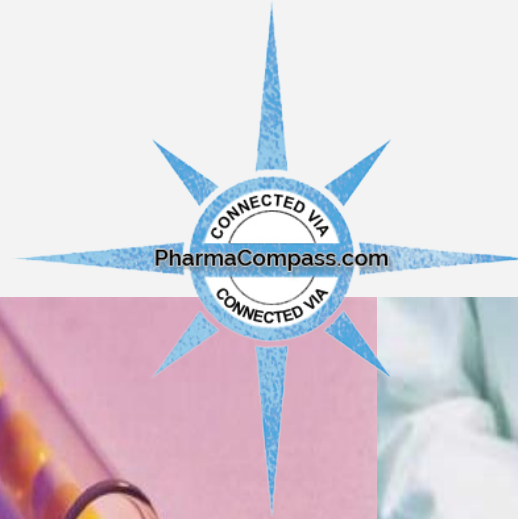


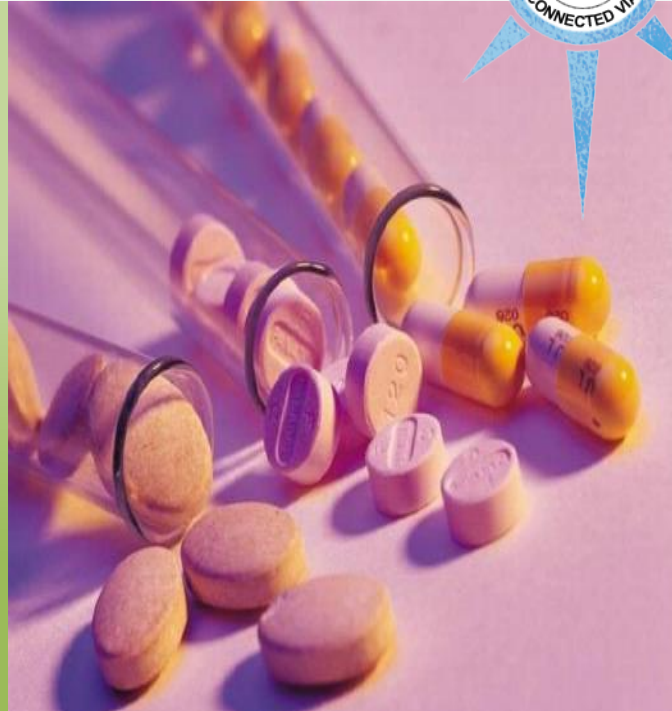


**PHARMADAX**  
INC



# PHARMADAX

IMPROVING QUALITY OF LIFE





# Content Overview

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- Mission and Vision
- Infrastructure
- Management Team
- Journey so far....
- Technology Platforms
- Products and Services
- **Pharmadax Advantage**



# Mission and Vision

Our Mission is to improve quality of life of all our stakeholders,

Of our Patients; by supplying high quality & cost effective generics

Of our Employees, by offering safe and healthy work environment

Of our Investors, by conducting business ethically and creating sustainable business value

**PHARMADAX**  
IMPROVING QUALITY OF LIFE



Our Vision is to build a leading generic specialty pharmaceutical company with enhanced focus on specialty modified release and become preferred development partner for global organization.

# Headquarter and R&D Facility

**PHARMADAX** focuses on developing and manufacturing specialty generic drugs and new drugs. PharmaDax commenced the business in 2008 and headquartered in Taipei, Taiwan.

Organization and Functions at headquarter:

- Research & Development
- GMP Management
- GMP Quality Center
- PK ,Biostatistics
- Clinical Management
- Quality Assurance
- Analytical & Validation Services
- Regulatory compliance
- Administration Management
- Finance& Accounting
- IT



5F-1, No. 236, Liancheng Rd.,  
Zhonghe District, New Taipei City 23553,  
Taiwan( R.O.C. )

**Total Headcount at HQ: 70 (28 in RnD)**  
**Total Area: 1,600 square meters**

# Manufacturing Facilities

**PHARMADAX** has its manufacturing facilities located in Guangdong province, China, with combined capacity of 600 Mn tablets/year with expansion possibilities for other dosage forms.



