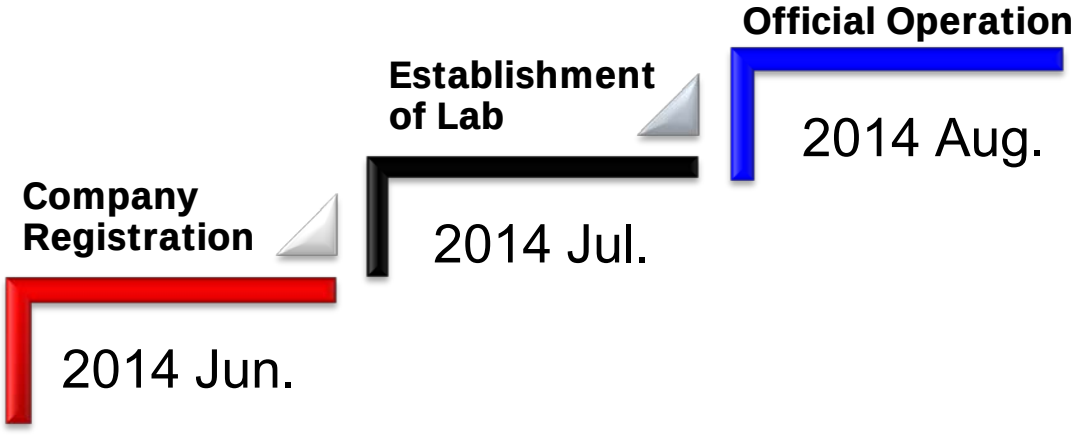

FOREFRONT
众强药业

Our Company

Brief History



Mission

Shanghai ForeFront Pharma is a R&D driven and innovation-focused novel biopharmaceutical company. The company focuses on high-end generics as well as innovative drugs.

For the high-end generics, ForeFront's portfolio includes difficult-to-synthesis molecules which may also involve semisynthetic, innovative drug delivery systems such as CR & SR formulation, fixed dose combination technologies, etc. The company targets to file P IV and 505b2 in US and Category 2 drugs in China independently and/or in collaboration with strategic partners.

Management Team

Dr. Yi Ren
General Manager

- 1992-1996, Ph.D., University of Toronto
- 1996-1998, Post-doc, University of Michigan
- 1998-2008, Roche Nutley
- 2008-2013, Head of CMC, Roche R&D Center China
- 2013-2015, General Manager, MediChem and Ruick
- 2015-present, General Manager, Shanghai ForeFront Pharma

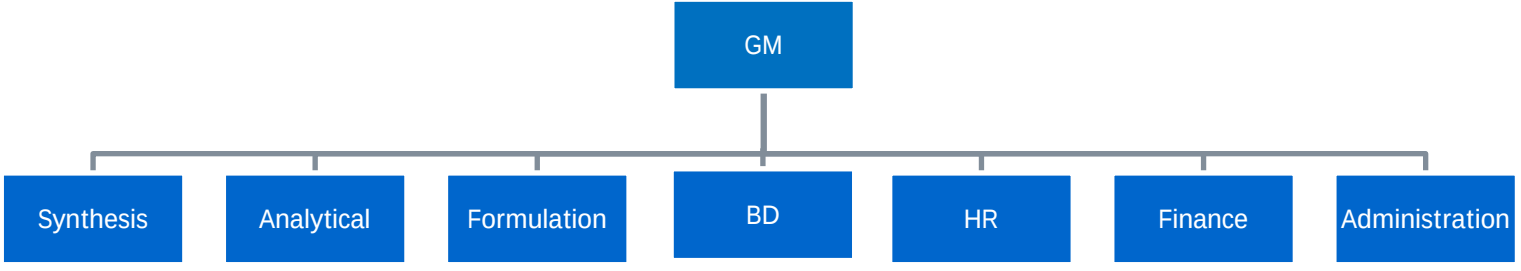
Dr. Chengjun Huang
Head of Process R&D

- 2000-2004, Ph.D., Shanghai Institute of Pharmaceutical Industry
- 2004-2011, Project Leader, Shanghai Institute of Pharmaceutical Industry
- 2011-2014, Head of Process Research Institute, Shanghai Acebright Pharmaceuticals Group Co., Ltd.
- 2014-present, VP, Shanghai ForeFront Pharma

