



Corporate Presentation (TWSE 4743)

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免責聲明

- The statements and contents included in this presentation that are not historical in nature are “forward-looking statements”. These forward-looking statements, which may include statements regarding our future results of operations, performance, financial condition, development or marketing of our products or business prospects, are subject to risks and uncertainties and are based on our current expectations. Actual results may differ materially from those expressed or implied in these forward-looking statements for a variety of reasons. Please be cautioned not to place undue reliance on these forward-looking statements which are based on information currently available. Our forward-looking statements at this time does not create any duty of disclosure beyond that which is imposed by law, and we expressly disclaim any obligation to publicly update or revise any forecasts or forward-looking statements, whether as a result of new information, future events or otherwise.

合一生技

- 2008年成立
- 2011年上櫃 (TWSE : 4743)
- 資本額：新台幣19.6億元
- 核心產品：ON101, OB318
- 核心生產基地

PIC/s GMP等級藥廠



GACP有機農場 (44公頃)



Product	Indication	Pre-clinical	Phase I	Phase II	Phase III	NDA	Note	Best-in-class	Unmet medical Need
ON101	Diabetic Foot Ulcer (DFU)	→					IND-TW/CN/US	✓	✓
OB318	Hepatocellular Carcinoma	→					IND-US/TW		✓

簡明資產負債表

(單位：千美元)

項 目	2016/12/31	2017/12/31	2018/09/30
流動資產	52,308	41,244	27,849
不動產、廠房及設備	5,825	15,190	18,108
無形資產	766	770	827
其他資產	26,290	26,842	26,482
資產總額	85,189	84,046	73,266
負債總額	1,047	882	932
股本	65,057	65,251	65,251
資本公積	25,714	25,486	20,391
保留盈餘	(475)	(5,182)	(6,821)
其他權益等	(6,154)	(2,391)	(6,487)
權益總額	84,142	83,164	72,334

2016-2018Q3 損益表

2016-2018 Q3 Financials

Currency in thousand USD	2018.Q3	2017	2016
Revenue	473	86	190
R&D Exp.	1,710	2,181	2,089
Net Profit	-6,580	-5,197	-475
Total Assets	73,266	84,046	85,189
Liabilities	932	882	1,047
Owner's Equity	72,334	83,164	84,142

2017-2018 Chart (NTD)



Previous
Close

Day's
Range

52-week
Range

Market Cap

0.92

0.90-0.93

0.63-1.44

180 Mn

22 Nov 2018

(Currency in USD)

