

懷特生技新藥股份有限公司

股票代號(4108)

2023年度法人說明會

公司設立: 1998年

股票上市: 2008年

資本額: NTD19.86億

負責人: 李伊俐

報告人

李伊伶總經理



懷特生技新藥(股)公司
PhytoHealth Corporation

免責聲明

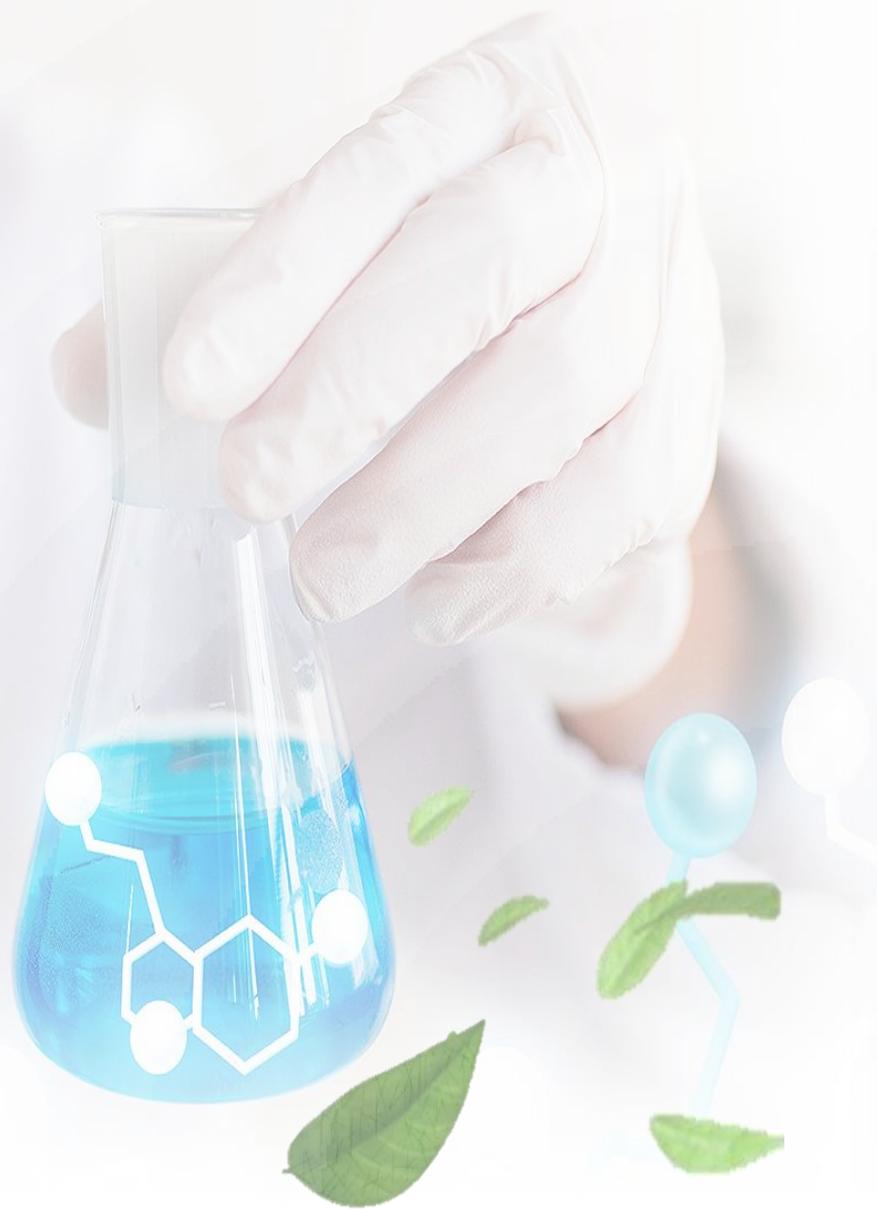
1. 除了過去資料外，本次說明會所列事項若為前瞻性看法，此前瞻性看法可能受重大風險和不確定性因素影響而與實際結果有所差異。
2. 本簡報中對於未來之展望，係反應本公司截至目前為止對於未來的看法。對於這些看法，倘若未來有因任何事件或環境變遷，本公司並不負有更新資料之責任。
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4. 本簡報內容包含所有歸屬於合併報表之個體。

