



# FY2019 營運成果報告

法人說明會

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# Safe Harbor Statement

Except for historical information contained herein, the matters set forth in this presentation are forward looking statements that are subject to risks and uncertainties that could cause actual results to differ materially. These forward looking statements are not based on historical facts but rather on management's expectations regarding future growth, results of operations, performance, future capital and other expenditures, competitive advantages, business prospects and opportunities. Statements in this presentation about our future plans and intentions, results, level of activities, performance, goals or achievements or other future events constitute forward looking statements. Wherever possible, words such as "anticipate", "believe", "expect", "may", "could", "will", "potential", "intend", "estimate", "should", "plan", "predict", or the negative or other variations of statements reflect management's current beliefs and assumptions and are based on the information currently available to our management. **Investors are cautioned not to place undue reliance on these forward looking statements, which are made as of the date of this presentation** and we assume no obligation to update or revise any forward looking statements.

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# 2019年度重要營運成果

- 受惠於特殊學名藥的全球外銷上市成果亮眼，**2019**年全年營收增長近**43%**
  - 戒毒癮用藥 **Buprenorphine/Naloxone sublingual film** 成功地在美國上市
  - 3**項領先業界之抗癌用藥搶先於部分歐洲國家上市，取得市場先機
- 重要戰略目標之計畫執行奠定長期成長動能
  - 收購近**50**張東南亞藥證、將亞太區幅員拓展至東南亞市場
  - 透過引進市場領先之原廠產品、為亞太區市場提供更多元化之產品組合
  - 成功地與原廠於美國市場和解血癌用藥**Lenalidomide**之相關專利訴訟
  - 簽訂超過**60**個全球經銷合作契約、強化外銷市場業務
- 南投工廠再次順利地通過美國**FDA**查廠、且未發現任何需注意事項，亦成功通過**5**個國際藥廠客戶查核，廠區生產及品質系統受到國際標準高度肯定
- 持續地投資研發能量、致力於基礎建設之升級，以確保業務之永續成長
  - 15**項研發中專案
  - 啟動**5**年度廠區全面升級計畫 (**5-year site master plan**)

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## 2019年度財務表現



# 2019年度 創下多項歷史紀錄、營運成果豐碩的一年



## 重要財務數字彙總

### Key Financials

(in NTD Millions, except EPS)

|                          | 2018    | 2019    | YoY % |
|--------------------------|---------|---------|-------|
| Net Sales                | 6,429   | 9,175   | 43%   |
| Cost of Goods            | 3,289   | 4,927   |       |
| Gross profit             | 3,139   | 4,248   | 35%   |
| %                        | 49%     | 46%     |       |
| Operating expenses       | (2,691) | (3,135) |       |
| Operating Income         | 449     | 1,113   | 148%  |
| %                        | 7%      | 12%     |       |
| Earnings before tax & MI | 164     | 876     |       |
| Net Income               | 124     | 678     | 447%  |
| EPS (TWD)                | 0.42    | 2.74    | 552%  |

