



合一生技股份有限公司

公司簡報

16th Morgan Stanley Healthcare Conference

2018 年 9 月

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重要里程碑

2008

- 合一生技創立，政府核定為「生技新藥」公司，以未滿足的醫療需求 (Unmet Medical Need) 為新藥開發目標

2011

- 證期局核准股票上櫃，9月23日正式掛牌交易 (4743)

2013

- 美國FDA同意重磅新藥ON101執行第一項MRCT三期臨床試驗

2015

- 經濟部通過ON101專案SBIR計畫

2016

- ON101三期臨床試驗期中分析達標，DFU完全癒合率62.7%，領先全球

2017

- 大陸CFDA同意ON101執行三期臨床試驗

2018

- 美國FDA同意ON101執行第二項MRCT三期臨床試驗
- 向台灣TFDA提出ON101新藥查驗登記(NDA)
- 屏東南州廠完工，規劃年產能5000萬條ON101新藥

簡明資產負債表

(單位：千美元)

項 目	2016/12/31	2017/12/31	2018/06/30
流動資產	52,308	41,244	32,462
不動產、廠房及設備	5,825	15,190	17,503
無形資產	766	770	835
其他資產	26,290	26,842	28,895
資產總額	85,189	84,046	79,696
負債總額	1,047	882	824
股本	65,057	65,251	65,251
資本公積	25,714	25,486	20,370
保留盈餘	(475)	(5,182)	(3,126)
其他權益等	(6,154)	(2,391)	(3,623)
權益總額	84,142	83,164	78,872

重磅新藥 - ON101



**Globally Unmet,
We Met.**

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

DFU (糖尿病足部傷口潰瘍)