Dr. Wei Li
Head of Analytics

- 2003-2006, Ph.D., Tianjin University
- 2006-2009, Principle Scientist & Group Leader, WuXi Apptec
- 2009-2014, Head of Preformation and Analytics, Roche R&D Center China
- 2014-present, VP, Shanghai ForeFront Pharma

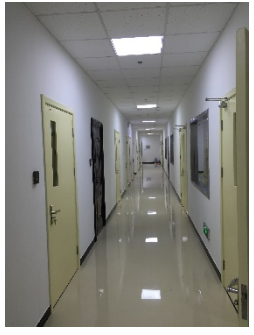
Organizational Structure



Our Lab

Location: 249 Faladi Road, Building 7
Shanghai Zhangjiang Hi-Tech Park

ZJ INNOPARK
张江高科技园区



Formulation Lab

Location: Fudan University
Shanghai Zhangjiang Hi-Tech Park

ZJ INNOPARK
张江高科技园区

Our Partners

Strategic Partners

Zhejiang Apeloa Kangyu Pharmaceutical Co. Ltd.

Fudan University, School of Pharmacy

Collaboration Partners

Beijing Cosi-Med

Shanghai Institute of Materia Medica

Columbia University

University of Waterloo

WuXi Apptec

Chempartner

Shanghai ABACHEM

Strategic Partners

Our manufacturing partner:

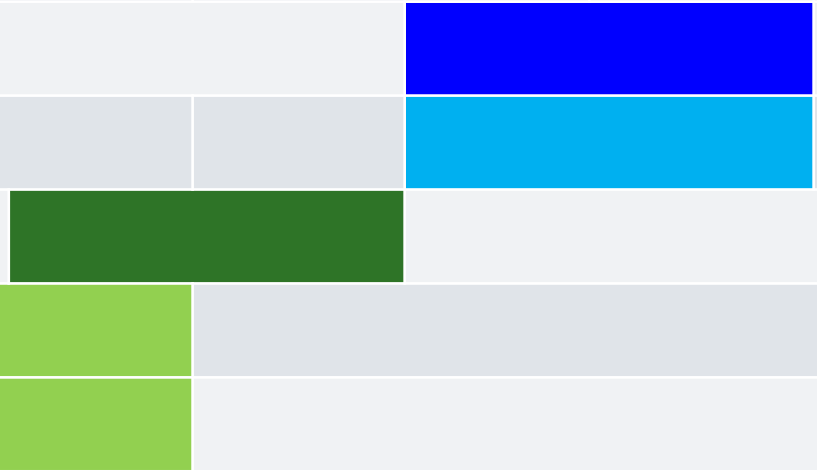
- **Zhejiang Apeloa Kangyu Pharmaceutical Co. Ltd.**
- GMP under FDA, EU, WHO, and China
- Listed on Shengzhen Stock Exchange

Our formulation partner:

- **Fudan University School of Pharmacy**
- Full range of modern formulation equipments for R&D and pilot production
- GMP-like production area suitable for registration purpose
- Consulting by distinguished faculties of Fudan

Our Portfolios

Name	Therapeutic Area	Status		
		R&D	Scale up	Commercial Manufacture
Ledipasvir	Virology (HCV)			
Daclatasvir	Virology (HCV)			
Velpatasvir	Virology (HCV)			
GS9857	Virology (HCV)			
Rolapitant	Oncology			



Note： API for R&D and registration purpose only. Intermediates could be sold to originator licensed companies.

HCV Platform

- FDA approved Gilead's Harvoni on October 10, 2014 (Genotype 1,4,5,6). Harvoni is a fixed dose combination of Sofosbuvir (400 mg) and **Ledipasvir** (90 mg) per tablet.
- FDA approved BMS's **Daclatasvir** on July 24, 2015 (Genotype 1,3). Daklinza (60 mg) is to be used in combination with Sofosbuvir (400 mg).
- FDA approved Gilead's Epclusa on June 28, 2016 (Genotype 1-6). Epclusa is a fixed dose combination of Sofosbuvir (400 mg) and **Velpatasvir** (100 mg) per tablet.
- The phase III data indicated that the new generation of all oral DAAs can achieve 90-99% SVR after 12 week treatment.
- The sales of Harvoni in 2015 was $18.1 billion. The sales of Daklinza in 2015 was $1.45 billion.
- Our project is focused on developing both patent and Non-Infringing process & polymorph of DAAs for (1) PIV and 505b2 filings, and (2) supplying for originator licensed companies for treatment use in 90 developing countries.