合併營收

+43%

受惠多項重要外銷品項順利上市，營收成長強勁



營業利益

+148%

營運效率持續提升



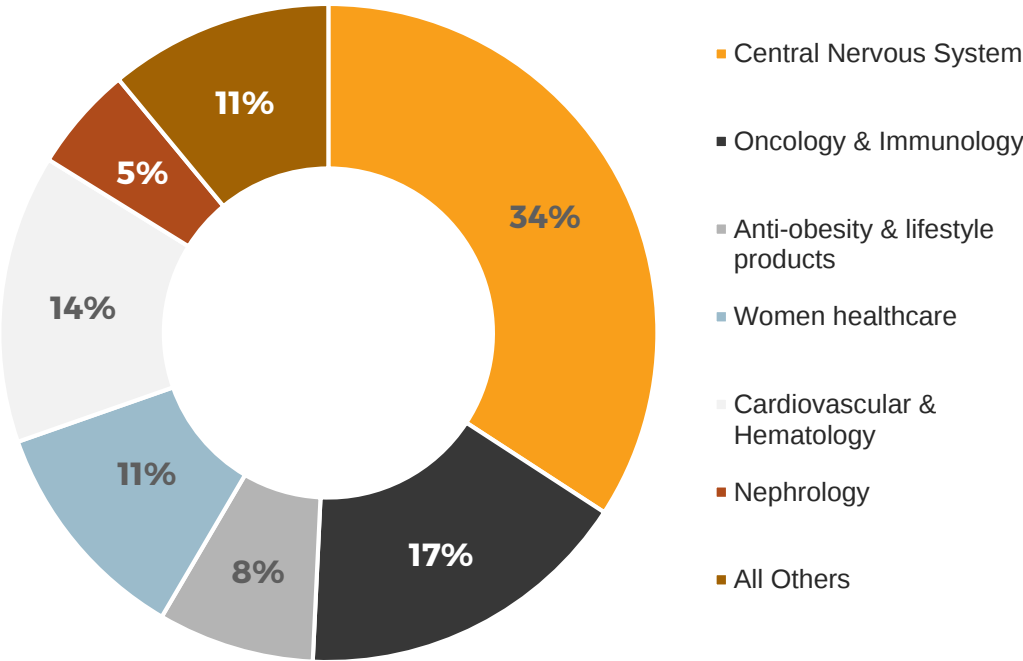
每股淨利

+552%

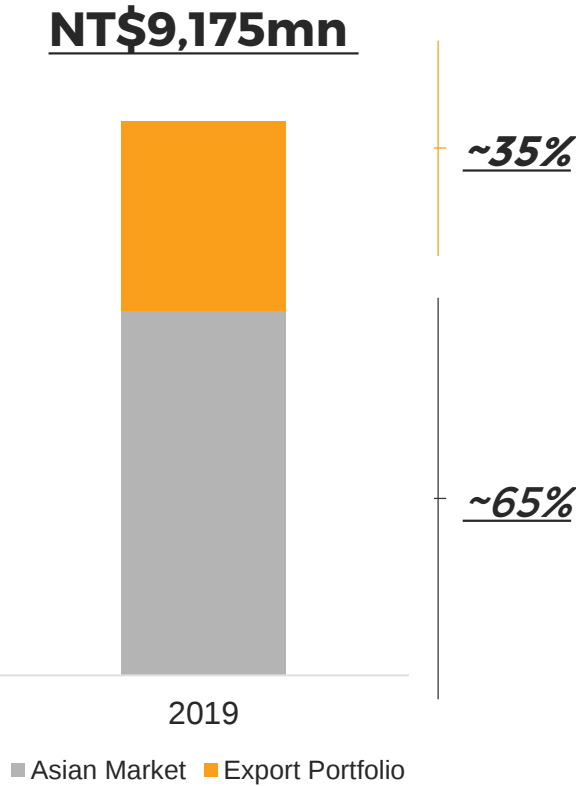
全年淨利創下歷史新高!