公司簡介



懷特生技新藥(股)公司
PhytoHealth Corporation

懷特生技新藥致力透過
西方科學驗證方式, 利
用上千年以來華人廣
為使用的植物藥材,
開發出符合西藥規
格的植物藥, 滿足目
前不被滿足的臨床
需求。



懷特生技新藥公司發展里程碑

1998

懷特生技新藥公司創立

2002

第一家新藥研發型公司通過
經濟部推薦以科技股上櫃

2008

依照「生技新藥產業發展條例」以
第一家**新藥研發型公司**上櫃轉上市

2009
~
2012

- 獲得衛生署**TFDA**成立後**第一個處方新藥藥證**：懷特血寶[®]注射劑
- **植物新藥精製廠**落成啟用
(通過衛福部PIC/S GMP認證)

2013
~
2016

- 懷特血寶[®]完成四期臨床試驗成果獲國際期刊發表
- 懷特痛寶[®]獲得新藥上市許可證
- 懷特血寶[®]獲得**健保給付**
- 懷特痛寶[®]上市銷售

2017
~
2023



懷特生技新藥(股)公司
PhytoHealth Corporation

懷特新藥產品開發：2項已取得TFDA藥證

產品功能/適應症
Product Function / Indication

臨床前試驗
Pre-Clinical

臨床一期
Phase I

臨床二期
Phase II

臨床三期
Phase III

新藥申請
NDA

獲得藥證
Approval

上市

懷特血寶®
治療癌因性疲憊症

全球唯一治療「癌因性疲憊症」(Cancer Related Fatigue)處方藥



懷特痛寶®
治療中到重度疼痛

新穎止痛 (Nalbuphine)口服劑型藥物



PHN031 (懷特骨寶®)
預防骨質疏鬆症

完成美國FDA核准Phase IIa臨床試驗



研發
中
新
藥

PHN033 (懷特糖寶®)
治療糖尿病腎病變

完成美國FDA核准Phase IIa 臨床試驗



懷特血寶®與抗癌藥物合
併使用(Combo Therapy)
治療癌症

啟動Phase II臨床試驗

懷特血寶®治療COVID-
19引起之細胞激素風暴

啟動先導性臨床試驗



全球植物藥市場在未來穩定成長

*Botanical and Plant-derived Drugs: Global Markets, BCC Research



\$38B

USD in 2023

\$50B

USD by 2029

4.78%

CAGR

植物新藥從開發到上市成功門檻高



懷特新藥20年來成果豐碩



法規認可

懷特血寶®獲得國內
TFDA 第一張新藥藥
藥證
(April, 2010)

懷特工廠為首家
PIC/S GMP 植物精製廠
(September, 2016)

TFDA 核發10張新藥藥
證中懷特取得2項
懷特血寶®: 癌因性疲憊症
(Cancer Related Fatigue)
懷特痛寶®: 治療中到重度疼痛
(2020.3)



臨床療效驗證

24篇懷特血寶®研究
文獻發表
前25% Top Leading
Medical & Cancer
Journals

懷特血寶®完成四期
臨床試驗(N=323)
randomized, double-
blind, multi-center
clinical trial

13項臨床研究發表
在醫學會
ASCO, MASCC, WCP,
and TJCC



市場接受度

懷特血寶®獲健保給付之
植物新藥
第一個獲健保給付之植物新藥
(2021.3)

懷特血寶被+70 家醫療
院所採用
18 醫學中心 36 區域醫院

持續累積癌因性疲憊症臨
床經驗
380+ 腫瘤專科醫師
10,000+ 病患使用經驗
5000+ 醫護人員持續教育



建立植物藥價值鏈商化成功模式





2022-2023 重要進展



懷特生技新藥(股)公司
PhytoHealth Corporation



**1. 懷特血寶合併化療研究於乳癌病患
發表於2023 ASCO (美國臨床腫瘤醫學會)**

2023 6月 ASCO 年會發表

● 乳癌臨床試驗

時間：02.21.18~12.31.21 (8/31'21所有病患已完成試驗)