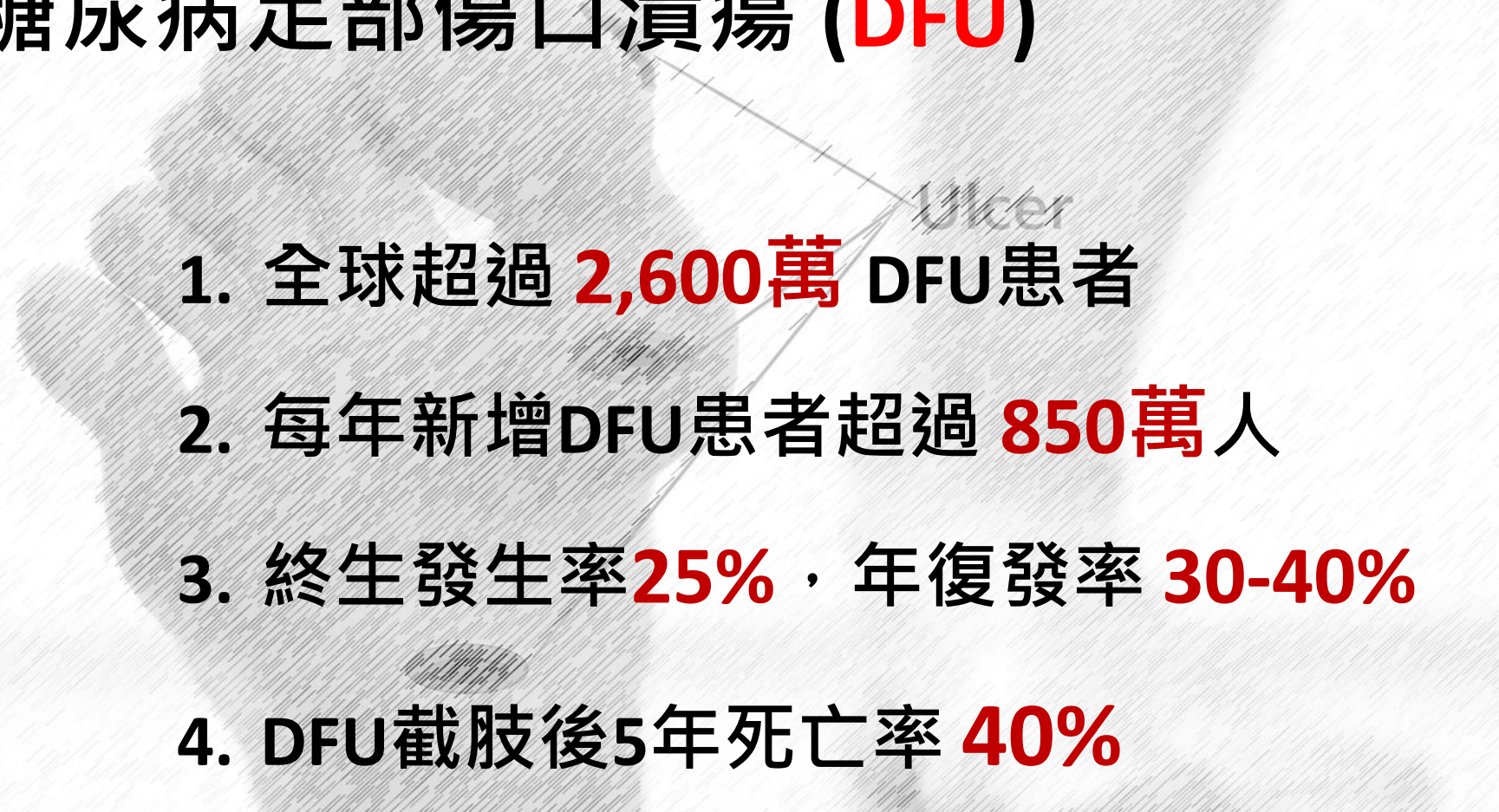
核心新藥 - ON101



**Globally Unmet,
We Met.**

The **Best-in-class for DFU**

糖尿病足部傷口潰瘍 (DFU)

- 
1. 全球超過 **2,600萬** DFU患者
2. 每年新增DFU患者超過 **850萬**人
3. 終生發生率**25%**，年復發率 **30-40%**
4. DFU截肢後5年死亡率 **40%**

**One of major complications of diabetic patients
with a chronic and costly process**

巨大財政負擔

Global expenditure > US\$60 bn

	<u>Current Treatment Cost (USD)</u>	<u>DFU Population</u>
Europe	\$ 13,561	2,960,000
U.S.	\$ 11,710	3,920,000
MENA	\$ 3,100	1,297,000
China	\$ 3,000	7,500,000
India	\$ 1,960	8,460,000