# 合併營收 - 多元且平衡之產品組合

2019年度合併營收 - 以科別分



2019年度主要市場營收貢獻



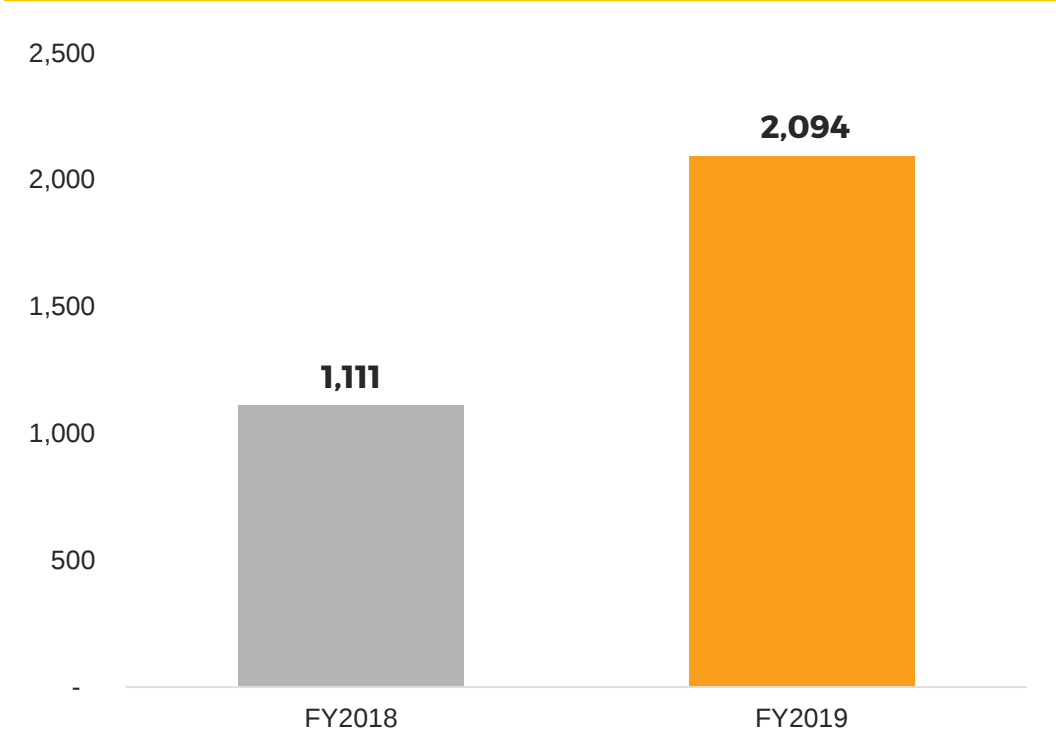
## 全球外銷市場

- gSuboxone貢獻約~30%
- 3項重要抗癌用藥全球首波上市

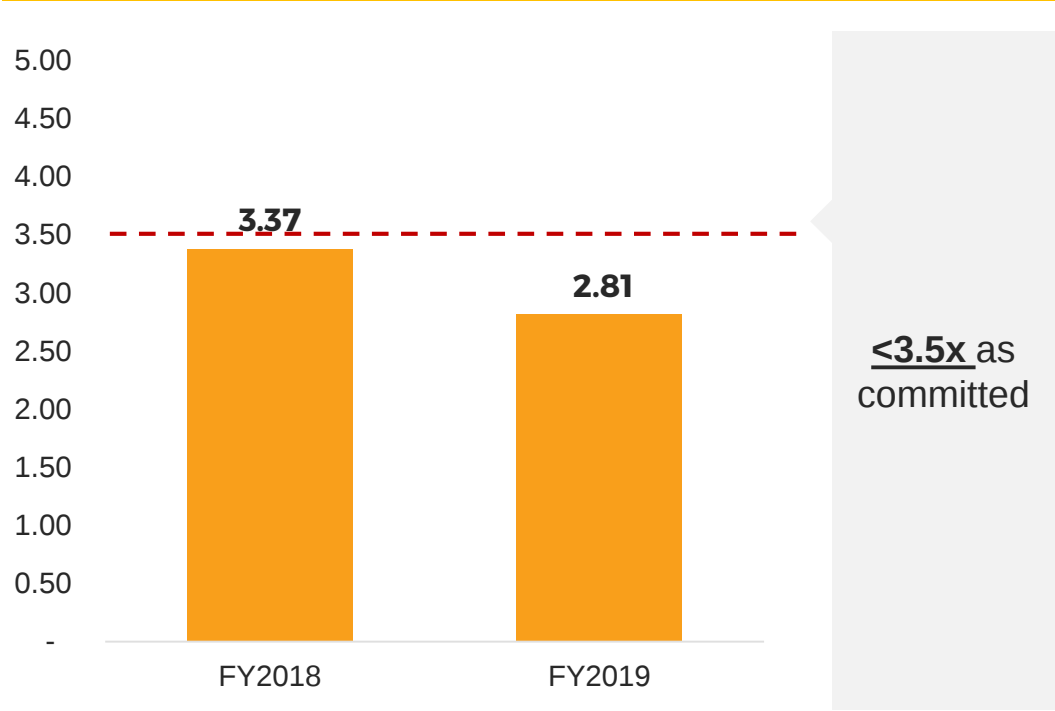
## 亞太區域市場

全年營收金額與去年相當；營收占比漸趨多元平衡

# 強化獲利能力使財務槓桿持續降低



\*EBITDA =EBIT + Depreciation + Amortization + Non-cash provisions



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# 2020年度工作重點及未來展望

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# 2020年度策略目標



## 積極整合研究開發、商業合作、法規部門能量，持續強化現有產品組合

- 戒毒癮用藥 **Buprenorphine/Naloxone** 市場份額持續提升
- 將於台灣市場提交**2**項生物相似藥 (**biosimilar**) 之藥證申請，期將產品組合由小分子學名藥延伸至大分子生物藥
- 血癌用藥 **Lenalidomide GDUFA TAD** 預計在**7**月份
- 現有**23**個全球授權合作專案協商中



