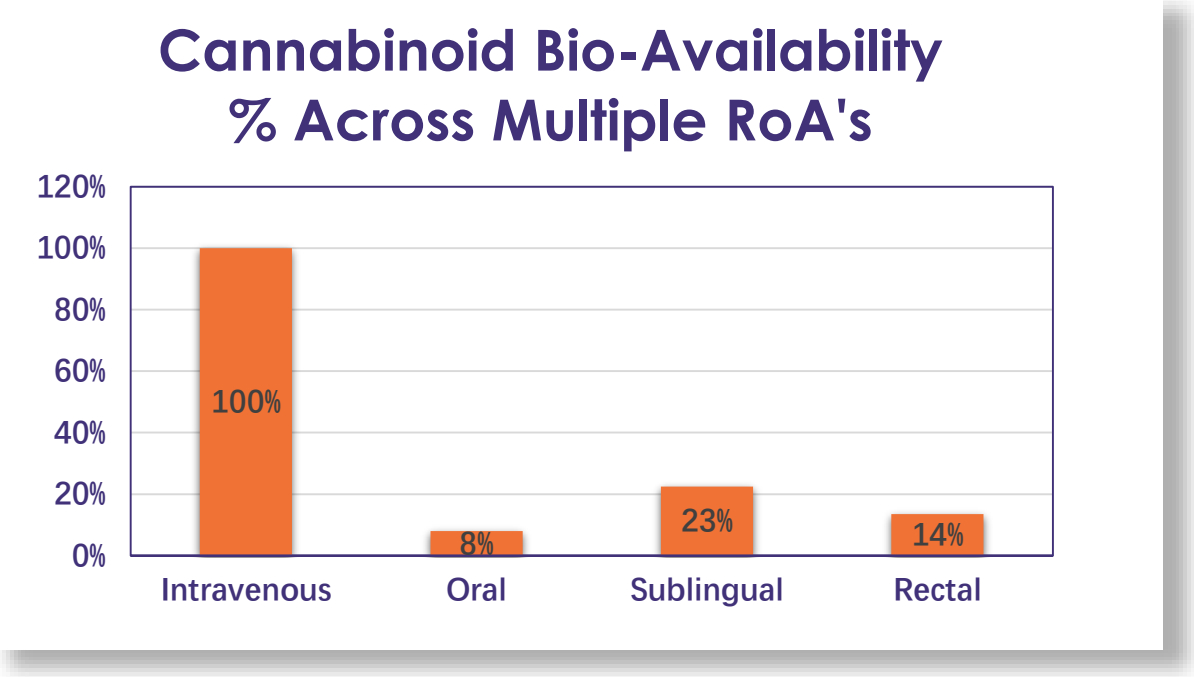
Research Objectives: Pre-Clinical Proof-of-Concept

- **Phase I** – Determine Pharmacology parameters Pk/Pd & MTD to show fast accrual of plasma and tissue concentrations
- **Phase 2** - Efficacy in transgenic mice model to investigate prophylactic and potentially rescue, of a recurring, spontaneous seizure event and to prevent recurrence after convulsive events

CONVULSIVE DISORDERS: EPILEPSY & REFRACTORY EPILEPSY
BIOAVAILABILITY COMPETITIVE ADVANTAGES

Parenteral vs. Non-Parenteral Bio-Availability Comparison

Intravenous (as a model for injected parenteral RoA) bio-availability of cannabinoids vastly outweighs that of other routes of administration



1. Huestis MA. Human cannabinoid pharmacokinetics. Chem Biodivers. 2007;4(8):1770-804.
2. D'Souza DC, Cortes-briones JA, Ranganathan M, et al. Rapid Changes in CB1 Receptor Availability in Cannabis Dependent Males after Abstinence from Cannabis. Biol Psychiatry Cogn Neurosci Neuroimaging. 2016;1(1):60-67.

MYOTONIC DYSTROPHY
INDICATION OVERVIEW

DEFINITIONS

MYOTONIC DYSTROPHY (DM)

Myotonic Dystrophy: Myotonic dystrophy is part of a group of inherited disorders called muscular dystrophies. It is the most common form of muscular dystrophy that begins in adulthood.