1st Proven-efficacy

among global phase III trials

Current Phase III Trials

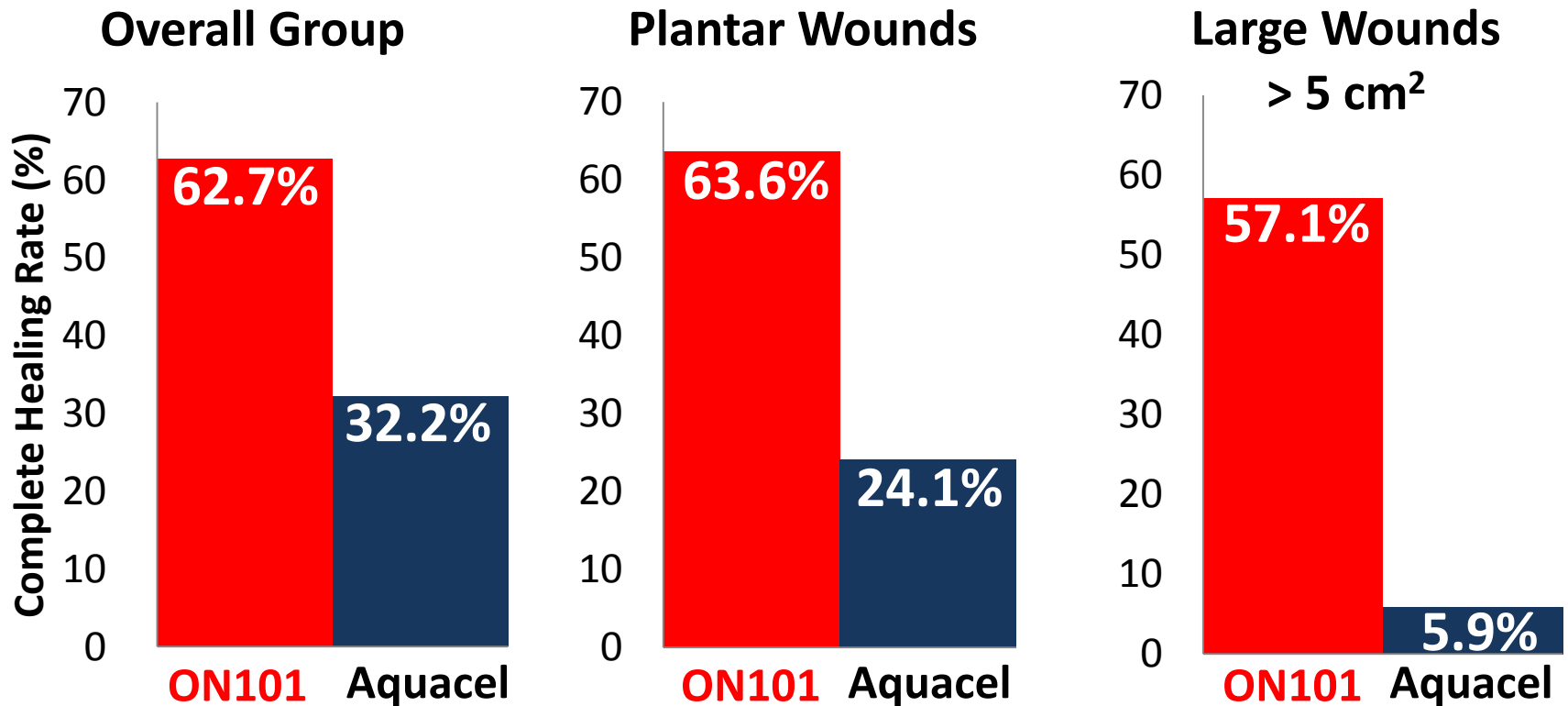
Drug	Company	Development Status	Category
ON101 Cream	Oneness Biotech Co., Ltd	1 st Phase III with interim results	Botanical Drug
ALLO-ASC-DFU	Anterogen Co., Ltd	Phase III ongoing	ADSC
DermaPro	CytoTools AG	Phase III ongoing	Small Molecule
VM202	ViroMed Co., Ltd	Phase III ongoing	Gene Therapy
Granexin Gel	FirstString Research, Inc	Phase III ongoing	Peptide

Phase III Trials failed in the past 3 years

Drug	Company	Year of Failure	Category
DSC-127	Derma Sciences, Inc.	2015	Peptide
CureXcell	Macrocare Ltd.	2015	Cell Therapy
Cogenzia	Innocoll, Inc.	2016	Small Molecule
BioChaperone	Adocia	2016	PDGF
Locilex	Dipexium Pharmaceuticals, Inc.	2016	Peptide