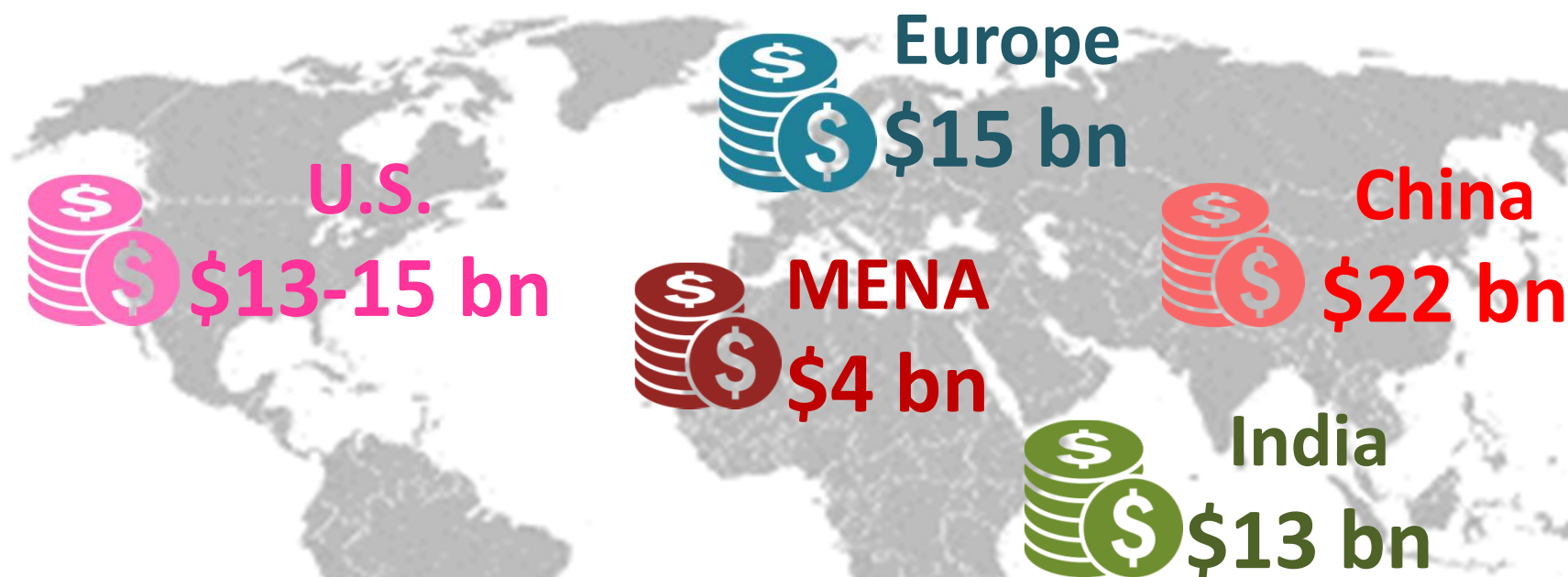
>26 million DFUs worldwide

>8.5 million new ulcers every year

65% ulcers remain **unhealed** in 12 months

30-40% recurrence every year

巨大財政負擔

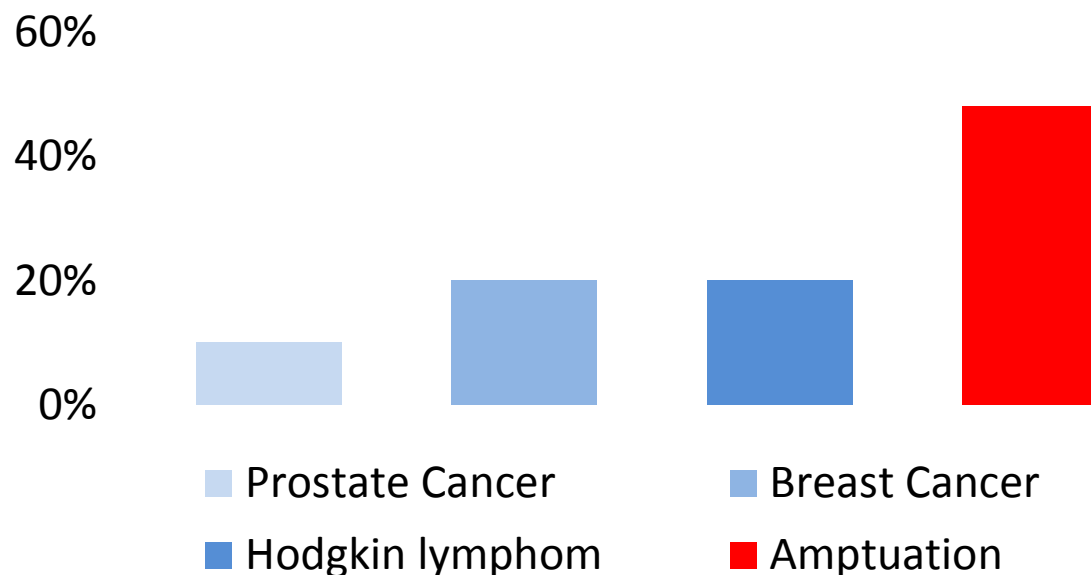


全球醫療支出超過600億美元

高死亡率

Nearly **50%**
mortality rate
in 5 yrs after
amputation

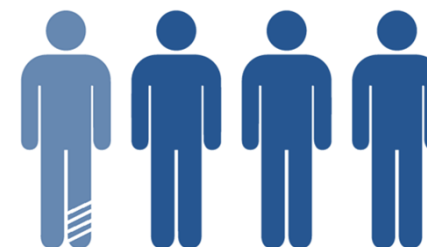