Myotonic dystrophy is characterized by progressive muscle wasting and weakness. People with this disorder often have prolonged muscle contractions (myotonia) and are not able to relax certain muscles after use. For example, a person may have difficulty releasing their grip on a doorknob or handle. Also, affected people may have slurred speech or temporary locking of their jaw.

TYPE 1 – TYPE 2

Signs and symptoms overlap, although type 2 tends to be milder than type 1. The muscle weakness associated with type 1 particularly affects the lower legs, hands, neck, and face. Muscle weakness in type 2 primarily involves the muscles of the neck, shoulders, elbows, and hips. The two types of myotonic dystrophy are caused by mutations in different genes.

MYOTONIC DYSTROPHY
2019 RESEARCH OBJECTIVES

Completion of Internal POC Investigation

Primary Endpoint:

- Reduction of myotonia by 1 point on the Myotonic Behavior Scale (MBS) after 12 weeks

Secondary Endpoint(s)- Including, but not limited to:

- The stiffness diary: all subjects shall fill in a 12 week diary of myotonia self-assessment by MBS
- Change from baseline in presence and activity of cannabinoids in video recordings of the hand-opening time
- Creatine kinase levels
- Use of any type of escape medication for myotonia

Phase I Human Trials

2019 Objectives:

- To complete pre-IND meeting with FDA
- Prepare for IND application with FDA
- Phase I human trials using Nexien's sublingual drug formulations

Nexien's Advantage

Sublingual Formulation Technology Development:
Non-psychoactive, non-habit forming, self administered advanced sublingual synthetic cannabinoid formulations to help manage and reduce the symptoms of myotonic dystrophy and myotonia.

MYOTONIC DYSTROPHY
MARKET OVERVIEW

1 in 8,000

Affected worldwide

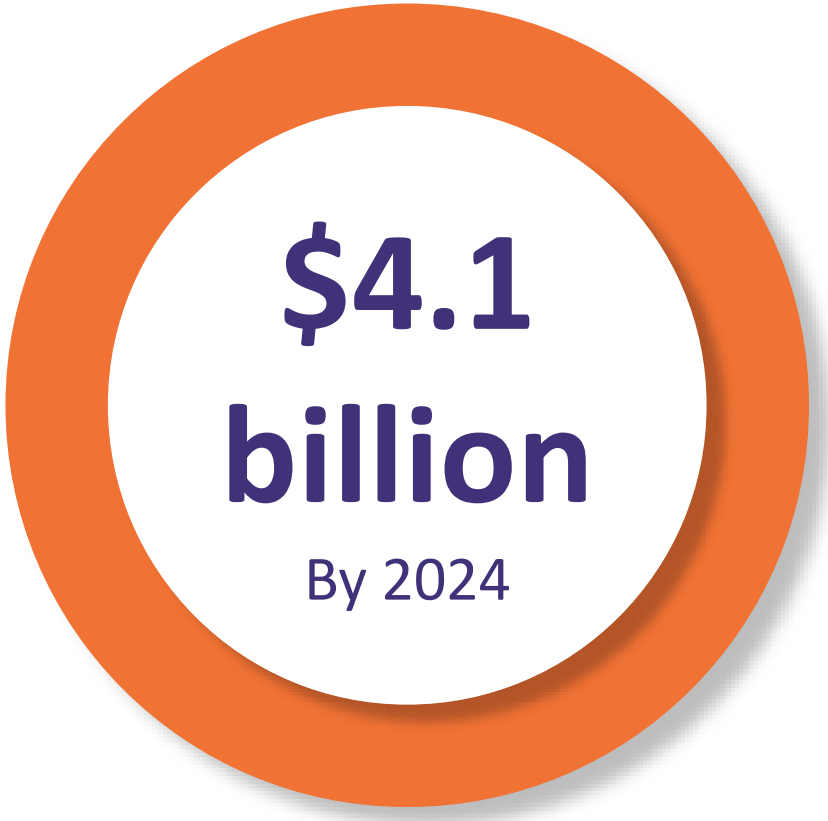
39.5 in 100,000

Affected by DM1 alone in the United States

U.S. Projected to Dominate DM Drug Market

Romitti PA, Zhu Y, Puzhankara S, James KA, Nabukera SK, Zamba GK, Ciafaloni E, Cunniff C, Druschel CM, Mathews KD, Matthews DJ, Meaney FJ, Andrews JG, Conway KM, Fox DJ, Street N, Adams MM, Bolen J; MD STARnet. Prevalence of Duchenne and Becker muscular dystrophies in the United States. Pediatrics. 2015 Mar;135(3):513-21.