- **Plant A:** Capacity of manufacturing 500 M tablets per year. It was inspected by FDA without Form 483 issued, which exhibits our commitment to compliance and quality

**Land Scale:** 6,666 square meters.



- **Plant B:** Construction completed in 2014 with potential manufacturing capacity of 100 M tablets per year, with large expansion capabilities for other dosage forms

**Land Scale:** 42,000 square meters.



**Total Area: 48,666 square meters**

# Our Leaders



**Yipin Huang**  
Chairman

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- St. John's University MSc in Industrial Pharmacy
- Anchen Inc.(US)-Director of the Board & Senior VP
- Anchen Inc. Taiwan Branch-Director of the Board & President
- Empax Pharma Inc.-Founder& Director of the Board& President
- 25+ years of experience in pharmaceutical industry



**Huiju Chan**  
President

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- Soochow University EMBA management
- Anchen Inc. Taiwan Branch-Director of the Board& Vice President
- Empax Pharma Inc-Founder& Director of the Board& Vice President
- 28+ years of experience in pharmaceutical industry

# Executive Team

**Margaret Choy**  
EVP



- University of Southern California MSc in Regulatory
- Par Pharmaceuticals - Senior VP, Regulatory Affairs.
- Anchen Pharmaceuticals Inc. - Senior VP, Regulatory Affairs.
- Watson Pharmaceuticals – Director, Regulatory Affairs.
- Filed over 25 US “First to File” ANDA.
- 28+ years of experience in pharmaceutical industry

Name	Position	Education Background	Work Experience	Experience in industry
Susan Liao	Vice President	China Medical University, Taiwan; BA in Medicine	<ul style="list-style-type: none"> <li>•Anchen Inc. Taiwan Branch-Senior Manager</li> <li>•Fujisawa Pharmaceutical Co. Ltd - QC/QA Manager (TW)</li> </ul>	32+ years
Stephen Wong	Director	California State Polytechnic University, Pomona MBA	<ul style="list-style-type: none"> <li>•Pharmadax Inc. the USBranch-Director</li> <li>•Anchen Inc.(US)-QC Manager</li> <li>•Associated Dir at Par and Anchen</li> <li>•Watson Pharma. (US)-R&amp;D Lab. Manager</li> </ul>	20+ years
Frank Lin PhD	Director of R&D	Tatung University; PhD in Chemical Eng.	<ul style="list-style-type: none"> <li>•Anchen Inc. Taiwan Branch-Director of R&amp;D department</li> <li>•Empax pharma Inc-Director of RD department of</li> </ul>	25+ years
Jason Wu PhD	Director of Medical Affair	Taipei Medical University; PhD in Pharmaceutical Science	<ul style="list-style-type: none"> <li>•China Chemical &amp; Pharmaceutical Co., Ltd-Vice Chairman of R&amp;D Dept.</li> <li>•Anchen Inc. Taiwan Branch - Vice Director</li> </ul>	15+ years

# Our journey so far...

- 2016 ● FDA Submission: 2 approved, 3 under review and 7 in pipeline  
**FDA approval and launch of Glyburide Tablets in US**
- 2015 ● Won the 12<sup>th</sup> annual Golden Torch Awards of Enterprise Excellence of R.O.C.
- 2014 ● ANDA Submission: Quetiapine Fumarate ER Tab
- 2013 ● **Plant A passed USFDA inspection, without 483s**  
**Listing on Taiwan Stock Exchange**
- 2012 ● **FDA approved Levetiracetam ER Tablet**  
 The 2<sup>nd</sup> GMP plant (Plant B) was established in China  
 GMP QC Lab was set up in Taipei, Taiwan
- 2011 ● ANDA Submission : Glyburide Tab & Metoprolol Succinate ER Tab
- 2010 ● First ANDA Submission : Levetiracetam 750, 500mg ER Tablet ( Keppra® XR )
- 2009 ● R&D center was set up in Taipei and China  
 Plant A got FDA production approval in China
- 2008 ● The GMP plant was set up in China (Plant A)  
 The headquarter of PharmaDax was established in Taipei