執行機構：義大癌醫、林口、基長情人湖、台北及高雄長庚醫院

收案：67人 可評估：61人 (61人)

Abstract # 537

Effect of Astragalus Polysaccharides (PG2) Treatment of Adjuvant Chemotherapy-induced Fatigue in Premenopausal Patients with Breast Cancer

Kun-Ming Rau¹, Wen-Chi Shen^{2,3}, Shin-Cheh Chen^{2,3}, Cheng-Hsu Wang⁴, Ruey-Kuen Hsieh⁵, Chao-Ming Hung¹, Meng-Ting Peng^{2,3}, Chien-Ting Liu⁶, Yueh-shih Chang⁴, Wen-Ling Kuo^{2,3}, Hsu-Huan Chou^{2,3}, Kun-Yun Yeh⁴, Tsung-Han Wu⁴, Chun-Feng Wu⁴, Pei-Hung Chang⁴, Yen-Min Huang⁴, Chi-Chang Yu^{2,3}, Chun-Hui Lee⁴

¹E-Da Cancer Hospital Kaohsiung, Taiwan; ²Chang Gung Memorial Hospital, Taoyuan Branch, Taiwan; ³Chang Gung Memorial Hospital, Taipei Branch, Taiwan; ⁴Chang Gung Memorial Hospital, Lakeview Branch, Keelung, Taiwan; ⁵MacKay Memorial Hospital, Taipei, Taiwan; ⁶Chang Gung Memorial Hospital, Kaohsiung Branch, Kaohsiung, Taiwan

Background

Fatigue is one of the most common symptoms of breast cancer (BC) patients who are receiving adjuvant chemotherapy. Astragalus Polysaccharides (PG2) had been proved to relieve cancer-related fatigue in advanced cancer patients. The aim of this study was to evaluate the efficacy of PG2 as a complementary treatment among stage II/III BC patients with adjuvant chemotherapy of epirubicin-cyclophosphamide (EC) regimen in reduction of chemotherapy-induced toxicity and encouraging compliance with chemotherapy.



Methods

Design:

- Double-blind, randomized, placebo controlled, multi-center trial

Patients:

- Stage II/III BC patients who would receive adjuvant EC at least 4 cycles to either PG2 500 mg or placebo on day 1, 3, 8 every 21 days as the combination.

Measurement Tools:

- Chemotherapy-related fatigue Score (CRFS) was assessed by the validated questionnaire Brief Fatigue Inventory (BFI)-Taiwanese Form.
- Health-Related Quality of Life (HRQL) was assessed by the validated questionnaires EORTC QLQ-C30 and Br23.
- Adverse events were evaluated by CTCAE v4.03.

Results

Figure 1. Study Flow Chart

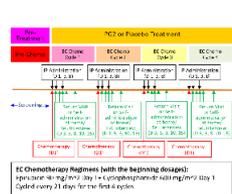
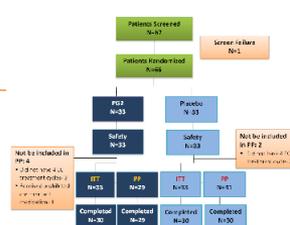


Fig 2. Subject Disposition



Conclusion:

- PG2 combined with adjuvant EC can significantly improve EC-induced fatigue in premenopausal BC patients.
- PG2 assists these patients with maintaining normal daily activities to care for family and manage job during chemotherapy.
- Patients treated PG2 might have better condition to complete the whole course of adjuvant chemotherapy.