臨床達標

第一個三期試驗期中分析



顯著療效

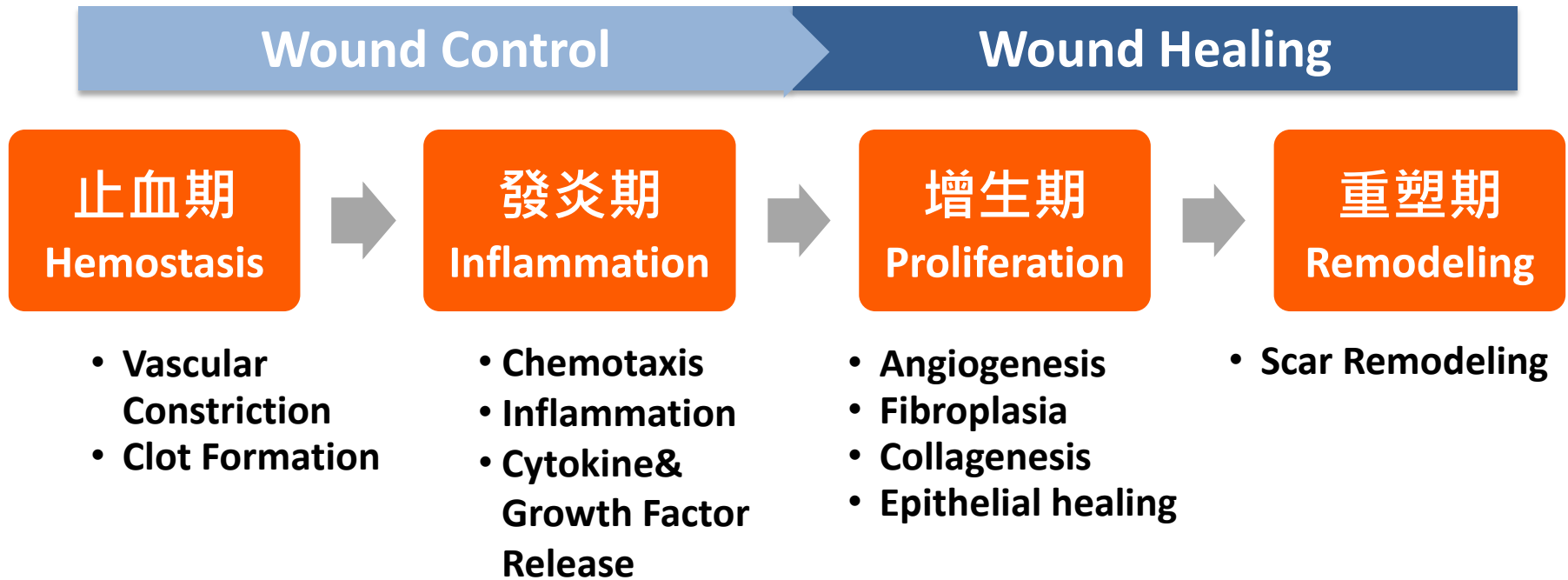
DM > 10 yrs, Ulcer duration 2 months,
Wound size **5.76 cm²**, Completely healed with in **8 weeks**



二期臨床試驗結果

**How does ON101 work in
DFU wound healing ?**

作用機制



DFU是相當複雜的疾病，並非單一靶向藥物可以完全治癒。

ON101 由兩種藥材萃取物組成，具有**抗發炎、促進血管新生、促進纖維組織增生合成膠原及表皮細胞上皮化**，加速傷口癒合作用。

專利佈局

配方及用途專利保護

- Topical formulation
- Method of treating wounds and skin disorders (**2017.7 application**)

活性成分專利保護

- Use of flavonoid compound in preparation of composition for healing wound

萃取物專利保護

- Plant extracts for treating skin disorders and enhancing healing of wounds for diabetic patients