# Business Reach

Pharmadax Group operates in the following geographies :

- ✓ Taiwan
- ✓ USA
- ✓ China
- ✓ Pharmerging

## 🌿 USA: Focused Market

USA being the largest generic market and having management experience in the region, it was the first choice. Current pipeline is focused on blockbuster opportunities, riding the 2<sup>nd</sup> wave.

## 🌿 China: Next Frontier

Generics had shown exponential growth and Pharmadax will leverage its manufacturing location and have initiated filings in the country, take for collaborative approach to push



Headquarter: New Taipei City, Taiwan

Manufacturing plant: Guangdong Province, China

US office: California, USA

European office: Slovenia, EU

India Office: Mumbai, India

**Number of Total Employees : 210**

# Dosage Form Development

Pharmadax is committed to develop modified release generics in various therapeutic segments. The team brings a good mix of innovation and timely execution to ensure efficient dossier filing

We have a patented technology platform of high precision modified release, which can be used on large gamut molecules.

Our scientists ensure that this cutting edge technology continues to be flexible to bring more bioequivalent products to market.

**Number of employees of R&D in TW and CN: 35**



**Formulation Development**

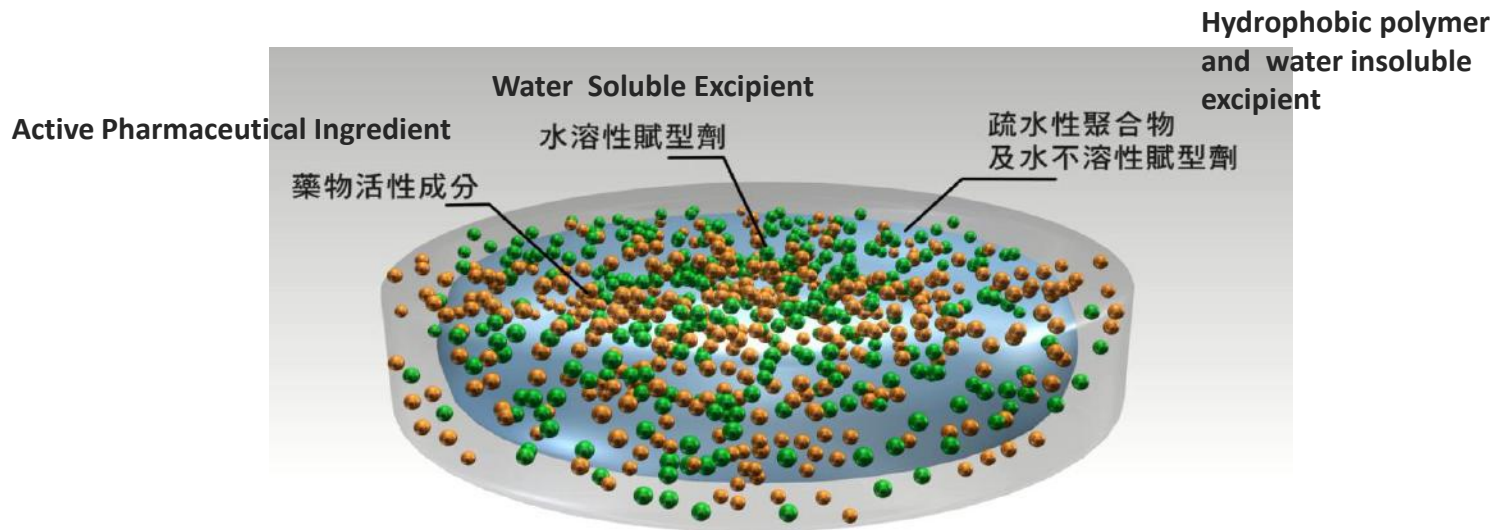


**Manufacturing Process**



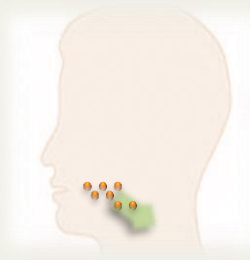
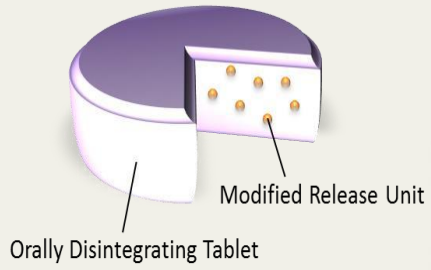
# Core Technology

**Pharmadax** uses Non- Erosive Adjustable Drug Delivery System “NEADDs” technology to develop our products with better cost efficiency and enhance process stability.



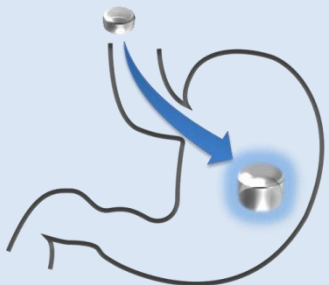
- US Patent : 62/066,917 Oral Controlled Release Matrix Tablet (NEADDs)
- Product Submitted to FDA Quetiapine Fumarate ER Tablets

# Core Technology



● **MR- ODT:**  
**Modified- Release Orally Disintegrating Tablet**

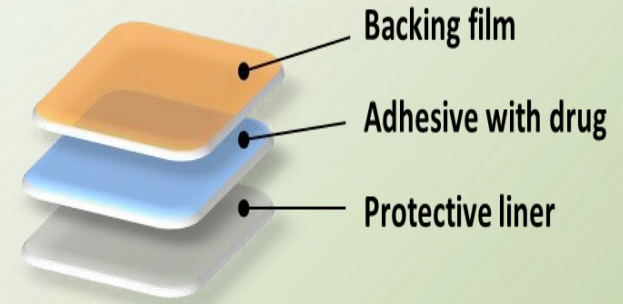
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● **Sustained release  
 gastroretentive dosage form**