QR code

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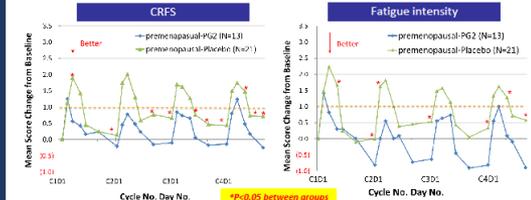
Table 1. Disease Characteristics

Characteristic	PG2 (N=33)	Placebo (N=33)	P-value
Age, Mean±SD	51.2 (4.2)	51.1 (4.1)	0.98
Mean±SD	22.5 (3.2)	22.6 (3.1)	0.95
Mean±SD	1.2 (0.3)	1.2 (0.3)	0.92
Baseline EORTC QLQ-C30	42.1 (10.2)	41.8 (10.1)	0.91
1			
Histologic Type			
Ductal	14 (42.4)	14 (42.4)	
Lobular	2 (6.1)	1 (3.0)	0.420
Other	1 (3.0)	0 (0.0)	
Unknown	29 (87.9)	32 (97.0)	
Menopausal Status			
Premenopausal	12 (36.4)	10 (30.3)	0.602
Postmenopausal			
Molecular			
TNBC, n (%)			
HR+/HER2-			
HER2+, n (%)			
Conservative	2 (6.1)	1 (3.0)	
Nodal	1 (3.0)	0 (0.0)	
Mastectomy	29 (87.9)	32 (97.0)	
Unknown	1 (3.0)	0 (0.0)	
Radiotherapy, n (%)	12 (36.4)	10 (30.3)	

For most characteristics, there was no significant difference among the treatment groups. Of note, the menopausal status was significantly different between the groups.

Despite there was no significant difference in the proportion of patients experiencing chemotherapy dose reduction and treatment delays among treatment groups, we noted that there were 3 patients (9.1%) in the placebo group reduced the dose of chemotherapy, but none in the PG2 group had dose reduction.

Fig 3. Summary of BFI Fatigue Score Change from Cycle 1 to Cycle 4 for the ITT Pre-menopausal Population

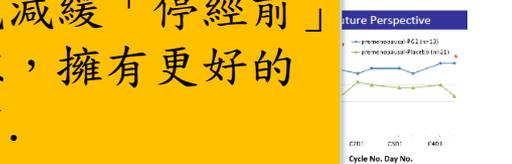


• CRFS: The arithmetic mean of all nine BFI items (score, 0-10)
• Fatigue Intensity: The worst level of fatigue in the last 24 h (BFI item 3) (score, 0-10)

Conclusion: 化療結合「癌因性疲憊症」藥物，能預防或減緩「停經前」女性乳癌化療時的疲憊，擁有更好的用藥順從性與生活品質。
<論文撰寫中...>

• were less aggravated after 4 cycles (PG2: 0.6; Placebo: 1.9, P = 0.02).

Figure 4. Summary of Insomnia Score Change from Cycle 1 to Cycle 4 for the ITT Pre-menopausal Population



• were less aggravated after 4 cycles (PG2: 0.6; Placebo: 1.9, P = 0.02).

Figure 5. Summary of Future Perspective Score Change from Cycle 1 to Cycle 4 for the ITT Pre-menopausal Population



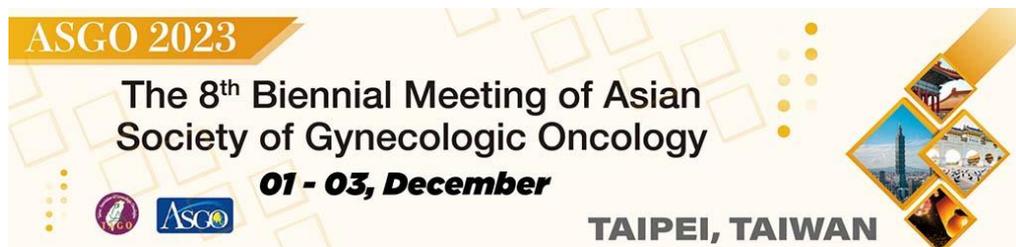
The effects of PG2 were observed in the premenopausal patients for reducing chemotherapy-induced fatigue and insomnia, and negative impact on future perspective, and global health status compared with the placebo group.