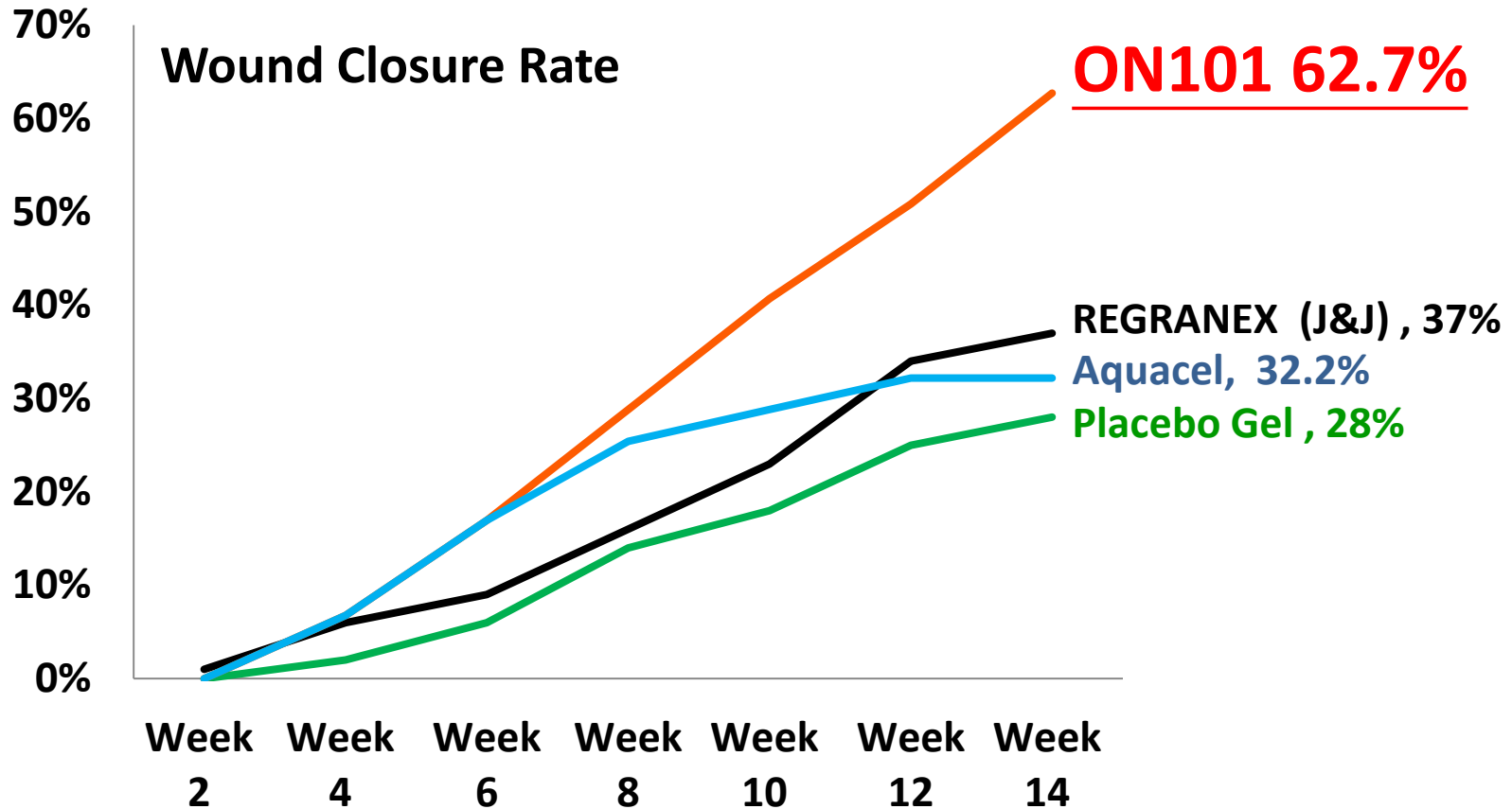
製程專利保護

- The process for preparing active pharmaceutical composition



優勢與市場

藥品療效優勢



(Source: ON101 1st Phase III Interim Analysis & Regranex Pivotal Trial)

藥品使用優勢

Revolutionary treatment. Just use at home.

Now (without ON101)

Ulceration



Hospital



- Reduced Productivity
- Hospital resources occupied
- Plateau effect
- Surgically expensive



Healed

Future (with ON101)