MYOTONIC DYSTROPHY
TREATMENT MARKET



Muscular Dystrophy (DMD and DM)

COST OF TREATMENT

Total costs per patient (US), (DM, types 1 and 2):

$32,236/year

Population-wide national costs (US):

$448 million/year

Larkindale, J. , Yang, W. , Hogan, P. F., Simon, C. J., Zhang, Y. , Jain, A. , Habeeb-Louks, E. M., Kennedy, A. and Cwik, V. A. (2014), Cost of illness for neuromuscular diseases in the United States. Muscle Nerve, 49: 431-438. doi:10.1002/mus.23942

MYOTONIC DYSTROPHY
INTERNAL PROOF OF CONCEPT INVESTIGATION

Nexien's Internal Proof of Concept Patient Investigation with World Renowned Myotonic Dystrophy Physician.

Design – Four (4) week, open-label individual treatment assessment in myotonic dystrophy using clinical surrogate markers a) Muscular Impairment Rating Scale (MIRS) Mathieu et al., 2001 b) The Myotonia Behaviour Scale (MBS) (Hammere et al. 2005)

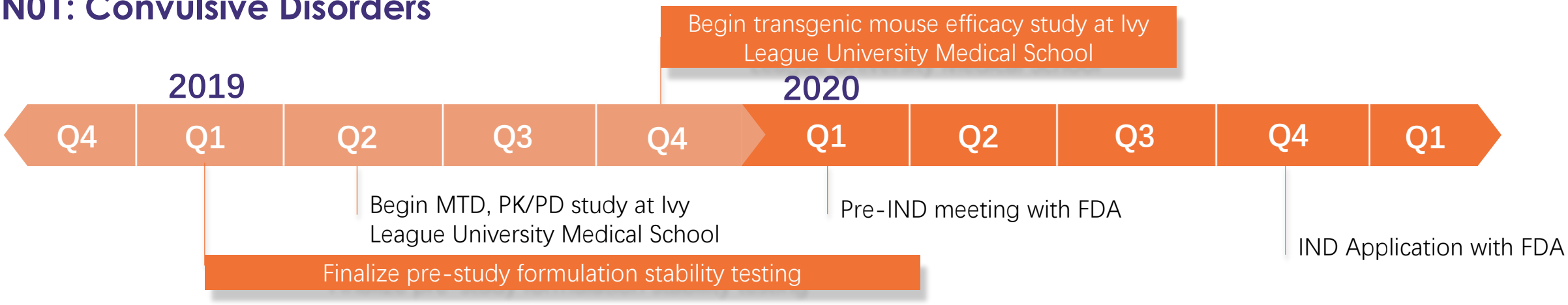
Sample size - Six (6) patients treated, three (3) male and three (3) female

Encouraging results of clinical observations of patient groups consisting of patients suffering from non-dystrophic myotonia and myotonic dystrophies (DM) type 1 and 2, indicating that specific cannabinoid formulations are supportive in relief of myotonia and DM symptoms.