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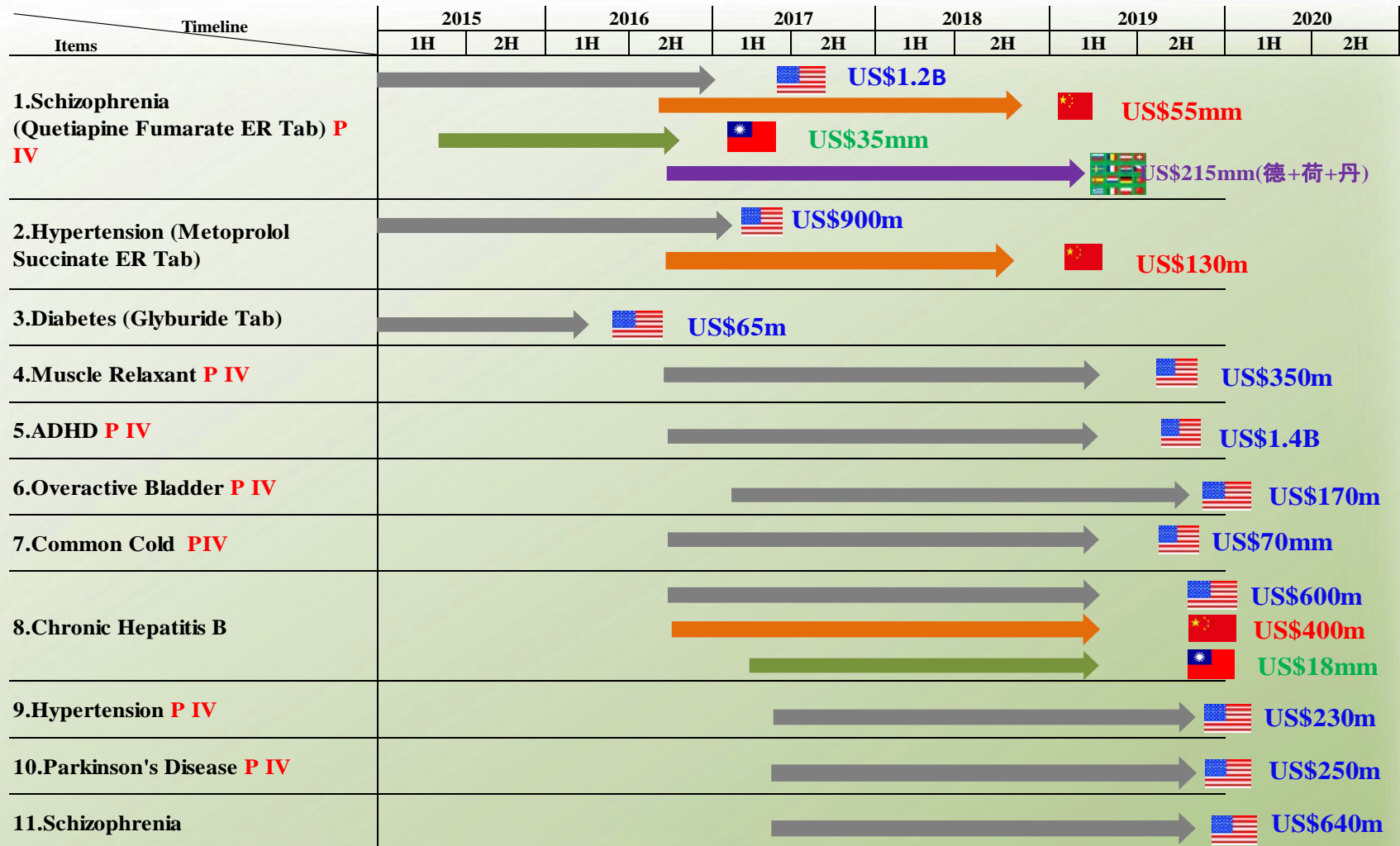
**Retention in stomach  
 and sustained release**



● **Ttransdermal patches:**

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# Portfolio



# We Offer.....



**Co-development and Marketing Partnerships**



**Regulated Market – CMO Opportunities – Tablets**



**Dossier development and Technology transfer services for Modified Release Products**

## Why Pharmadax

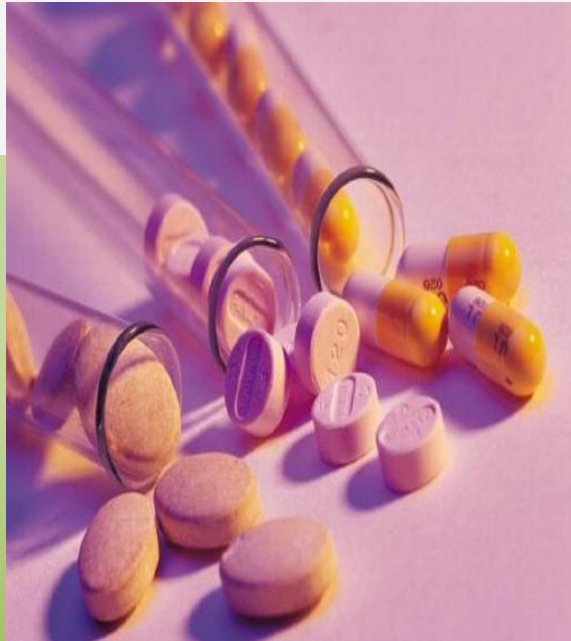
We believe in professionalism, we work with honesty and we perform decisively.