Ulceration



Hospital



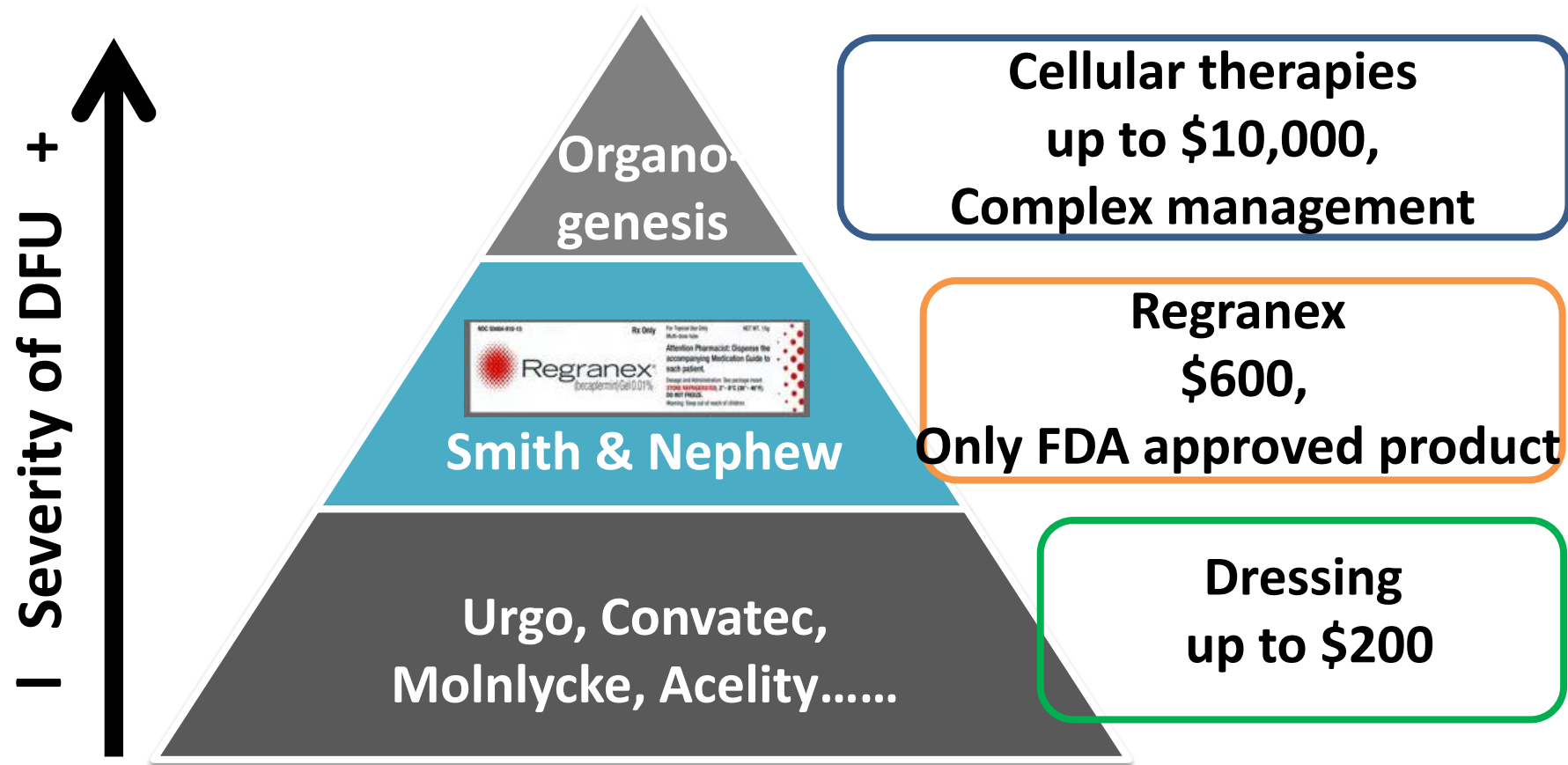
Home care



Healed

藥品訂價優勢

A cost-effective treatment for DFU



藥品供應優勢

by streamlined control from cultivation to production

We have established

- **A GACP site for mass cultivation of the raw material**
In compliance with US FDA "Botanical Drug Development - Guidance for Industry" (2016.12)
- **PIC/s GMP plant for global supply (capacity with 50 mn tubes in 1st stage)**

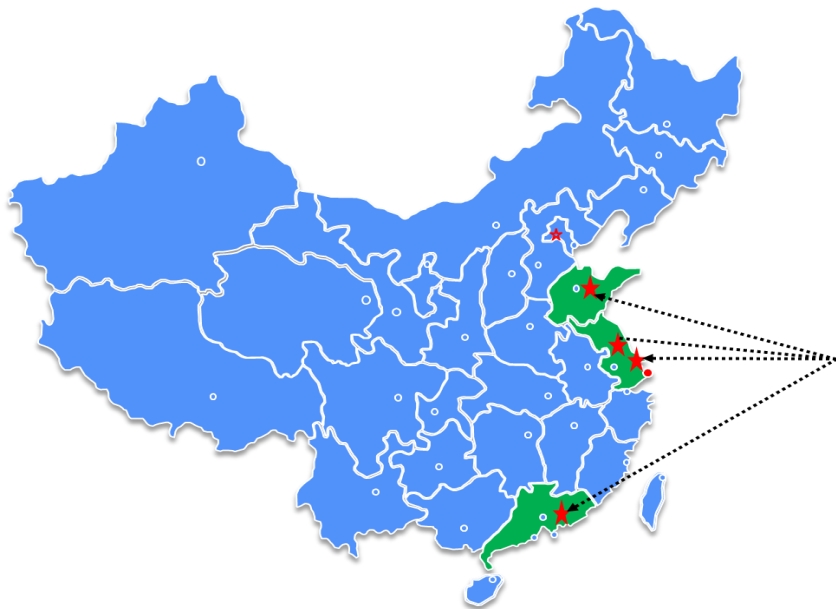
44-acre GACP Cultivation Site



PIC/s GMP Plant



大陸上市 - 全球最大DFU市場



- ✓ Phase III MRCT Trial started in 2018
- ✓ NDA expected in 2019
- ✓ Marketed during **2019-2020**