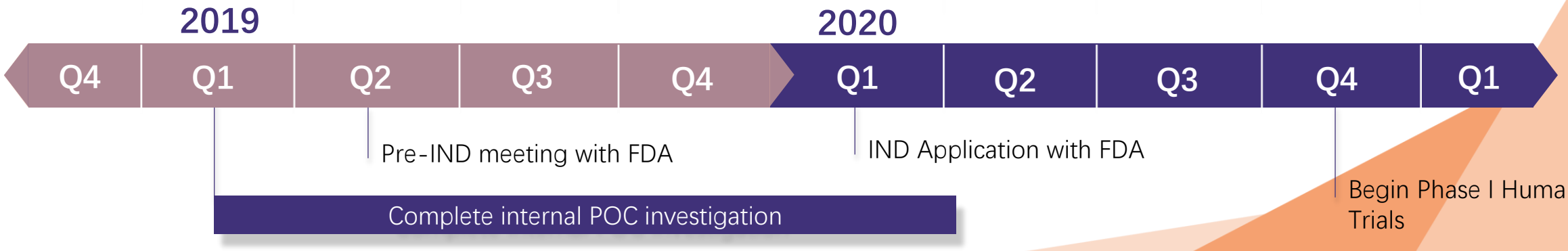
Nexien intends to proceed with related clinical studies in accordance with U.S. Food and Drug Administration (FDA) protocols, commencing with the filing of a Pre-IND meeting request.

SUMMARY OF MILESTONES FOR FLAGSHIP PROGRAMS
CATALYSTS ON THE HORIZON

NXEN01: Convulsive Disorders



NXEN04: Myotonic Dystrophy



EARLY SUB-LICENSING REVENUE OPPORTUNITIES
EXCLUSIVE ACCU-BREAK LICENSE

Exclusive License

- Nexien has an exclusive license from Accu-Break for the use of Accu-Break technology including at least one cannabinoid, for use in humans and animals.

Nexien's Advantage

- Proprietary drug delivery technology for cannabinoid-based treatment for humans and animals
- Dosing Flexibility: Accubreak allows for dosing of humans and animals at a "wider-than-normal" dose range to effectively dose human and animal subjects across the entire normal distribution of weight and body mass - St. Bernard vs. a Chihuhua or 120lb female vs. 240lb male
- **Early revenue opportunity: sub-licensing Accu-Break technology**

Top Layer contains drug formulation

Bottom Layer contains no formulation

Tablets can have

- ✓ Different shapes
- ✓ Different scoring patterns
- ✓ Different release profile (CR/XR/ER)
- ✓ Chewable/flavored formulas
- ✓ Drug loading up to 800mg

MANAGEMENT TEAM AND SCIENTIFIC ADVISORY BOARD

Alex Wasyl, Chief Executive Officer
- CEO/Co-Founder, CRx Bio Holdings
- Managing Director, Elevated Life Sciences
- BS, The College of New Jersey

Frank J. Manganella, VP - Corporate Development
- Interim CFO/Managing Partner, CRx Bio Holdings
- Co Global Head of FICC, Handelsbanken Capital Markets
- Head of Emerging Markets Trading, Credit Suisse
- MBA from Durham University Business School in the UK

Robert I. Goldfarb, JD, Chief Operating Officer
- Senior Vice-President/General Counsel, Andrx Corporation
- President & General Counsel, Accu-Break Pharmaceuticals
- Partner, Hughes Hubbard & Reed
- BA, University of Connecticut; J.D., University of Florida

Joseph Aceto, JD, PhD, VP – Legal/IP Counsel; Director, Translational Research
- Counsel, Obermayer Rebmann Maxwelll and Hippel LLP
- General Counsel/Managing Partner, CRx Bio Holdings
- Board of Directors, Pennsylvania Drug Discovery Institute
- MS, Drexel; Ph.D, Lewis Katz School of Medicine Temple University; J.D., Widener U.

Evan Wasoff, CPA, Chief Financial Officer
- CFO, Falcon Oil & Gas Ltd
- Principal, AZCO Financial Mgmt. LLC
- CFO, Kantiva Inc.
- BS, State University of NY; MBA, University Of Colorado, Boulder

Scientific Advisory Board:

Robert McKean, PhD, Scientific Advisory Board
- VP & Senior Director, Teva Pharmaceuticals
- Scientific Advisory Board Member, CRx Bio Holdings
- Director, Rhone-Poulenc Rorer
- PhD, University of Massachusetts

Michael Fenn, PhD, Scientific Advisory Board
- Director, Healthcare and Life Sciences, Harvard Innovation Labs
- Director, Center for Medical Materials and Biophotonics
- Founder/Managing Director, SciCoLab Ventures
- BS and MS, University of Florida;
- Ph.D, J. Crayton Pruitt University of Florida