## 有效率地如期執行新產品上市計畫

- 今年度計畫將有**5**項產品上市



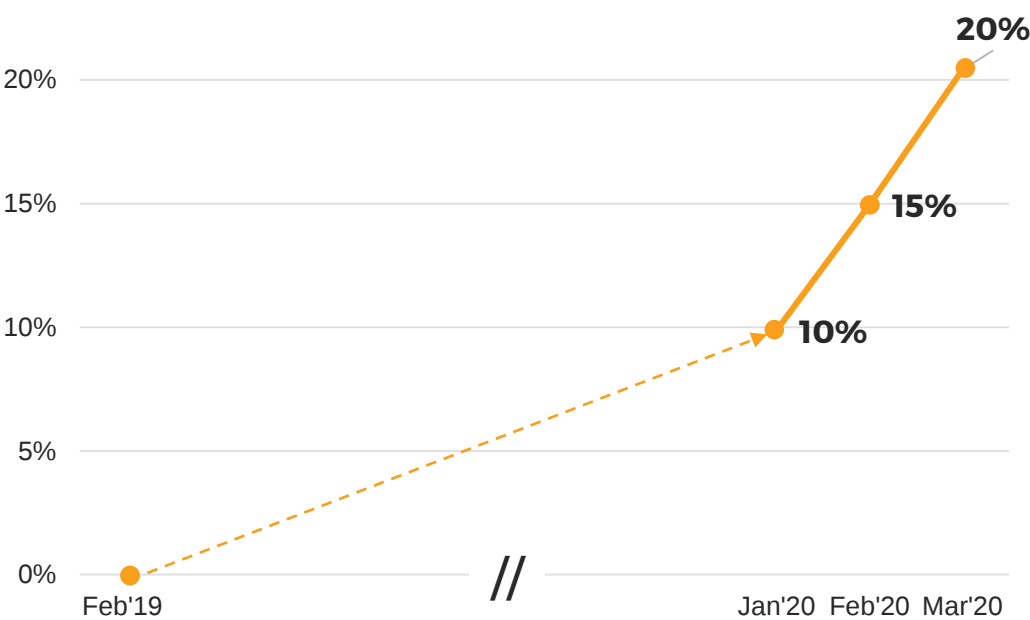
## 持續地投資研發能量，以確保業務之永續成長

- 積極強化口服抗癌產品組合
- 啟動 **505(b)2** 抗癌用藥品項研發
- 擴大品牌/自有品項之產品合作

# 重要品項成功上市之持續耕耘

## Buprenorphine/Naloxone 市場份額

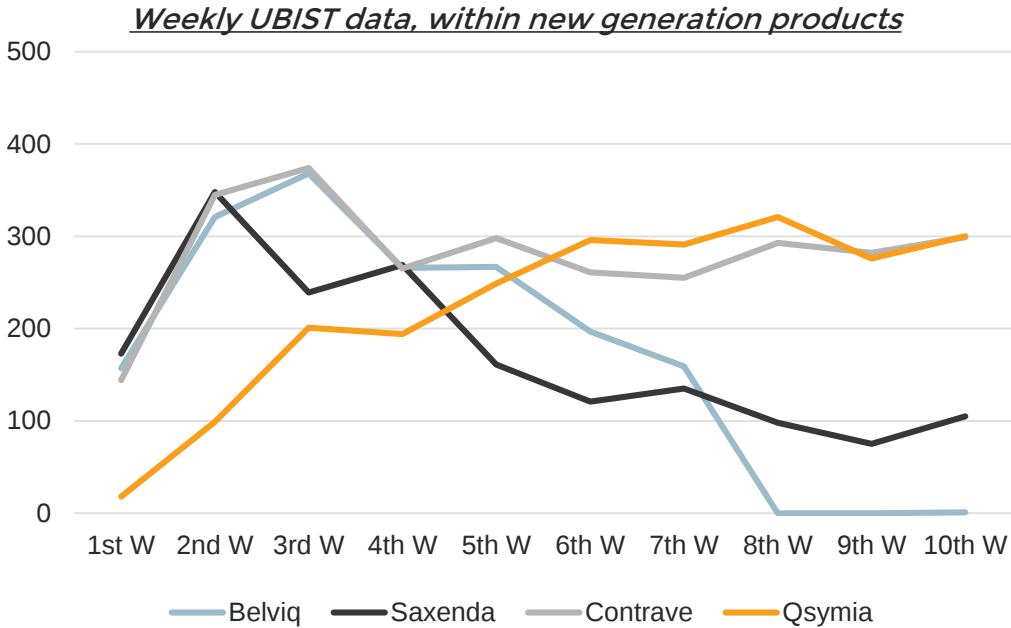
Buprenorphine/Naloxone 市場份額持續提升，符合預期



Source: IQVIA; Company data

## Qsymia 上市進度

Qsymia 於上市後6周起即取得市場領導地位



Source: UBIST

# 重要研發品項進度報告

| Focus on high value innovation for patients and customers |                          |                                                                                                            |                                |                                         |                                                |                          |                                                                                                              |
|-----------------------------------------------------------|--------------------------|------------------------------------------------------------------------------------------------------------|--------------------------------|-----------------------------------------|------------------------------------------------|--------------------------|--------------------------------------------------------------------------------------------------------------|
| KEY ONCOLOGY PROJECT                                      |                          |                                                                                                            |                                |                                         |                                                |                          |                                                                                                              |
|                                                           | Generic Name             | Indication                                                                                                 | IQVIA market size '19 (US\$mn) | Formulation                             | BE & CT                                        | Submission               | Approval                                                                                                     |
| 1                                                         | Lenalidomide             | Multiple Myeloma<br>血癌                                                                                     | Global: 10,000                 | Out-licensing scope continues to expand | Settled in US and launched in selected markets |                          |  GDUFA<br>TAD =<br>Jul'20 |
| 2                                                         | Enzalutamide softgel     | Castration-resistant prostate cancer<br>去勢抗性的轉移性前列腺癌                                                       | Global: 2,144                  |                                         |                                                | Tentative Approval in TW |                                                                                                              |
| 3                                                         | LP173                    | Late stage hepatocellular carcinoma, renal cell carcinoma, thyroid carcinoma<br>晚期肝細胞癌、晚期腎癌、分化型甲狀腺癌 (皆非一線) | Global: 673                    |                                         |                                                |                          |                                                                                                              |
| 4                                                         | LP661                    | Multiple Myeloma<br>血癌                                                                                     | Global: 1,516                  |                                         |                                                |                          |                                                                                                              |
| 5                                                         | LP670                    | Treatment for advanced or metastatic breast cancer<br>乳癌                                                   | Global: 5,458                  |                                         |                                                |                          |                                                                                                              |
| 6                                                         | LP657 (SoftGel capsules) | Treatment for acute myeloid leukemia (AML)<br>急性骨髓性白血病                                                     | Global: 205                    |                                         |                                                |                          |                                                                                                              |