5-Year Mortality Rate



Every 30 secs
a limb is amputated



Up to **25%** diabetes patients
develop an ulcer
over lifetime

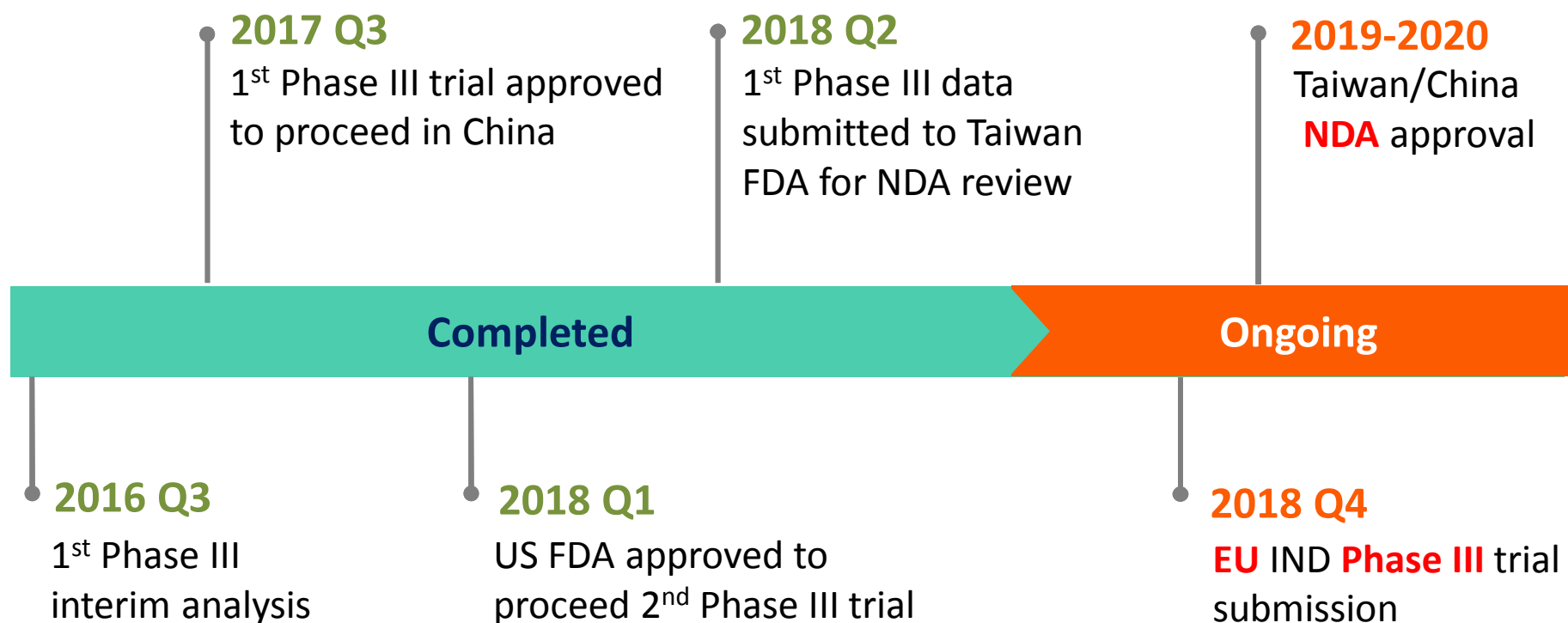


大陸上市



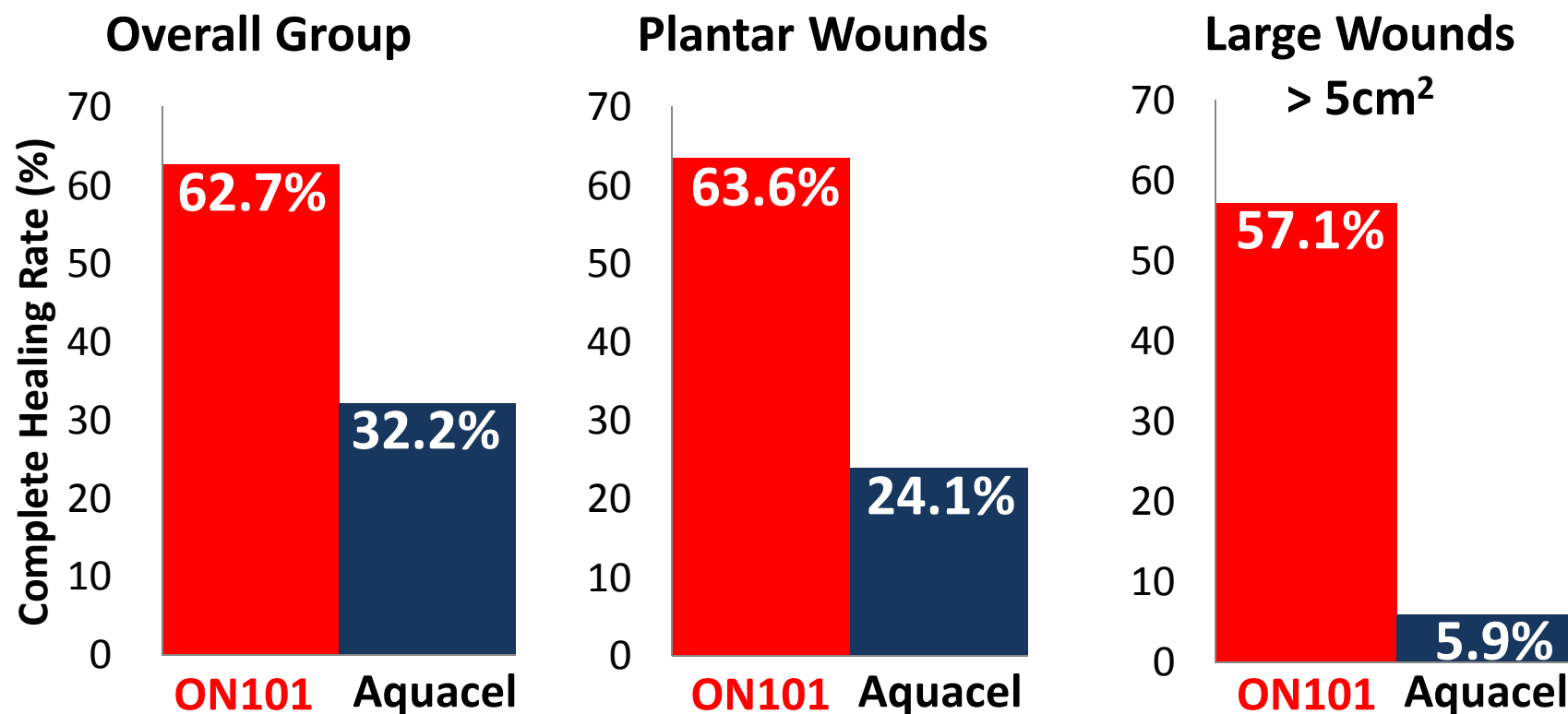
- ✓ Phase III MRCT Trial co-developed with national diabetes KoLs
- ✓ NDA expected in the near future
- ✓ Commercialization with local partner