APPENDIX

PEER LANDSCAPE
CANNABINOID PHARMACEUTICAL COMPANIES

COMPANY	DESCRIPTION	DOSING	APPROVED	(2/28/19, $mm) MARKET CAP
abbvie	Marinol® synthetic THC compound for chemotherapy-induced nausea and vomiting (CINV)	Oral capsules	1985 (US)	**116,974**
GW pharmaceuticals	Epidiolex® natural, plant-based purified form of CBD for treatment of rare, severe pediatric epilepsies	Oral tincture	2018 (US)	**5,271**
	Sativex® natural, plant-based form of CBD and THC approved in 28 countries (excluding the United States) for patients with moderate to severe MS spasticity. Sativex® is a 1:1 combination of CBD and THC	Oral spray-sublingual	Not approved in US to date	
INSYS THERAPEUTICS, INC.	Second-line treatment for CINV and for anorexia associated with weight loss in patients with AIDS	Oral capsules	1992 (US)	**470**
MEDA PHARMACEUTICALS	Cesamet® synthetic cannabinoid approved by the FDA for use by patients with CINV	Oral capsules	1985 (US)	**n/a**
CURE PHARMACEUTICAL	A drug formulation and delivery technology company researching and developing drugs in the cannabinoid family of molecules	n/a	n/a	**102**
Zynerba® PHARMACEUTICALS	Focused on the development of transdermal pharmaceutically-produced cannabinoid treatments for rare and near-rare diseases/disorders	n/a	n/a	**91**
NEMUS BIOSCIENCE	A biopharmaceutical company focused on the discovery, development, and commercialization of cannabinoid-based therapeutics	n/a	n/a	**65**

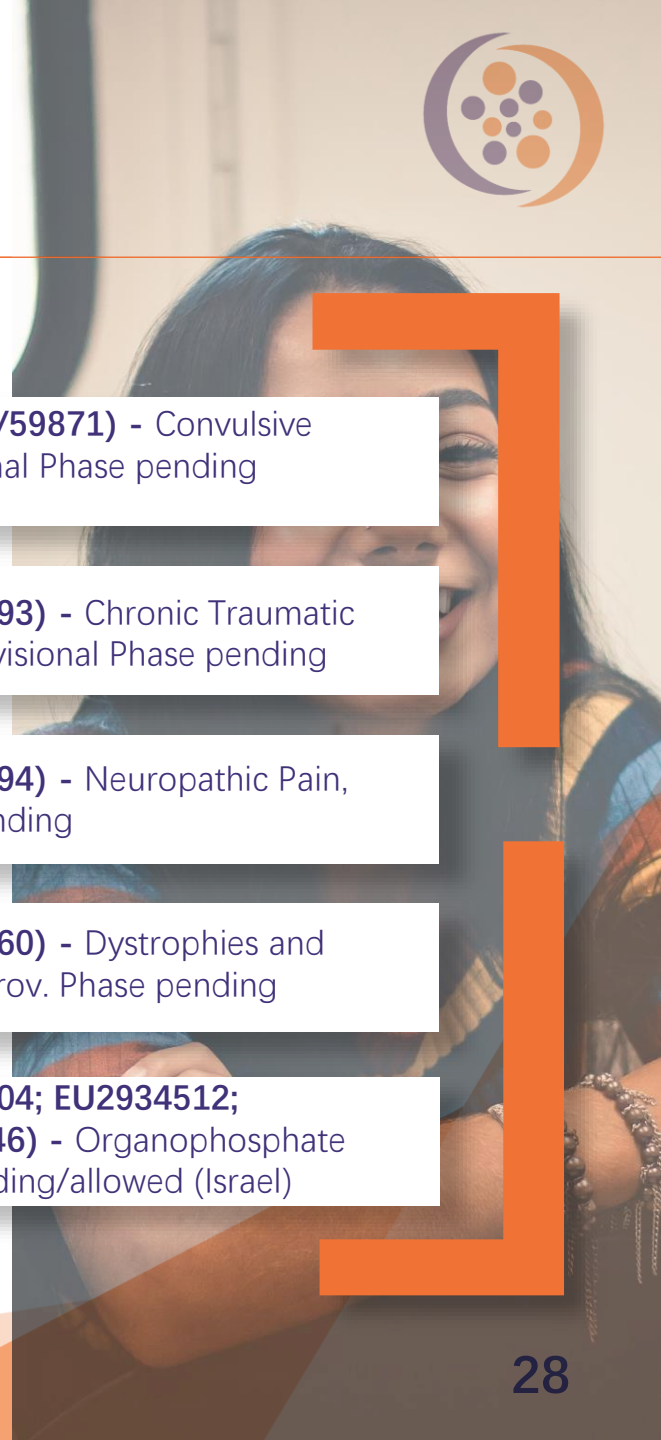
INTELLECTUAL PROPERTY SUMMARY: FLAGSHIP PROGRAMS