2023 懷特血寶 國內外學術發表

學術發表

項次	論文名稱	發表日	期刊或醫學會名稱
1	Combination of Astragalus Polysaccharides (PG2) to reduce Persistent Cancer-related Fatigue in Gynecologic Cancer Patients under Chemotherapy	12/1/2023-12/3/2023	第八屆亞洲婦癌雙年會The 8th Biennial Meeting of Asian Society of Gynecologic Oncology (ASGO 2023)
2	Characteristics of Cancer-Related Fatigue and an Efficient Model to Identify Patients with Gynecological Cancer Seeking Fatigue-Related Management 鑑別婦科癌症患者癌因性疲勞的特徵和尋求疲勞相關處置的有效模式	05/06/2023	2023.4 Cancers (Accept) 第二十七屆台灣癌症聯合學術年會 (2023/5/6)
3	Effect of Astragalus Polysaccharides (PG2) Treatment of Adjuvant Chemotherapy-induced Fatigue in Premenopausal Patients with Breast Cancer.	06/04/2023	2023 ASCO Annual Meeting

2023 ASCO[®]
ANNUAL MEETING



2. 與各界合作強化「癌因性疲憊症」 醫病決策



國內調查顯示92%病患罹癌期間有癌因性疲憊症(Cancer Related Fatigue, CRF)問題

92% 台灣癌症患者罹癌期間有疲憊問題

- 第一次全台灣癌症病患「癌因性疲憊症」流行病學調查研究

- 期間為2015年2月至5月
- 共23家醫院進行研究
- 共1,207病患參與調查
- 問卷

癌因性疲憊(BFI-T, ICD-10)
生活品質量表(FACT-G7)
癌症症狀困擾嚴重度量表

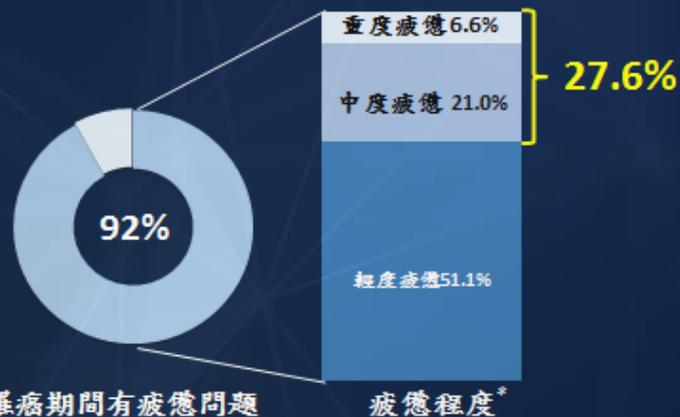


罹癌期間有疲憊問題

2015 Palliative Care in Oncology Symposium, Boston; Oct 9-10, 2015, Abstract # 153471, 2016 MASCC Poster # MASCC-0488.

10

大於1/4 癌症病患有中重度疲憊



罹癌期間有疲憊問題

* The three groups were calculated from the average of nine items from BFI and categorize into mild (<4), moderate (4-6.99), Severe (≥ 7).

2015 Palliative Care in Oncology Symposium, Boston; Oct 9-10, 2015, Abstract # 153471, 2016 MASCC Poster # MASCC-0488.

12

依據「癌因性疲憊診療與照護指引」*, 中到嚴重程度疲憊必須經過藥物治療

黃耆多糖注射劑有臨床實證顯示可改善中重度癌因性疲憊症

(藥物治療推薦第一順位, Level 1A, GradeA)

*註：Management of Cancer Related Fatigue in Taiwan-An Evidence Based Consensus of screening, assessment and treatment: Japanese Journal of Clinical Oncology (JJCR 2022 Volume 53, Issue 1, January 2023). 2023. 11 台灣癌症安寧緩和醫學會 發表更新