Quality and Compliance is our core ideology, which is exhibited in our products, people and partnerships.



**PHARMADAX**  
INC

# THANK YOU



For collaboration opportunities:

[reachus@pharmadax.com](mailto:reachus@pharmadax.com) OR

Call: +886-2- 2223-1552

Corporate Office: Pharmadax Inc. 5F-1., No.236, Liancheng Rd., Zhonghe Dist., New Taipei City 235, Taiwan (R.O.C.)

**PHARMADAX**

IMPROVING QUALITY OF LIFE

# PHARMADAX Product

## Glyburide Tablet 1.25 mg, 2.5 mg, 5 mg ( Micronase<sup>®</sup> )



### ● Indication :

–Type 2 diabetes

### ● Market Scenario

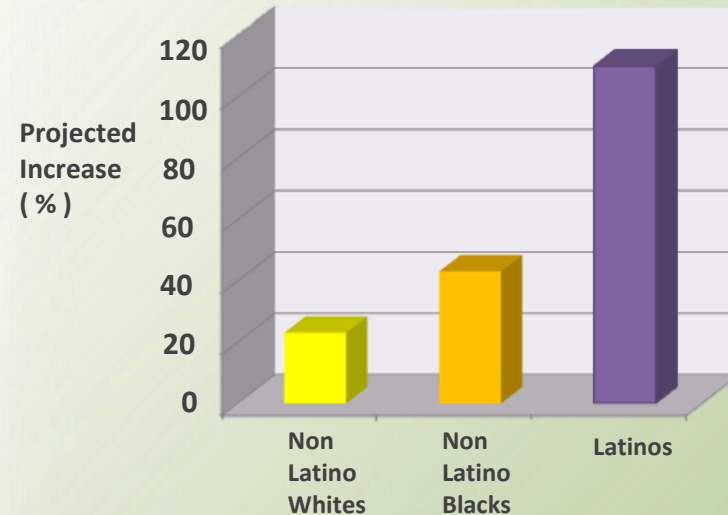
– Launched in Q2 2016

### ● Certification Level :

– (Paragraph II) Niche Market Product

– Launched Q1 2016

Diabetes Population Increasing in the US



The Statistic of Diabetes is referred to American Diabetes Association Diabetes Care.

The figure projected increases in the US population with diagnosed diabetes by 2020.

**Market Size in US: Around USD 65 Million**



# PHARMADAX Product

## Quetiapine Fumarate Extended-Release Tablet

50 mg, 150 mg, 200 mg, 300 mg, 400 mg

(Seroquel XR®)

### ● Indication :

- A typical antipsychotics, mainly treating certain mental/ mood condition and depression

### ● Market Scenario

- The Branded (AstraZeneca) product is protected by patent until Nov. 2017
- PharmaDax successfully challenged AstraZeneca Patent and settled the lawsuit with no additional cost. This enables PharmaDax to launch our generic product as early as 1<sup>st</sup> Nov. 2016.

### ● Certification Level :

- (Paragraph IV) Blockbuster Product
- Expected Approval Q4 '2016



**Market Size in US:  
Around USD 1.3 Billion**

# PHARMADAX Product

## Metoprolol Succinate Extended-Release Tablet

25 mg, 50 mg, 100 mg, 200 mg

(Toprol XL®)

### ● Indication:

–A beta-blocker used to treat chest pain, heart failure, and high blood pressure

### ● Market Scenario:

–The patent has expired over 10 years  
 –With its high entry barriers of formulation and low yield rate of mass production, there are still limited competitors in the market

### ● Certification Level:

– (Paragraph II) Difficult-to-Formulate & Blockbuster Product  
 – Expected approval Q4'16/Q1 '17



**Market Size in US:  
 Around USD 1.2 Billion**