Intellectual Property Position:

Patent claims focus on the protection of therapeutic methods for the use of cannabinoid-based pharmaceuticals, their composition of matter, and medical delivery devices where applicable

IP protection in multiple countries and regions world-wide including major markets (US, Europe, Canada etc.)

Nexien has a total of 8 provisional patents (1 allowed in Israel) for 8 targeted indications.



NXEN01 (PCT/US18/59871) - Convulsive Disorders, International Phase pending

NXEN02 (US62617193) - Chronic Traumatic Encephalopathy. Provisional Phase pending

NXEN03 (US62638194) - Neuropathic Pain, Provisional Phase pending

NXEN04 (US15899160) - Dystrophies and Myotonia, US Non-Prov. Phase pending

NXEN08 (US16004004; EU2934512; CA2895805; IL238946) - Organophosphate Toxicity, Various pending/allowed (Israel)

PARENTERAL ROA OF CANNABINOIDS

Core Differentiation from Oral Administration: Parenteral Administration Advantages

Bio-availability:

- ✓ Oral formulations suffer from poor bio-availability (avg. ~<10%), first pass metabolism variability, and less controllable Pk/Pd

Favorable Economics:

- ✓ No wasted API due to bioavailability advantages
- ✓ Utilizing existing medical devices, i.e. autoinjectors, provides for favorable commercial economics

Precision:

- ✓ Advanced formulations and delivery systems for parenteral cannabinoid administration allow for scientific and medical precision (bio-availability, Pk/Pd, etc.)

Meeting Demand for Alternative and Adjunct Therapies:

- ✓ Cannabinoid therapeutics have received FDA approval for convulsive disorders
- ✓ There is a strong precedent for rapid intervention therapies using parenteral RoA, i.e. EvZio®, EpiPen®, Humalog ®, GlucaPen®

CONVULSIVE DISORDERS: EPILEPSY & REFRACTORY EPILEPSY
NEXIEN VS. CURRENT STANDARD OF CARE

Current Standard of Care: (Benzodiazepines)

PROS:
- Currently available to help manage generalized and refractory epilepsy patients

CONS:
- Diminishing efficacy due to GABA receptor down-regulation
- Very limited efficacy for refractory epilepsy
- Habit forming, addictive, potential for abuse

LEFT: Diazepam Oral (Chronic Administration)
MIDDLE: Diastat® (Rectal Administration)
RIGHT: Diaject® (IM/IV Administration)

CONVULSIVE DISORDERS: EPILEPSY & REFRACTORY EPILEPSY
NEW TREATMENT OPPORTUNITIES

New Treatment Opportunity: **(Cannabinoids)**

NX01R1, NX01R2
NX01L1, NX01L2

ADVANTAGES

- **Nexien's L Series Formulations:** Sustained release, non-psychoactive, and non-habit forming. Existing clinical efficacy for cannabidiol (GW Pharma Epidiolex®) is strong for these indications. **Offers 100% bio-availability** vs. 6-9% for Epidiolex ®

- **Nexien's R Series Formulations:** Can Provide the **first safe rescue** treatment for refractory epilepsy and generalized epilepsy without the concerns associated with BZDs