懷特生技新藥(股)公司
PhytoHealth Corporation

與各界合作強化「癌因性疲憊症」醫病決策



3. 懷特痛寶正式上市銷售



懷特生技新藥(股)公司
PhytoHealth Corporation

懷特痛寶: 急性術後中到重度止痛藥物 理想選擇

Oraphine® (nalbuphine HCl 60mg Soft Capsules)
懷特痛寶® 軟膠囊
Easy way to end pain now

Relieving Pain
Brightening Lives

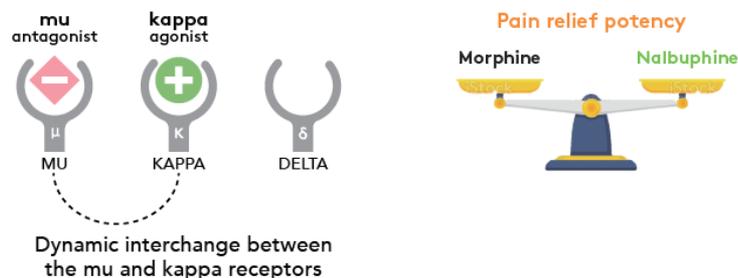
Relieve moderate to severe acute pain

PhytoHealth

Oraphine® is the first choice of oral analgesia for moderate to severe pain because it provides rapid onset, powerful efficacy and better safety profile.

Unique mechanism of action¹

- Mu-opioid receptor (MOR) antagonist and Kappa-opioid receptor agonist
- Low addiction and high safety when compared to MOR agonists
- Pain relief potency is approximately equivalent to morphine



- 各大醫院進用中：三軍總醫院、禾馨、烏日林新...etc

A hand pointing upwards, overlaid with a network of white dots and lines, set against a blurred background of a person's arm. The text '4. 國外展業' is centered in blue.

4. 國外展業

2023 US BIO Boston 台灣館: 懷特攤位



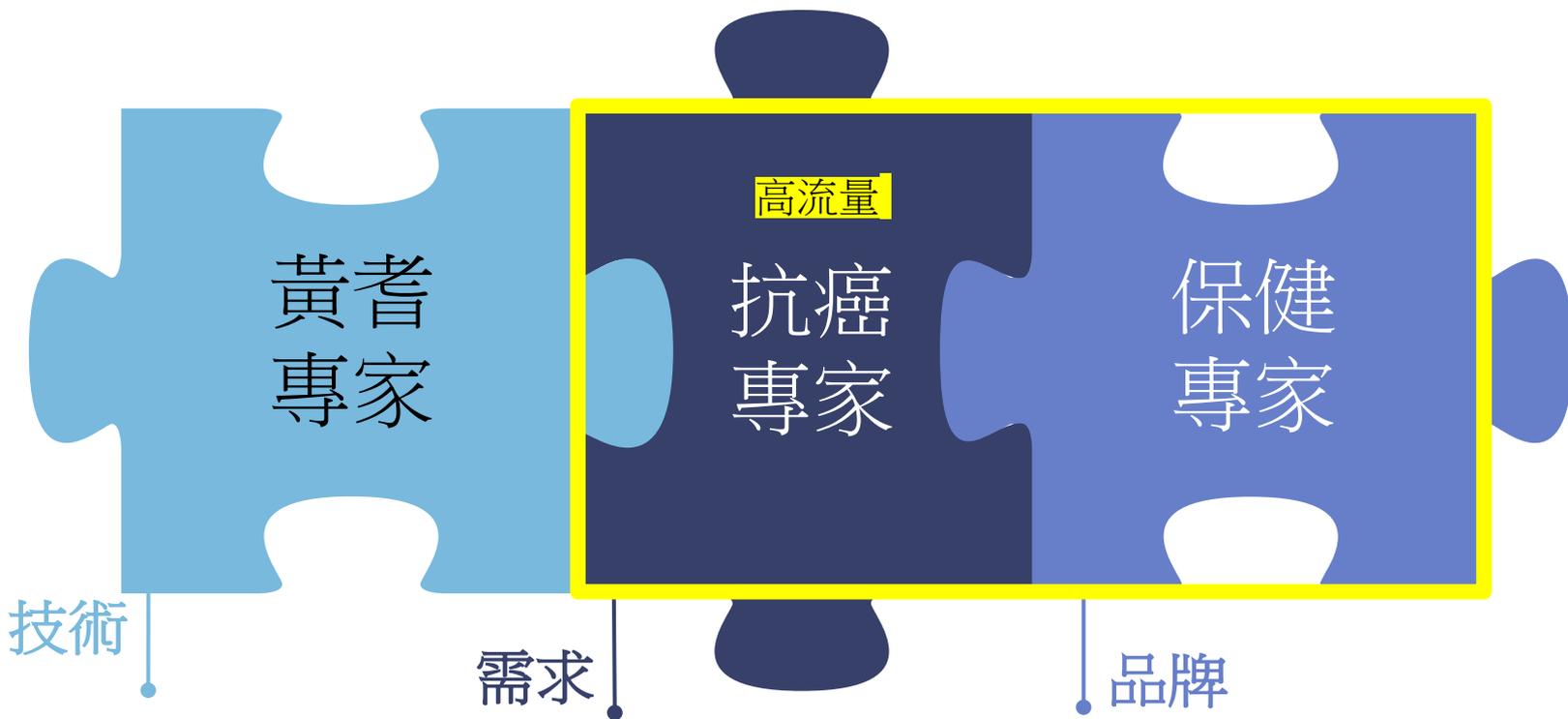
A hand pointing upwards with a glowing network overlay. The background is a light blue and white gradient with a network of white lines and glowing nodes. A hand is visible, pointing upwards with the index finger. The text '5. 以新藥研發精神跨足保健' is overlaid in the center.