Ledipasvir: Current Progress

New synthetic route of key intermediate: 1378387-81-5

- Two more efficient and cost-effective routes have been developed.
- Two China patents have been filed and **one is granted**; 1 PCT patent have been filed.
- Scale up of this intermediate is achieved at hundred kg scale.

Patent route of Ledipasvir API

- The whole patent route has been fully developed and QbD works are ongoing. No column purification is used in current route which can be scaled up easily.
- The quality of final API fully meets the requirement of ICH guideline: HPLC purity NLT 99.5%, individual impurity NMT 0.10%.

Non-infringing route of Ledipasvir API

- New non-infringing route has been developed which is more efficient than the patent route.
- One process patent has been filed. One PCT patent is filed.
- Further QbD works are ongoing.

New solid form of Ledipasvir API

- New and non-infringing solvates of API are developed which have better stability than the patent solvates.
- One patent has been filed.

Solid dispersion of Ledipasvir API

- Stable and high quality solid dispersion obtained through Spray Drying

We are in position to support PIV filing and 505b2 with our new technologies.

Daclatasvir: Current Progress

Non-infringing early intermediate

- A non-infringing early intermediate was developed which is much more cost competitive than patent route.
- A patent is filed.

Patent route of Daclatasvir API

- The whole patent route has been fully developed and QbD works are near completion. No column purification is used in current route which can be scaled up easily.
- The quality of final API fully meets the requirement of ICH guideline: HPLC purity NLT 99.5%, individual impurity NMT 0.10%.
- The process has been scaled up in hundred kilo scale.

Non-infringing route of Daclatasvir API

- New non-infringing route has been developed which is more efficient than the patent route.
- Further QbD works are ongoing.

New solid form of Daclatasvir API

- New and non-infringing salts of API are developed which have better stability than the HCl salts.
- One patent has been filed.

We are in position to support PIV filing and 505b2 with our new technologies.

Velpatasvir (GS5816): Current Progress

- **Patent route is fully developed**
- **1438383-89-1 (di-bromo) key intermediate can be manufactured at tens of KG scale**
- **N-2, N-1 (H3PO4 & HCl) can be provided in KG scale**
- **API can be provided in KG scale**
- **Solid dispersion of Velpatasvir (N+1) is under investigation with early success**
- **Formulation of Velpatasvir with Sofosbuvir is under investigation**

IP

	Patent No.	Patent Name	Type of patent	Status of patent	Holder of patent
1	CN201410668438.7	芬乙酮衍生物的制备方法	Invention	Granted	Shanghai Forefront Pharma
2	CN201410668957.3	芬乙酮衍生物的制备方法	Invention	Substantive Examination	
3	CN201510117997.3	雷迪帕韦及其衍生物的制备方法及用于制备雷迪帕韦的中间体化合物	Invention	Substantive Examination	
4	CN201510393767.X	雷迪帕韦新晶型及其制备方法	Invention	Substantive Examination	
5	CN201510390769.3	一种雷迪帕韦中间体单硫酸盐、其晶型及其制备方法	Invention	Substantive Examination	
6	CN201510672012.3	一种合成达卡他韦中间体的新方法	Invention	Substantive Examination	
7	CN201610050738.8	达卡他韦新晶型及其制备方法	Invention	Filed	
8	P2016-0885-1CNCN	一种维帕他韦中间体新晶型	Invention	Filed	
9	P2016-0945-1CNCN	一种达卡他韦的合成新方法	Invention	Filed	
10	PCT/CN2015/093114	芬乙酮衍生物的制备方法	Invention	Filed	
11	PCT/CN2016/075358	雷迪帕韦及其衍生物的制备方法	Invention	Filed	
12	PCT/CN2016/087090	雷迪帕韦新晶型及其制备方法	Invention	Filed	

CRO Services

- Extensive experience in API **process** R&D
- Extensive experience in **preformulation** and **analytical** R&D
- Strong collaboration with Fudan University in providing **formulation** R&D services
- Finished DMF and dossier **document** writing for 3 internal projects
- Strong **communication** skill
- Very familiar with **MNC**'s culture, standard, and practice

We Aim at ForeFront of Innovation!

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