- Solution for chronic management patients and caregivers who are currently using non-pharmaceutical CBD formulations via federally illegal state-wide sources with serious quality control issues

TOP: Rapid release cannabinoid matrix solution (Rescue Administration)
BOTTOM: Sustained release cannabinoid matrix depot (Chronic Management)

CONVULSIVE DISORDERS: EPILEPSY & REFRACTORY EPILEPSY
PK/PD COMPETITIVE ADVANTAGES

Non-Parenteral Formulation References

Problem: Slow onset (peak plasma concentrations) and low relative bio-availability

FIGURE 1. GWPD9901: Mean Plasma Cannabinoid Concentrations Following Adminstration of CBD:THC, 1:1 Sublingual Drops

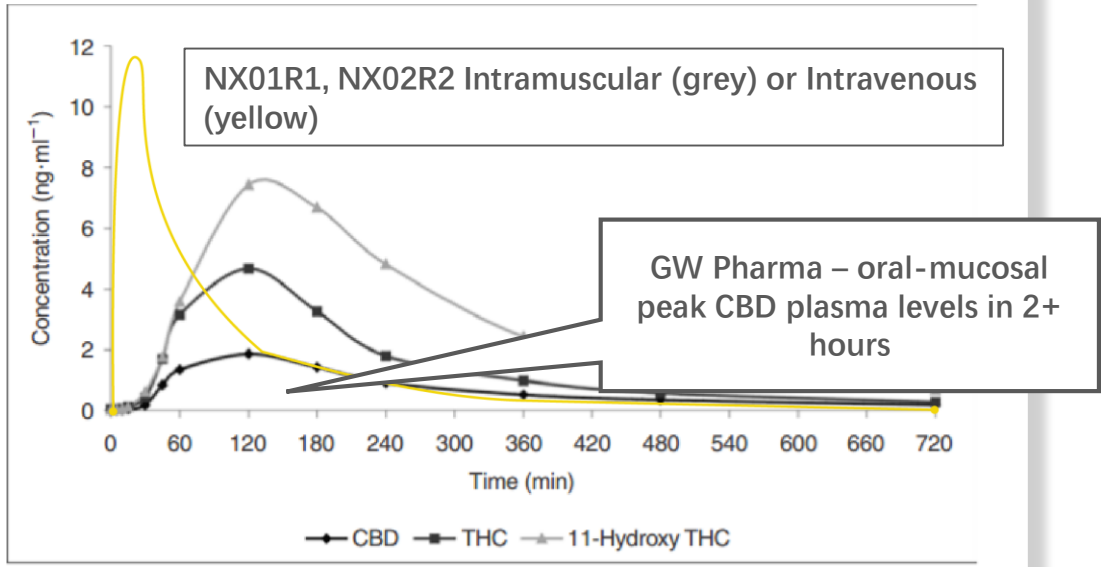


TABLE 6. Mean Pharmacokinetic Parameters

Time (min)	Mean Pharmacokinetic Parameters				
	T_{max} (min)	C_{max} (ng/ml)	AUC_{0-t} (ng/ml.min)	$t_{1/2}$ (min)	$AUC_{0-\infty}$ (ng/ml.min)
CBD					
CBD:THC SL Drops	100	2.58	209.30	118.33	578.89
High CBD SL Drops	130	2.05	156.13	NC	NC
Aerosol	141	2.60	325.93	143.77	811.75
Nebuliser	36	9.49	564.35	65.71	726.81
THC					
CBD:THC SL Drops	100	6.50	737.48	78.53	928.42
High THC SL Drops	110	5.77	628.80	65.53	818.10
Aerosol	130	3.69	636.11	83.00	776.09
Nebuliser	32	12.46	786.33	47.13	899.77
11-Hydroxy THC					
CBD:THC SL Drops	140	8.25	1842.75	117.68	2066.30
High THC SL Drops	110	7.29	1163.78	99.55	1373.19
Aerosol	160	6.23	1568.20	138.11	1838.04
Nebuliser	38	1.65	65.15	132.56	495.67

NC = Not acceptable

Source: GW Pharmaceuticals. Guy and Flint.

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