臨床進度



臨床達標

第一個三期試驗期中分析



明確臨床效益

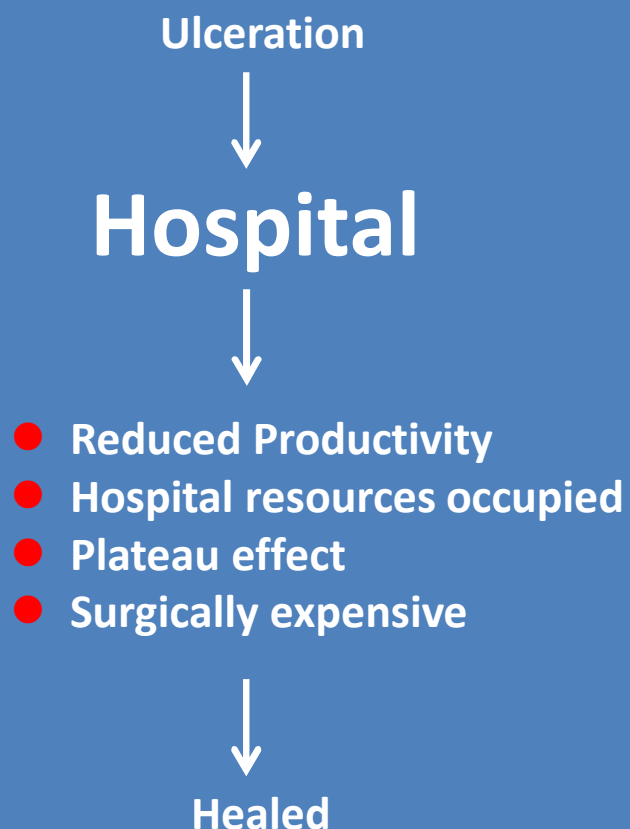


- ✓ **Rapid Healing**
- ✓ **Superior Complete Healing Rate**
- ✓ **Consistent Efficacy**
- ✓ **Easy Home Care, Higher Compliance**
- ✓ **Odorless Wounds**
- ✓ **No Safety Concern in Cancer Risk**

居家用藥

Revolutionary treatment. Just use at home.