# 重要研發品項進度報告 (續)

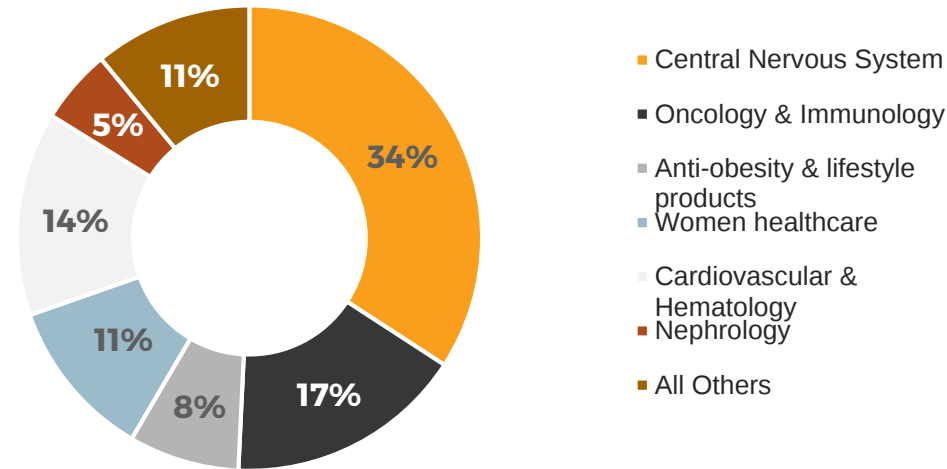
| Focus on high value innovation for patients and customers |              |                                                                                  |                                |                        |         |            |          |
|-----------------------------------------------------------|--------------|----------------------------------------------------------------------------------|--------------------------------|------------------------|---------|------------|----------|
| NON-ONCOLOGY PROJECT                                      |              |                                                                                  |                                |                        |         |            |          |
|                                                           | Generic Name | Indication                                                                       | IQVIA market size '19 (US\$mn) | Formulation            | BE & CT | Submission | Approval |
| 1                                                         | LP117        | Treatment for moderately to severely active rheumatoid arthritis (RA)<br>類風溼性關節炎 | Global: 1,432                  | <div><div></div></div> |         |            |          |

| 505(b)2 PROJECT |              |                            |                                |                        |           |            |          |
|-----------------|--------------|----------------------------|--------------------------------|------------------------|-----------|------------|----------|
|                 | Generic Name | Indication                 | IQVIA market size '19 (US\$mn) | Phase I                | Phase III | Submission | Approval |
| 1               | AK-R216      | Type II diabetes<br>第二類糖尿病 | Global: 432                    | <div><div></div></div> |           |            |          |

# 美時製藥擁有絕佳之競爭優勢能在近期COVID-19逆風中勝出

## 擁有多元且平衡之產品組合

2019 營收組合 - 以科別分

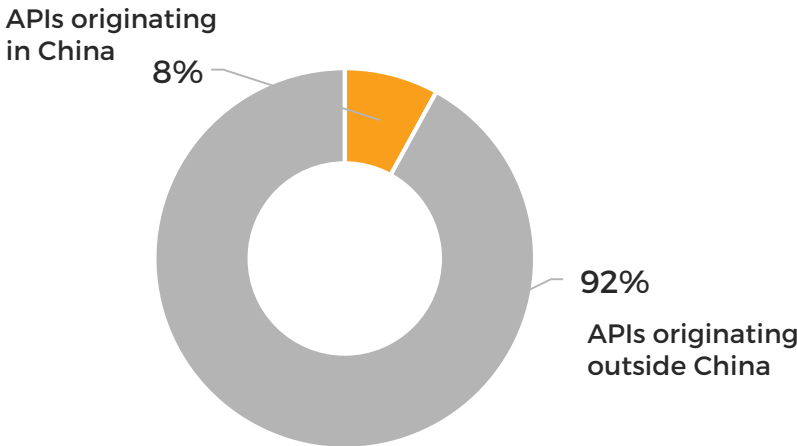


### 雙引擎策略有效降低整體影響 -

- 短期看法與整體市場趨勢相同，預期對韓國市場業務有短暫之影響，然仍於掌握範圍內
- 全球外銷市場的拓展將能分散可能之風險

## 提前規劃之採購策略

- API 原料藥來自中國之比率低
- 目前原料藥庫存可支援約4-12個月之生產需求
- 第二供應商採購策略亦同步進行中



# 2020年度重要里程碑計畫