5. 以新藥研發精神跨足保健



懷特生技新藥(股)公司
PhytoHealth Corporation

懷特新藥 以新藥研發精神跨入保健



精製黃耆多醣
技術領先全球

先聚焦需高度專業的病後保健品
和主力抗癌注射用藥對齊方向

懷特新藥—全方位的保健專家
持續強化"懷特新藥"形象
擴充產品線 跨足大眾市場



2023 New!

<https://www.phytohealth.com.tw/>

財務資訊



懷特生技新藥(股)公司
PhytoHealth Corporation

簡明「資產負債表」

財務結構健全

- 1.現金充足
- 2.負債比率低

單位:仟元

科目	112.9.30	%	111.12.31	%
流動資產	1,521,568	65	1,568,464	66
非流動資產	824,139	35	796,164	34
資產總計	2,345,707	100	2,364,628	100
流動負債	52,644	2	62,118	3
非流動負債	25,117	1	25,057	1
負債合計	77,761	3	87,175	4
股本	1,986,189	85	1,986,189	84
資本公積/累計虧損等	(65,083)	(3)	(78,257)	(4)
母公司權益	1,921,106	82	1,907,932	80
非控制權益	346,840	15	369,521	16
權益合計	2,267,946	97	2,277,453	96
負債與權益總計	2,345,707	100	2,364,628	100



簡明「綜合損益表」

1. 營收成長14%
2. 損失大幅減少65%

單位:千元

科目	112年 1-9月		111年 1-9月		增減率%
	(A)	%	(B)	%	(A-B)/B
營收淨額	115,885	100	101,651	100	14
營業毛利	48,274	42	42,790	42	13
營業費用	(127,702)	(110)	(144,372)	(191)	(12)
營業損失	(79,428)	(68)	(101,522)	(149)	(22)
營業外收支淨額	40,481	35	36,446	10	11
稅前淨損	(38,947)	(33)	(65,076)	(139)	(40)
本期淨損-合併	(38,947)	(33)	(65,076)	(139)	(40)
淨損歸屬於母公司	(15,200)	(13)	(42,937)	(102)	(65)
每股盈餘(元)	(0.08)		(0.22)		



The background is a vibrant blue gradient with a futuristic, high-tech aesthetic. On the left, a globe is depicted with a grid overlay, and a circular logo with a stylized 'R' is positioned above it. A bright, glowing beam of light originates from the logo and extends towards the right. In the bottom right corner, a blue and white capsule with a logo is visible. The overall scene is filled with abstract lines and patterns, suggesting a digital or scientific environment.

Thank You !