7.5 mn DFU patients Incidence: 8.1%

IDF大會受邀口頭報告

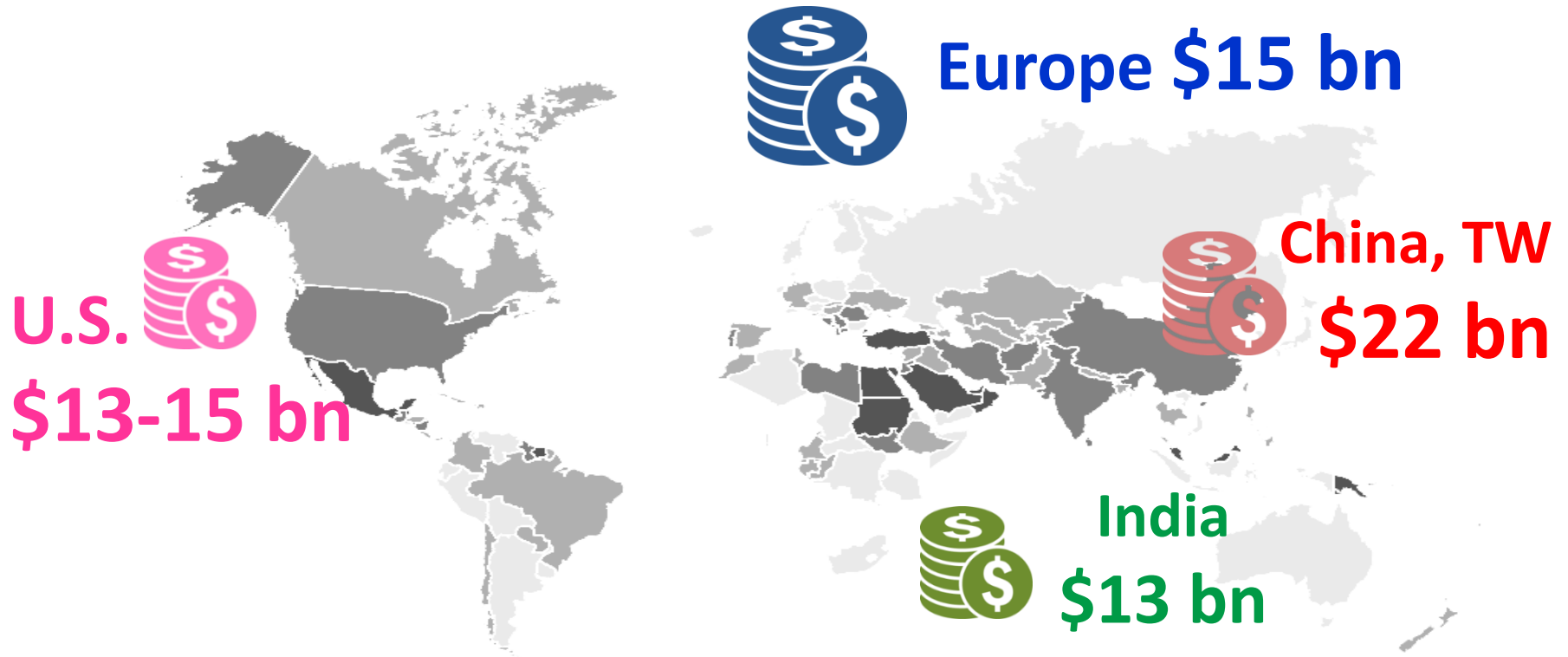
Title: First new drug with over 60% complete wound closure in diabetic foot ulcers from phase III trial interim analysis report

Presenter: Min-Liang Kuo, Ph.D.



上市計畫

From 2019



Execute
2019



Accelerate
2020



Expand
2021



**Globaliza-
-tion**



Globalization by Innovation