Now (w/o ON101)



Future (w/ ON101)



生產基地

Streamlined Control on Price

We have established

- A GACP site for mass cultivation of the raw material
- PIC/s GMP plant for global supply (capacity with 50 mn tubes in 1st stage)

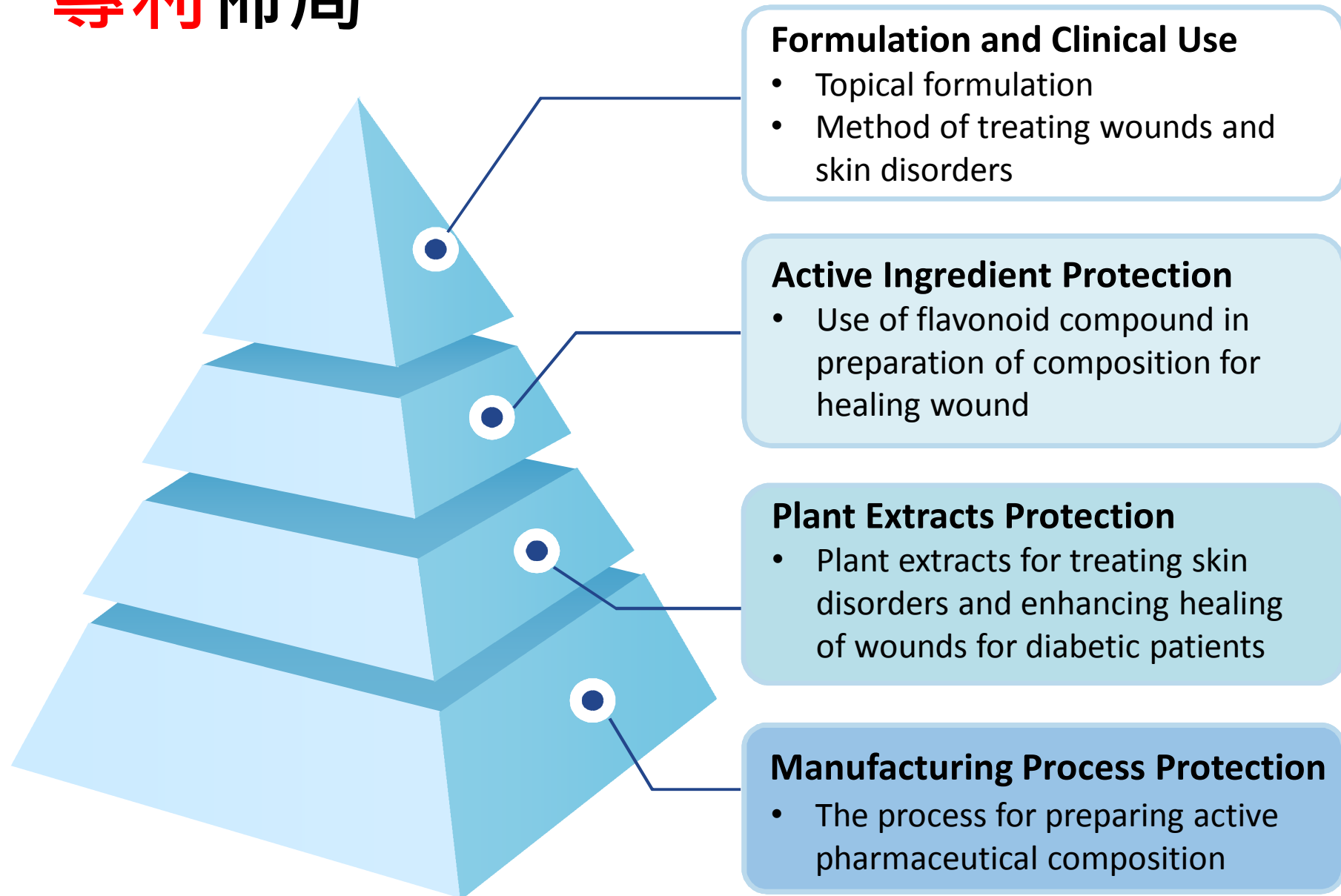
44-acre GACP Cultivation Site



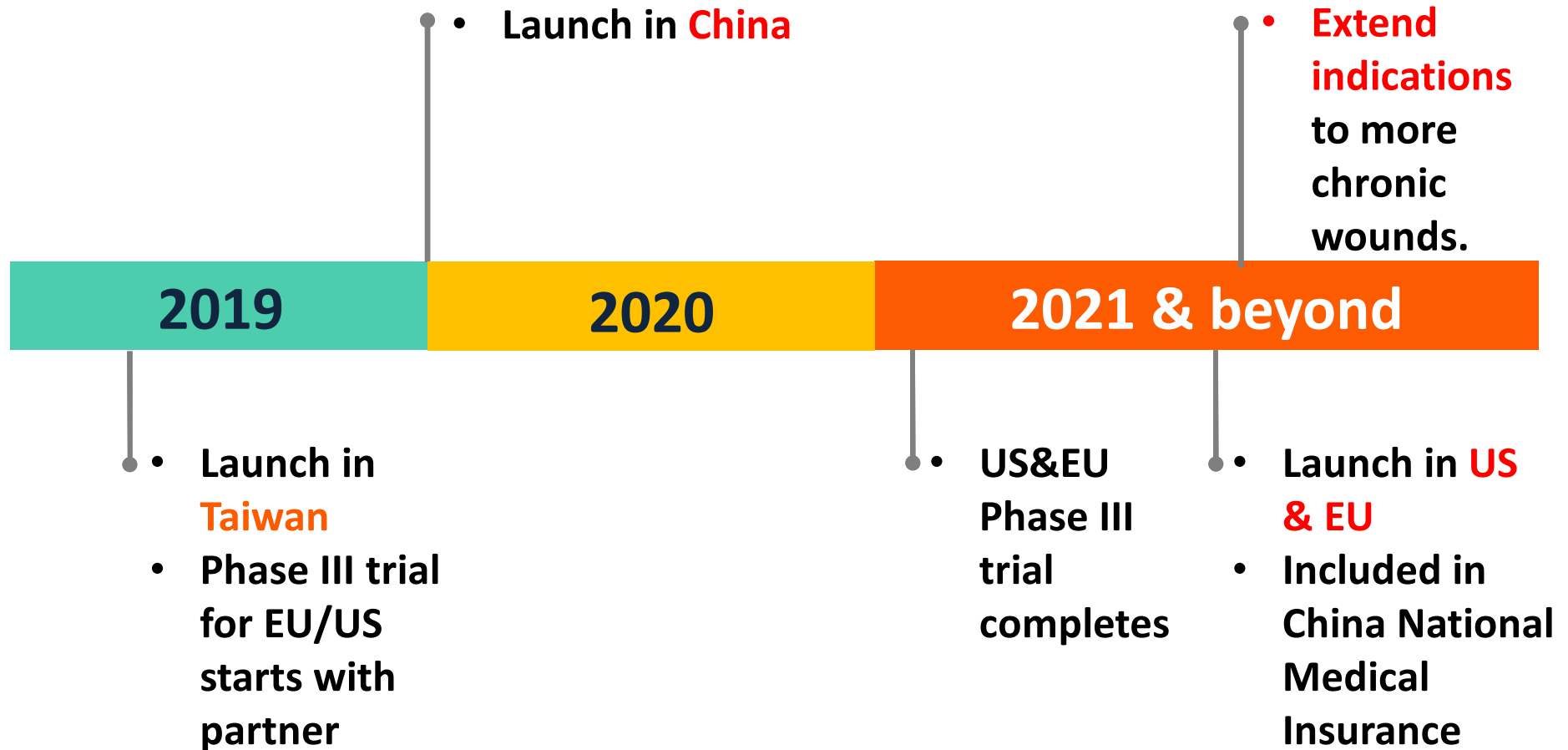
PIC/s GMP Plant



專利佈局



上市預期計畫



IDF大會口頭報告

The above breakthrough findings of ON101 in treatment of DFU will be presented orally at IDF congress.



**Diabetes Complications
Congress 2018**



Hyderabad, India - 25-27 October

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

Presenter: Jui-Ching Chen, Ph.D.



ONENESS

首創新藥與國際連結

Contact

Zoe Chen, Business Development
Zoe.Chen@onenessbio.com.tw

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